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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 information on authorised medicines

- Viread (*tenofovir disoproxil*) - extension to the existing indication
  Use in children aged 2 to less than 12 years with chronic hepatitis B infection

Cancer

Positive CHMP opinions on new medicines

- Pazenir (*paclitaxel*) generic of Abraxane
  Treatment of metastatic breast cancer and non-small cell lung cancer (NSCLC)
- Lorviqua (*lorlatinib*) C
  Treatment of non-small cell lung cancer (NSCLC)

New information on authorised medicines

- Lynparza (*olaparib*) - new indication
  Treatment of breast cancer

Key to symbols used

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

Other information

- Doxolipad (*doxorubicin hydrochloride*) - review of CHMP negative opinion at the request of the applicant
  Treatment of breast and ovarian cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Ondexxya (*andexanet alfa*) C
  Antidote to the anticoagulant (clot-preventing) medicines apixaban and rivaroxaban

Arbitration procedures

- Syner-Kinase and associated names (*urokinase*) - Outcome: medicine benefits outweigh risks
  Medicine used to dissolve blood clots

Withdrawal of applications for new medicines

- Epjevy (*pacritinib*)
  Treatment of symptoms of myelofibrosis associated with severe thrombocytopenia

Dermatology

Positive CHMP opinions on new medicines

- Skyrizi (*risankizumab*)
  Treatment of psoriasis

Diabetes

Positive CHMP opinions on new medicines

- Zynquista (*sotagliflozin*)
  Adjunct to insulin, treatment of type 1 diabetes mellitus

Gastro-intestinal system

New medicines authorised

- Rizmoic (*naldemedine*)
  Treatment of constipation

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

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  Treatment of metastatic breast cancer and non-small cell lung cancer

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Immune system

Positive CHMP opinions on new medicines

- Dectova (*zanamivir*) E
  Treatment of influenza

New information on authorised medicines

- Dupixent (*dupilumab*) - extension to existing indication
  Treatment of certain forms of severe asthma
- Trydonis and Riarify (*beclometasone / formoterol / glycopyrronium bromide*) - new indication
  Treatment for severe asthma

Metabolic disorders

Positive CHMP opinions on new medicines

- Waylivra (*volanesorsen*) C
  Treatment of familial chylomicronaemia syndrome (FCS, an inherited disorder of triglyceride metabolism which results in high risk for pancreatitis)
- Palynziq (*pegvaliase*)
  Treatment of phenylketonuria (inability to break down the amino acid phenylalanine, which then builds up in the blood and brain)

Nervous system

New medicines authorised

- Macimorelin Aeterna Zentaris (*macimorelin)*
  Diagnostic medicine to test the ability of the body to produce growth hormone

Respiratory system

Positive CHMP opinions on new medicines

- Pazenir (*paclitaxel*) generic of Abraxane
  Treatment of metastatic breast cancer and non-small cell lung cancer (NSCLC)
- Lorviqua (*lorlatinib*) C
  Treatment of non-small cell lung cancer (NSCLC)

New medicines authorised

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

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New information on authorised medicines

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  Treatment of certain forms of severe asthma
- Trydonis and Riarify (*beclometasone / formoterol / glycopyrronium bromide*) - new indication
  Treatment for severe asthma

Safety communication update

- Review of Fenspiride - review started (risk of heart rhythm problems) / Open call for data submission
  Treatment of chronic obstructive pulmonary disease (COPD)

Rheumatology

Negative CHMP opinions on new medicines

- Eladynos *(abaloparatide)*
  Treatment of osteoporosis (a disease that makes bones fragile)

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Role of big data for evaluation and supervision of medicines in the EU - Report
  Deadline for comments: 15 April 2019
- Risk classification of antimicrobials used in animals opens for public consultation
  Deadline for comments: 30 April 2019
- Draft Alectinib product-specific bioequivalence guidance
  Deadline for comments: 30 June 2019
- Draft Palbociclib product-specific bioequivalence guidance
  Deadline for comments: 30 June 2019
- Draft guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials
  Deadline for comments: 01 August 2019
- Draft guideline on clinical investigation of medicinal products for the treatment of gout
  Deadline for comments: 08 August 2019

Adopted guidelines

- Octreotide acetate product-specific bioequivalence guidance
- Adjustment for cross-over in estimating effects in oncology trials

- Qualification opinion on Cellular therapy module of the European Society for Blood & Marrow Transplantation (EBMT) Registry

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - January 2019
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: February 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
- Revised Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP)
- Revised Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP)
- Revised Rules of procedure for the PCWP and HCPWP
- Revised Mandate, objectives and rules of procedure for the CHMP Biologics Working Party (BWP)

Other publications

- 102nd Management Board Meeting (12-13 December 2019) - Minutes
- European Court of Auditors (ECA) final report on the annual accounts of the European Medicines Agency (EMA) of the financial year 2017
- New safety features for medicines sold in the EU
- Booklet 'From lab to patient: the journey of a centrally authorised medicine'
- Infographic on Article 58 procedure
- Orphan medicines figures 2000-2018
- Orientation guide for delegates - Spark building
- Rules for reimbursement of expenses for delegates attending meetings with effect from 30 March 2019
- Change of time zone due to EMA's relocation in March 2019
- EMA in London (1995-2019)
- Two additional countries to benefit from EU-US mutual recognition agreement for inspections
- EU and Switzerland to improve information-sharing on good manufacturing practice through use of the EudraGMDP database

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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