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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

- Orbactiv (*oritavancin*)
  Treatment of acute bacterial skin infections
- Sivextro (*tedizolid phosphate*)
  Treatment of acute bacterial skin infections

Cancer

New medicines authorised

- Cyramza *(ramucirumab)* O
  Treatment of cancer of the stomach and of the junction between the stomach and gullet
- Lynparza (*olaparib*) O
  Treatment of ovarian, fallopian tube and primary peritoneal cancers

Key to symbols used

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

- Vargatef (*nintedanib*)
  Treatment of non-small cell lung cancer

New information on authorised medicines

- Abraxane (*paclitaxel*) - new indication
  Treatment of non-small cell lung cancer
- Aloxi (*palonosetron*) - new indication
  Prevention of nausea and vomiting associated with chemotherapy in children

Withdrawal of application for a change to the indication

- Teysuno (*tegafur / gimeracil / oteracil*)
  Intended to treat gastric cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Kengrexal (*cangrelor*)
  Reduction of problems caused by blood clots, such as heart attack

Dermatology

Positive CHMP opinions on new medicines

- Orbactiv (*oritavancin*)
  Treatment of acute bacterial skin infections
- Sivextro (*tedizolid phosphate*)
  Treatment of acute bacterial skin infections

Gynaecology & Obstetrics

New medicines authorised

- Duavive (*oestrogens conjugated / bazedoxifene*)
  Treatment of symptoms of menopause

HIV

Positive CHMP opinions on new medicines

- Dutrebis (*lamivudine / raltegravir*)
  Treatment of HIV-1 infection

Haematology

New information on authorised medicines

- Jakavi (*ruxolitinib*) O - new indication
  Treatment of polycythaemia vera (blood disease leading to production of too many red blood cells)

Hormone system

New medicines authorised

- Ketoconazole HRA (*ketoconazole*)
  Treatment of Cushing's syndrome

Metabolic system

Positive CHMP opinions on new medicines

- Saxenda (*liraglutide*)
  Weight management in obese or overweight patients

Nervous system

New medicines authorised

- Duloxetine Lilly (*duloxetine*)
  Treatment of depression, anxiety and diabetic nerve pain
- Paliperidone Janssen (*paliperidone*)
  Treatment of schizophrenia

Arbitration procedure

- Merisone / Myoson (*tolperisone*) - start
  Treatment of post-stroke spasticity (muscle spasm after a stroke)

Ophthalmology

Positive CHMP opinions on new medicines

- Ikervis (*ciclosporin*)
  Treatment of severe keratitis (inflammation of the cornea) in patients with dry eye disease

New information on authorised medicines

- Eylea (*aflibercept*) - new indication
  Treatment of visual impairment due to macular oedema

Respiratory system

Positive CHMP opinions on new medicines - re-adopted

- Vantobra (*tobramycin*)
  Management of chronic pulmonary infection in patients with cystic fibrosis

Safety communication update

- Review of ambroxol and bromhexine-containing medicines - PRAC recommendation (risk of severe allergic reactions found to be small)
  Expectorants (to clear the airways), relief of sore throat and treatment of breathing disorders in premature and newborn babies

Vaccines

New information on authorised medicines

- Prevenar 13 (*pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)*) - change in indication
  Prevention of invasive disease, pneumonia and acute otitis media in infants, children and **adolescents** from 6 weeks to 17 years of age.
  Active immunisation for the prevention of invasive disease and **pneumonia** in adults **18 years** of age or over

Other medicines

Positive CHMP opinions on new medicines

- Raplixa (*human fibrinogen / human thrombin*)
  Treatment to stop bleeding in patients undergoing surgery

Arbitration procedures

- GVK Biosciences review: suspension of some medicines due to flawed studies

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on clinical investigation of recombinant and human plasma-derived factor IX products
  Deadline for comments: 07 February 2015

Adopted guidelines

- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Q3D on elemental impurities - Step 4
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use topic E 2 B (R3): Questions and answers: Data elements for transmission of individual case safety reports - Step 5
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) M2 on electronic common technical document (eCTD) - file format criteria - Step 5

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - December 2014
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: January 2015
- 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 Rheumatology-Immunology Working Party 2015
- Work plan for the Cardiovascular Working Party 2015
- Work plan for the Central Nervous System Working Party 2015
- Work plan for the Organisational Matters Drafting Group 2015
- Work plan for the Safety Working Party 2015
- Work plan for the PCWP 2015
- Work plan for the HCPWP 2015

Other publications

- 20th anniversary of EMA
- New international standard to improve safety of medicines
- Europe to boost international cooperation on generics
- EU report provides basis for effective fight against development of resistant bacteria
- Record number of medicines for rare diseases recommended for approval in 2014
- Central repository to facilitate assessment of medicines safety reports
- News bulletin for small and medium-sized enterprises - Issue 30
- Introduction to pharmacovigilance and rules for expedited reporting of Individual Case Safety Reports (ICSRs) in Europe - March 2015
- Science, Medicines, Health: Patients at the heart of future innovation - March 2015
- World Health Organization international consultation on regulatory systems strengthening - Geneva, Switzerland - January 2015
- Workshop on development pathways for advanced-therapy medicinal products - December 2014 - meeting report

- EMA/EFPIA workshop on the importance of dose finding and dose selection for the successful development, licensing and lifecycle management of medicinal products - December 2014 - meeting documents
- PCWP meeting with all eligible organisations - November 2014 - meeting documents
- Training session for patients and consumers involved in European Medicines Agency activities - November 2014 - training material

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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