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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

- Delstrigo (*doravirine / lamivudine / tenofovir disoproxil*)
  Treatment of HIV infection
- Pifeltro (*doravirine*)
  Treatment of HIV infection
- Vabomere (*meropenem/vaborbactam*)
  Treatment of bacterial infections

Cancer

Positive CHMP opinions on new medicines

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

Key to symbols used

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

- Apealea (*paclitaxel*)
  Treatment of ovarian cancer
- Fulphila (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- Pelmeg (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- 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 medicines authorised

- Kymriah (*tisagenlecleucel*)
  Treatment of acute lymphoblastic leukaemia (ALL) and diffuse large B-cell lymphoma (DLBCL) (blood cancers)
- Nerlynx (*neratinib*)
  Treatment of breast cancer
- Yescarta (*axicabtagene ciloleucel*)
  Treatment of diffuse large cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL) (blood cancers)

New information on authorised medicines

- Cabometyx (*cabozantinib*) - new indication
  Treatment of hepatocellular carcinoma (liver cancer)
- Venclyxto (*venetoclax*) - extension of indication
  Treatment of chronic lymphocytic leukemia (blood cancer)
- Xtandi (*enzalutamide*) - new indication
  Treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer

Supply shortages

- Trisenox (*arsenic trioxide*) - shortage resolved
  Treatment of acute promyelocytic leukaemia (blood cancer)

Cardiovascular system

Withdrawal of applications for new medicines

- Treprostinil SciPharm Sarl (*treprostinil*)
  Intended for the treatment of pulmonary hypertension

Withdrawal of authorised medicines

- Angiox (*bivalirudin*)
  Prevention of blood clots and treatment of unstable angina

Safety communication update

- Review of sartan medicines
  Treatment of high blood pressure, recent heart attack and heart failure
  - 13 September Update of risk calculation
  - 21 September Review of impurities extended to other sartan medicines
  - 28 September EU inspection finds Zhejiang Huahai site non-compliant for manufacture of valsartan

Dermatology

Positive CHMP opinions on new medicines

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

New medicines authorised

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Vabomere (*meropenem/vaborbactam*)
  Treatment of bacterial infections

New medicines authorised

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Apealea (*paclitaxel*)
  Treatment of ovarian cancer

New medicines authorised

- Ulipristal Acetate Gedeon Richter *(ulipristal acetate)* generic of Esmya
  Treatment of uterine fibroids (non-cancerous tumors of the womb)

Haematology

Positive CHMP opinions on new medicines

- Jivi (*damoctocog alfa pegol*)
  Treatment of haemophilia A (congenital factor VIII deficiency)
- Fulphila (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients

- Pelmeg (*pegfilgrastim*) biosimilar of Neulasta
  Treatment of neutropenia (low level of white blood cells) in cancer patients
- 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 medicines authorised

- Cablivi (*caplacizumab*)
  Treatment of acquired thrombotic thrombocytopenic purpura (a clotting disorder)
- Kymriah (*tisagenlecleucel*)
  Treatment of acute lymphoblastic leukaemia (ALL) and diffuse large B-cell lymphoma (DLBCL) (blood cancers)
- Veyvondi (*vonicog alfa*)
  Treatment of von Willebrand disease (inherited bleeding disorder)
- Yescarta (*axicabtagene ciloleucel*)
  Treatment of diffuse large cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL) (blood cancers)

New information on authorised medicines

- Venclyxto (*venetoclax*) - extension of indication
  Treatment of chronic lymphocytic leukemia (blood cancer)

Supply shortages

- Trisenox (*arsenic trioxide*) - shortage resolved
  Treatment of acute promyelocytic leukaemia (blood cancer)

HIV

Positive CHMP opinions on new medicines

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

Immune system

New medicines authorised

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

Nervous system

Positive CHMP opinions on new medicines

- Emgality (*galcanezumab*)
  Prevention of migraine

New information on authorised medicines

- Gilenya (*fingolimod*) - extension of indication
  Treatment of multiple sclerosis (inflammatory nerve disease) in patients aged 10 and older

Ophthalmology

Positive CHMP opinions on new medicines

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

New medicines authorised

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

Respiratory system

Positive CHMP opinions on new medicines

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

New information on authorised medicines

- Elebrato Ellipta / Trelegy Ellipta (*fluticasone furoate / umeclidinium / vilanterol*) - extension of indication
  Treatment of chronic obstructive pulmonary disease (COPD)

Rheumatology

New medicines authorised

- Hulio (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory and autoimmune disorders

New information on authorised medicines

- RoActemra (*tocilizumab*) - new indication
  Treatment of juvenile arthritis in patients one year of age and older

Vaccines

Withdrawal of authorised medicines

- Intanza *(influenza vaccine (split virion, inactivated))*
  Prevention of influenza

Key to symbols used

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Other medicines

Positive CHMP opinions on new medicines

- Buvidal (*buprenorphine*) generic of Subutex
  Treatment of opioid dependence

Withdrawal of applications for new medicines

- Entolimod TMC (*entolimod*)
  Intended for the treatment of acute radiation syndrome

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate - Revision 1
  Deadline for comments: 16 December 2018

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - August 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: September 2018
- 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
- PCWP meeting - 25 September 2018 - agenda
- PCWP and HCPWP joint meeting - 25 September 2018 - agenda
- HCPWP meeting - 26 September 2018 - agenda

Other publications

- EMA's Committee for Medicinal Products for Human Use (CHMP) elects new chair
- Committee for Orphan Medicinal Products (COMP) elects new chair
- Companies stepping up efforts to ensure medicine supply post Brexit
- Portugal to also benefit from EU-US mutual recognition agreement for inspections
- Improving understanding of biosimilars in the EU
- Scientific advice and protocol assistance adopted during the CHMP meeting 17 – 20 September 2018
- Scientific publication - Harnessing the potential of real world data through a 'learning healthcare system'
- Scientific publication - Defining orphan conditions in the context of the European orphan regulation: challenges and evolution
- Third industry stakeholder platform on research and development support - minutes - May 2018
- Report of the annual workshop of the European Network of Paediatric Research at the EMA (Enpr-EMA) - June 2018
- Report of the 2018 annual face-to-face meeting of Enpr-EMA members and the Enpr-EMA Coordinating Group (CG) - June 2018
- 12th Pharmacovigilance stakeholder forum - September 2018 - agenda

Events

- European Medicines Agency stakeholder interaction on the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) - December 2018

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease.

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.

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.

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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