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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

- Efavirenz/Emtricitabine/Tenofovir disoproxil Krka (*efavirenz / emtricitabine / tenofovir disoproxil*) generic of Atripla
  Treatment of HIV infection

New information on authorised medicines

- Truvada (*emtricitabine / tenofovir disoproxil*) - extension to existing indication
  Treatment of HIV infection

Cancer

Positive CHMP opinions on new medicines

- Herzuma (*trastuzumab*) biosimilar of Herceptin
  Treatment of breast and stomach cancer

Key to symbols used

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

New information on authorised medicines

- Yervoy (*ipilimumab*) - extension to existing indication
  Treatment of melanoma (skin cancer)

Negative CHMP opinions on new medicines

- Aplidin (*plitidepsin*)
  Intended for the treatment of multiple myeloma (cancer of the bone marrow)

Safety communication update

- Review of Xofigo (*radium Ra223 dichloride*) - review started (increased risk of death and fractures reported in an ongoing clinical trial)
  Treatment of prostate cancer

Diabetes

Positive CHMP opinions on new medicines

- Ozempic (*semaglutide*)
  Treatment of type 2 diabetes

Gynaecology & Obstetrics

Safety communication update

- Review of Esmya (*ulipristal acetate*) - review started (triggered following cases of liver injury)
  Treatment of uterine fibroids (non-cancerous tumours of the womb)

HIV

Positive CHMP opinions on new medicines

- Efavirenz/Emtricitabine/Tenofovir disoproxil Krka (*efavirenz / emtricitabine / tenofovir disoproxil*)
  generic of Atripla
  Treatment of HIV infection

New information on authorised medicines

- Truvada (*emtricitabine / tenofovir disoproxil*) - extension to existing indication
  Treatment of HIV infection

Hormone system

Positive CHMP opinions on new medicines

- Alkindi (*hydrocortisone*)
  Treatment of adrenal insufficiency (rare hormonal disorder)

Immune system

Positive CHMP opinions on new medicines

- Anagrelide Mylan (*anagrelide*) generic of Xagrid
  Reduction of platelets in thrombocythaemia (a blood clotting disorder)

New information on authorised medicines

- Taltz (*ixekizumab*) - new indication
  Treatment of active psoriatic arthritis

Safety communication update

- Mycophenolate: updated recommendations for contraception for men and women
  Used to prevent rejection of transplanted organs

Metabolic disorders

Positive CHMP opinions on new medicines

- Crysvita (*burosumab*) O C
  Treatment of X-linked hypophosphataemia (rare bone disorder)

Musculoskeletal system

Positive CHMP opinions on new medicines

- Crysvita (*burosumab*) O C
  Treatment of X-linked hypophosphataemia (rare bone disorder)

Nervous system

Withdrawal of applications for new medicines

- Qizenday (*d-biotin*)
  Intended for the treatment of multiple sclerosis

Other medicines

Positive CHMP opinions on new medicines

- Alofisel (*Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue*) O
  Treatment of anal fistulas in patients with Crohn's disease

New medicines authorised

- Nyxoid (*naloxone*)
  Treatment of opioid overdose

Key to symbols used

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Safety communication update

- Review of paracetamol-modified release (*paracetamol*) - CMDh Position (modified-release paracetamol-containing products to be suspended from EU market)
  Relief of pain and fever

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft qualification opinion on Proactive in chronic obstructive pulmonary disease (COPD)
  Deadline for comments: 29 January 2018
- Concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics
  Deadline for comments: 31 March 2018
- ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management
  Deadline for comments: 18 December 2018

Adopted guidelines

- ICH guideline E17 on general principles for planning and design of multi-regional clinical trials
- ICH Guideline S3A: Note for guidance on toxicokinetics: the assessment of systemic exposure in toxicity studies - Questions and answers - Step 5 - First version

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - November 2017
- 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

- Work plan for the Safety Working Party 2018
- Work plan for the CHMP Biologics Working Party 2018
- Work plan for the Vaccine Working Party 2018
- Work plan for the joint CHMP/ CVMP Quality Working Party for 2018
- Annual report of the Good Manufacturing and Distribution Practice Inspectors Working Group 2016

Other publications

- EMA Management Board: highlights of December 2017 meeting
- EMA Management Board meeting: 13-14 December 2017 - meeting documents
- European Commission closes infringement procedure against Roche
- End of year message from EMA's Executive Director
- Orphan medicines in the EU – leaving no-one behind
- Orphan medicines in the EU - leaflet
- Call for patient organisation representatives to join the Committee for Orphan Medicines
- PRAC strategy on measuring the impact of pharmacovigilance activities - updated
- The European regulatory system for medicines and the EMA - A consistent approach to medicines regulation across the EU - updated
- European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting - meeting documents - October 2017
- European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting - meeting documents - November 2017

Events

- Second international awareness session for international regulators, academia and non-governmental organisations - March 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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