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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

- Cresemba (*isavuconazole*) O
  Treatment of fungal infections (aspergillosis and mucormycosis)
- Zerbaxa (*ceftolozane / tazobactam*)
  Treatment of intra-abdominal, kidney and urinary tract infections

New information on authorised medicines

- Cubicin (*daptomycin*) - change in indication
  Treatment of complicated skin and soft-tissue infections

Cancer

Positive CHMP opinions on new medicines

- Imlygic (*talimogene laherparepvec*)
  Treatment of melanoma (skin cancer)

Key to symbols used

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

New information on authorised medicines

- Emend (*aprepitant*) - extension of indication
  Prevention of nausea and vomiting associated with chemotherapy

New medicines authorised

- Pemetrexed Lilly (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- Pemetrexed Sandoz (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New information on authorised medicines

- Xalkori (*crizotinib*) - new indication
  Treatment of advanced non-small cell lung cancer (first-line)

Cardiovascular system

New medicines authorised

- Praluent (*alirocumab*)
  Treatment of high levels of cholesterol

New information on authorised medicines

- Volibris (*ambrisentan*) - change in indication
  Treatment of pulmonary arterial hypertension

Dermatology

New information on authorised medicines

- Cubicin (*daptomycin*) - change in indication
  Treatment of complicated skin and soft-tissue infections

Haematology

Withdrawal of applications for new medicines

- VeraSeal (*human fibrinogen / human thrombin*)
  Treatment of bleeding during vascular (blood vessel) surgery

HIV

New information on authorised medicines

- Edurant (*rilpivirine*) - change in indication
  Treatment of HIV-1 infection

Safety communication update

- Updated advice on body fat changes and lactic acidosis with HIV medicines

Immune system

New information on authorised medicines

- Cosentyx (*ecukinumab*) - new indication
  Treatment of psoriatic arthritis (inflammation of the joints) and ankylosing spondylitis (inflammation of the spinal joints)

Safety communication update

- EMA recommends additional measures to prevent use of the transplant medicine mycophenolate in pregnancy

Metabolic system

Negative CHMP opinions on new medicines

- Heparesc (*human heterologous liver cells*)
  Intended for the treatment of urea cycle disorders

Musculoskeletal system

Safety communication update

- Review of Inductos (*dibotermin alfa*) - CHMP opinion (recommends suspension over non-compliance with manufacturing requirements)
  Used in patients with spinal disc problems and leg fractures

Nephrology

New medicines authorised

- Fexeric (*ferric citrate coordination complex*)
  Treatment of hyperphosphataemia (high blood phosphate levels) in patients with kidney disease

Nervous system

New medicines authorised

- Intuniv (*guanfacine*)
  Treatment of attention deficit hyperactivity disorder (ADHD)

Withdrawal of authorised medicines

- Sonata (*zaleplon*)
  Used for the treatment of insomnia

Safety communication update

- Updated recommendations to minimise the risk of the rare brain infection progressive multifocal leukoencephalopathy with Tecfidera

Rheumatology

New information on authorised medicines

- Cosentyx (*secukinumab*) - new indication
  Treatment of psoriatic arthritis (inflammation of the joints) and ankylosing spondylitis (inflammation of the spinal joints)

Other medicines

New medicines authorised

- Zalviso (*sufentanil*)
  Treatment of post-operative pain

Safety communication update

- EMA recommends additional measures to prevent use of the transplant medicine mycophenolate in pregnancy

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft tacrolimus granules for oral suspension 0.2 and 1 mg product-specific bioequivalence guidance
  Deadline for comments: 01 January 2016
- Draft lenalidomide hard gelatine capsules 2.5, 5, 7.5, 10, 15 and 25mg product-specific bioequivalence guidance
  Deadline for comments: 01 January 2016
- Draft entecavir film-coated tablets 0.5 and 1 mg, oral solution 0.05mg/ml product-specific bioequivalence guidance
  Deadline for comments: 01 January 2016
- Draft rivaroxaban film-coated tablets 2.5, 10, 15 and 20mg product-specific bioequivalence guidance
  Deadline for comments: 01 January 2016
- Draft ticagrelor film-coated tablets 90mg product-specific bioequivalence guidance
  Deadline for comments: 01 January 2016
- Draft guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins
  Deadline for comments: 31 January 2016

Adopted guidelines

- Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man - Condition specific guidance

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - September 2015
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines: October 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

Other publications

- EMA's Management Board nominates Guido Rasi as Executive Director
- EMA Management Board: highlights of October 2015 meeting
- Annual report on European Medicines Agency's interaction with patients, consumers, healthcare professionals and their organisations (2014)
- Committee for Orphan Medicinal Products: Chair and Vice-chair re-elected
- Public consultation starts on PRIME - a new scheme to optimise development of priority medicines and facilitate patients' access
- Collecting high-quality information on medicines through patient registries
- Improved electronic reporting of suspected adverse reactions for better health protection
- News bulletin for pharmacovigilance programme update - Issue 5
- News bulletin for small and medium-sized enterprises - Issue 33
- Supporting responsible use of veterinary antibiotics in Europe
- 2015 annual European Union Good-clinical-practice Inspectors Working Group workshop - October 2015
- Workshop on good clinical practice for bioequivalence trials/generics - October 2015
- European network of paediatric research at the EMA Coordinating Group members meeting - October 2015
- Training session for patients and consumers interested in EMA activities - Agenda - November 2015
- EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations - Agenda - November 2015

Key to symbols used

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- Innovative Medicines Initiative WEB-RADR workshop - December 2015
- Demonstrating significant benefit of orphan medicines concepts, methodology, and impact on access - December 2015
- EMA workshop on extrapolation of efficacy and safety in medicine development - May 2016

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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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