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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

New medicines authorised

- Xerava (*eravacycline*)
  Treatment of complicated bacterial infections in adults

Safety communication update

- Review of fluoroquinolone and quinolone containing medicines - PRAC recommendation (long-lasting effects mainly affecting musculoskeletal and nervous systems)
  Treatment of bacterial infections

Cancer

Positive CHMP opinions on new medicines

- Ogivri (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast cancer

Key to symbols used

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

New medicines authorised

- Braftovi (*encorafenib*) and Mektovi (*binimetinib*)
  Combination treatment of metastatic melanoma (skin cancer)
- Gefitinib Mylan (*gefitinib*) generic of Iressa
  Treatment of non-small cell lung cancer
- Imfinzi (*durvalumab*)
  Treatment of non-small cell lung cancer
- Lenalidomide Accord (*lenalidomide*) generic of Revlimid
  Treatment of multiple myeloma (cancer of the bone marrow)
- Pelgraz (*pegfilgrastim*) biosimilar of Neulasta
  Reduction of the duration of neutropenia (low level of white blood cells) in cancer patients
- Verzenios (*abemaciclib*)
  Treatment of metastatic breast cancer
- Vyxeos (*daunorubicin / cytarabine*)
  Treatment of acute myeloid leukaemia (AML) (blood cancer)

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Adjuvant treatment of melanoma (skin cancer)

Withdrawal of authorised medicines

- Imatinib Teva B.V. (*imatinib*) generic of Glivec
  Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancer of the stomach and bowel)

Cardiovascular system

- Review of sartan medicines - EU authorities take further action in ongoing review of sartans
  Treatment of high blood pressure, recent heart attack and heart failure

Dermatology

New medicines authorised

- Braftovi (*encorafenib*) and Mektovi (*binimetinib*)
  Combination treatment of metastatic melanoma (skin cancer)
- Ilumetri (*tildrakizumab*)
  Treatment of moderate to severe plaque psoriasis

New information on authorised medicines

- Keytruda (*pembrolizumab*) - new indication
  Adjuvant treatment of melanoma (skin cancer)

Gastro-intestinal system

Withdrawal of authorised medicines

- Imatinib Teva B.V. (*imatinib*) generic of Glivec
  Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancer of the stomach and bowel)

Haematology

New medicine authorised

- Pelgraz (*pegfilgrastim*) biosimilar of Neulasta
  Reduction of the duration of neutropenia (low level of white blood cells) in cancer patients
- Vyxeos (*daunorubicin / cytarabine*)
  Treatment of acute myeloid leukaemia (AML) (blood cancer)

New information on authorised medicines

- Novoseven (*eptacog alfa (activated)*) - change in indication
  Prevention of bleeding in surgeries for people suffering from bleeding disorders

Withdrawal of authorised medicines

- Imatinib Teva B.V. (*imatinib*) generic of Glivec
  Treatment of leukaemia (blood cancer) and gastrointestinal stromal tumours (cancer of the stomach and bowel)
- Raplixa (human fibrinogen / human thrombin)
  Reduction of bleeding during surgery

Immune system

Positive CHMP opinions on new medicines

- Takhzyro (*lanadelumab*)
  Treatment of hereditary angioedema (swelling beneath the skin)

New medicines authorised

- Ilumetri (*tildrakizumab*)
  Treatment of moderate to severe plaque psoriasis

Musculoskeletal system

Positive CHMP opinions on new medicines

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

Nervous system

New medicines authorised

- Onpattro (*patisiran*)
  Treatment of transthyretin amyloidosis (build-up of abnormal deposits of amyloid protein)
- Slenyto (*melatonin*)
  Treatment of insomnia in children and adolescents with autism spectrum disorder

Respiratory system

Positive CHMP opinions on new medicines

- Bevespi Aerosphere (*glycopyrronium / formoterol fumarate dihydrate*)
  Maintenance treatment of chronic obstructive pulmonary disease (COPD)

New medicines authorised

- Gefitinib Mylan (*gefitinib*) generic of Iressa
  Treatment of non-small cell lung cancer
- Imfinzi (*durvalumab*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Kalydeco (*ivacaftor*) - extension of indication
  Treatment of cystic fibrosis in children from 12 months of age

Rheumatology

New medicines authorised

- Onpattro (*patisiran*)
  Treatment of transthyretin amyloidosis (build-up of abnormal deposits of amyloid protein)

Vaccines

Positive CHMP opinions on new medicines

- Dengvaxia (*dengue tetravalent vaccine (live, attenuated)*)
  Prevention of dengue fever
- Flucelvax Tetra (*influenza vaccine surface antigen inactivated prepared in cell cultures*)
  Prevention of influenza in adults and children

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Adopted reflection paper on the use of extrapolation in the development of medicines for paediatrics - Revision 1

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2018
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: October 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

Other publications

- EMA Management Board: highlights of October 2018 meeting - meeting documents
- Update on EMA's Brexit preparedness
- EMA tracking tool: relocation to Amsterdam - Main milestones
- Boosting the development of medicines for children - action plan
- A common data model for Europe - Why? Which? How? - Workshop report
- Report on Haemophilia Registries Workshop
- 12th pharmacovigilance stakeholder forum - meeting documents
- Multistakeholder workshop to launch consultation on European Medicines Agency (EMA) human regulatory science to 2025 - agenda
- Workshop on the development of antimicrobial medicinal products for paediatric patients - meeting documents
- Sales of antibiotics for use in food-producing animals drop across the EU - report
- Expert meeting on genome editing technologies used in medicine development

Events

- Multi-stakeholder workshop with the Heads of Medicines Agencies / European Medicine Agency task force on availability of authorised medicines - November 2018
- 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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