105 **Issue 105**
December 2017

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.

To receive each new issue of the newsletter, please click here RSS feeds, choose 'Human medicines highlights newsletter' and then click on 'Subscribe to this feed'. Please note, in order to be able to view RSS feeds you need one of the following: a modern web browser; a web-based news reader or a desktop news reader. For a list of RSS readers please refer to our RSS guide and follow the instructions from the selected RSS reader in order to add our newsletter feed.

Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Darunavir Krka d.d. (*darunavir*) / Darunavir Krka (*darunavir*) generics of Prezista
  Treatment of HIV infection
- Prevymis (*letermovir*) O
  Prevention of cytomegalovirus (CMV) reactivation (viral infection)

New medicines authorised

- Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan (*efavirenz / emtricitabine / tenofovir disoproxil*) generic of Atripla
  Treatment of HIV infection
- Ritonavir Mylan (*ritonavir*) generic of Norvir
  Treatment of HIV infection

Key to symbols used

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

New information on authorised medicines

- Genvoya (*elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide*) - extension to existing indication
  Treatment of HIV infection

Cancer

Positive CHMP opinions on new medicines

- Fulvestrant Mylan (*fulvestrant*) generic of Faslodex
  Treatment of breast cancer
- Mvasi (*bevacizumab*) biosimilar of Avastin
  Treatment of cancers of the colon, breast, lung, kidney, ovaries and cervix

New medicines authorised

- Tookad (*padeliporfin*)
  Treatment of prostate cancer
- Zejula (*niraparib*)
  Treatment of ovarian, fallopian tube or peritoneum cancer

New information on authorised medicines

- Adcetris (*brentuximab vedotin*) - new indication
  Treatment of CD30+ cutaneous T-cell lymphoma (CTCL) (blood cancer)

Withdrawal of authorised medicines

- Kyomarc (*bevacizumab*) biosimilar of Avastin
  Used for the treatment of cancers of the colon, breast, lung, kidney, ovaries and cervix

Withdrawal of applications for extension of indication

- Keytruda (*pembrolizumab*)
  Intended to be used in combination with chemotherapy for non-small cell lung cancer (NSCLC)

Dermatology

New medicines authorised

- Cyltezo (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory conditions

Gastro-intestinal system

Positive CHMP opinions on new medicines

- Jorveza (*budesonide*)
  Treatment of eosinophilic oesophagitis (inflammation of the oesophagus)

New medicines authorised

- Cyltezo (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory conditions

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Intrarosa (*prasterone*)
  Treatment of vulvar and vaginal atrophy in postmenopausal women

New medicines authorised

- Zejula (*niraparib*)
  Treatment of ovarian, fallopian tube or peritoneum cancer

Haematology

Positive CHMP opinions on new medicines

- Adynovi (*rurioctocog alfa pegol*)
  Treatment and prevention of bleeding in patients with haemophilia A

HIV

New medicines authorised

- Darunavir Krka d.d. (*darunavir*) / Darunavir Krka (*darunavir*) generics of Prezista
  Treatment of HIV infection
- Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan (*efavirenz / emtricitabine / tenofovir disoproxil*)
  generic of Atripla
  Treatment of HIV infection
- Ritonavir Mylan (*ritonavir*) generic of Norvir
  Treatment of HIV infection

New information on authorised medicines

- Genvoya (*elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide*) - extension to existing indication
  Treatment of HIV infection

Immune system

Positive CHMP opinions on new medicines

- Fasenra (*benralizumab*)
  Treatment of eosinophilic asthma

New medicines authorised

- Cyltezo (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory conditions

New information on authorised medicines

- Nplate (*romiplostim*) - extension of existing indication
  Treatment of thrombocytopenic purpura (a bleeding disorder)

Withdrawal of applications for new medicines

- Plivensia (*sirukumab*)
  Intended for the treatment of rheumatoid arthritis

Supply shortages

- Cinryze (*C1 inhibitor (human)*) - resolved
  Treatment of angioedema (swelling)

Metabolic disorders

New medicines authorised

- Miglustat Gen.Orph (*miglustat*) generic of Zavesca
  Treatment of type-1 Gaucher disease

Nervous system

Positive CHMP opinions on new medicines

- Ocrevus (*ocrelizumab*)
  Treatment of multiple sclerosis

Safety communication update

- Review of Zinbryta (*daclizumab*) - CHMP Opinion (to be used in restricted patient group, with strict liver monitoring)
  Treatment of multiple sclerosis

Ophthalmology

New medicines authorised

- Cyltezo (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory conditions

Respiratory system

Positive CHMP opinions on new medicines

- Fasenra (*benralizumab*)
  Treatment of eosinophilic asthma

New information on authorised medicines

- Orkambi (*lumacaftor / ivacaftor*) - extension to existing indication
  Treatment of cystic fibrosis

Rheumatology

New medicines authorised

- Cyltezo (*adalimumab*) biosimilar of Humira
  Treatment of various inflammatory conditions

Withdrawal of applications for new medicines

- Plivensia (*sirukumab*)
  Intended for the treatment of rheumatoid arthritis

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Adopted guidelines

- Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials - Revision 1
- Guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)
- Guideline on the evaluation of anticancer medicinal products in man

Scientific committee and working party activities

- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: December 2017
- 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 and HCPWP joint meeting: info session on antimicrobial resistance - report - September 2017
- PCWP meeting with all eligible organisations - meeting documents - November 2017

Other publications

- Minutes of the 97th meeting of the Management Board: 5 October 2017
- EU Ombudsman confirms EMA's correct handling of declared interests
- EMA to relocate to Amsterdam, the Netherlands
- EMA gets ready for relocation decision
- EMA to work with stakeholders to improve the product information for EU medicines
- EMA and EUnetHTA finalise joint work plan for 2017-2020
- European Antibiotic Awareness Day: Statement by Guido Rasi, Executive Director of EMA
- We work together to fight antibiotic resistance keeping Europeans healthy - visual guide
- ENCePP: 10 years for excellence in medicines safety
- New guidelines on good manufacturing practices for advanced therapies
- New EudraVigilance system is live
- Towards a single development programme for new antibiotics in EU, Japan and US
- Juvenile animal studies (JAS) and impact on anti-cancer medicine development and use in children
- Report on the annual accounts of the European Medicines Agency for the financial year 2016 together with the Agency's reply
- Introduction to the European Union regulatory system and European Medicines Agency for international regulators and non-governmental organisations - meeting documents - September 2017
- Training session for patients and consumers interested in EMA's activities - meeting documents - November 2017
- Third tripartite meeting held between EMA, PMDA and FDA to discuss regulatory approaches for the evaluation of antibacterial agents - meeting documents - November 2017

Events

- Workshop on site and histology - Independent indications in oncology - December 2017
- EudraVigilance information day - December 2017
- Innovation and biomarkers in cancer drug development (IBCD) 2018 - November 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.

Visit our website

Further information about the European Medicines Agency and the work it does is available on our website:

http://www.ema.europa.eu

In particular, you may be interested in these links:

About us

Patients and carers

Healthcare professionals

European public assessment reports

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union