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September 2015

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

- Rebetol (*ribavirin*) - changes to the terms of marketing authorisation
  Treatment of hepatitis C

Safety communication update

- Review of fusafungine containing medicinal products - review started (following reports of serious allergic reactions)
  Treatment of infections of the upper airways (such as sinusitis and tonsillitis)

Cancer

Positive CHMP opinions on new medicines

- Blincyto (*blinatumomas*) O C
  Treatment of Philadelphia chromosome-negative acute lymphoblastic leukaemia

Key to symbols used

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

- Ciambra (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- Cotellic (*cobimetinib*)
  Treatment of melanoma (skin cancer)
- Kyprolis (*carfilzomib*)
  Treatment of multiple myeloma (cancer of the bone marrow)
- Pemetrexed Hospira (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer
- Pemetrexed medac (*pemetrexed*)
  Treatment of pleural mesothelioma (cancer of the lung lining) and non-small cell lung cancer

New medicines authorised

- Docetaxel Hospira UK Limited (*docetaxel*)
  Treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer
- Farydak (*panobinostat*)
  Treatment of multiple myeloma
- Odomzo (*sonidegib*)
  Treatment of basal cell carcinoma (a type of skin cancer)
- Unituxin (*dinutuximab*)
  Treatment of neuroblastoma (cancer of the nerve cells)

New information on authorised medicines

- Opdivo (*nivolumab*) - new indication
  Treatment of non-small cell lung cancer
- Vidaza (*azacitidine*) - new indication
  Treatment of acute myeloid leukaemia

Cardiovascular system

Positive CHMP opinions on new medicines

- Entresto (*sacubitril / valsartan*)
  Treatment of chronic heart failure

New medicines authorised

- Ivabradine Anpharm (*ivabradine*)
  Treatment of angina and heart failure

Diabetes

Positive CHMP opinions on new medicines

- Ebymect (*dapagliflozin / metformin*)
  Treatment of type 2 diabetes mellitus

- Edistride (*dapagliflozin*)
  Treatment of type 2 diabetes mellitus

Supply shortages

- Insuman Rapid, Basal and Comb (*insulin human*) - resolved
  Treatment of diabetes type 1 and 2

Haematology

Positive CHMP opinions on new medicines

- Blincyto (*blinatumomas*) O C
  Treatment of Philadelphia chromosome-negative acute lymphoblastic leukaemia
- Elocta (*efmoroctocog alfa*) O
  Treatment and prevention of bleeding in haemophilia A
- Praxbind (*idarucizumab*)
  To be used for rapid reversal of the anticoagulant effects of *dabigatran etexilate*

New medicines authorised

- Farydak (*panobinostat*) O
  Treatment of multiple myeloma

New information on authorised medicines

- Vidaza (*azacitidine*) - new indication O
  Treatment of acute myeloid leukaemia

HIV

Positive CHMP opinions on new medicines

- Genvoya (*elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide*)
  Treatment of HIV infection

Hormone system

Positive CHMP opinions on new medicines

- Cinacalcet Mylan (*cinacalcet*)
  Used in patients with hyperparathyroidism (including in patients with kidney disease) and parathyroid carcinoma

Immune system

Positive CHMP opinions on new medicines

- Nucala (*mepolizumab*)
  Treatment of asthma

Metabolic system

Positive CHMP opinions on new medicines

- Kolbam (*cholic acid*) O - revised opinion
  Treatment of inborn errors in primary bile acid synthesis (defects in bile acid production)
- Ravicti (*glycerol phenylbutyrate*) O
  Treatment of urea cycle disorders

New medicines authorised

- Strensiq (*asfotase alfa*) O E
  Treatment of paediatric-onset hypophosphatasia (a rare inherited bone disorder)
- Kanuma (*sebelipase alfa*) O
  Treatment of lysosomal acid lipase deficiency

Musculoskeletal system

New medicines authorised

- Strensiq (*asfotase alfa*) O E
  Treatment of paediatric-onset hypophosphatasia (a rare inherited bone disorder)

Supply shortages

- Inductos (*dibotermin alfa*)
  Used in patients with spinal disc problems and leg fractures

Nephrology

Positive CHMP opinions on new medicines

- Cinacalcet Mylan (*cinacalcet*)
  Used in patients with hyperparathyroidism (including in patients with kidney disease) and parathyroid carcinoma

Nervous system

Positive CHMP opinions on new medicines

- Aripiprazole Accord (*aripiprazole*)
  Treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder
- Numient (*levodopa / carbidopa*)
  Treatment of Parkinson's disease

New medicines authorised

- Aripiprazole Sandoz (*aripiprazole*)
  Treatment of schizophrenia and prevention of manic episodes in bipolar I disorder
- Pregabalin Accord (*pregabalin*)
  Treatment of epilepsy and generalised anxiety disorder

New information on authorised medicines

- Gilenya (*fingolimod*) - change of indication
  Treatment of multiple sclerosis

Ophthalmology

New information on authorised medicines

- Eylea (*aflibercept*) - new indication
  Treatment of impaired vision due to myopic choroidal neovascularisation

New medicines authorised

- Omidria (*phenylephrine / ketorolac*)
  Maintenance of pupil dilation during lens replacement surgery and prevention of pain
- Raxone (*idebenone*) O E
  Treatment of impaired vision in patients with Leber's hereditary optic neuropathy

Respiratory system

Positive CHMP opinions on new medicines

- Nucala (*mepolizumab*)
  Treatment of asthma
- Orkambi (*lumacaftor / ivacaftor*) O
  Treatment of cystic fibrosis

New medicines authorised

- Respreeza (*human alpha1-proteinase inhibitor*)
  Treatment of alpha1-proteinase inhibitor deficiency (a condition mainly affecting the lungs)

New information on authorised medicines

- Kalydeco (*ivacaftor*) - new indication and presentations O
  Treatment of cystic fibrosis

Safety communication update

- Review of fusafungine containing medicinal products - review started (following reports of serious allergic reactions)
  Treatment of infections of the upper airways (such as sinusitis and tonsillitis)

Other medicines

Positive CHMP opinions on new medicines

- Ionsys (*fentanyl*)
  Treatment of post-operative pain

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft guideline on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products
  Deadline for comments: 31 March 2016

Adopted guidelines

- Guideline on the evaluation of medicinal products for the treatment of chronic constipation (including opioid induced constipation) and for bowel cleansing

Scientific committee and working party activities

- Medicinal products for human use: monthly figures - August 2015
- CHMP - agendas, minutes and highlights
- CHMP - applications for new human medicines under evaluation: September 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
- Updated work plan for the GMP/GDP Inspectors Working Group 2015

Other publications

- EC, EMA and WHO step up cooperation to better protect global public health
- Annual activity report 2014
- Agenda for the 89th meeting of the Management Board
- CHMP Chair re-elected
- Call for civil society members to join two EMA committees

- Update on publication of clinical data
- EMA's medical literature monitoring enters into full operation
- Demonstrating significant benefit of orphan medicines
- Accelerated development of appropriate patient therapies: a sustainable, multi-stakeholder approach from research to treatment outcomes (ADAPT SMART project) kick-off meeting - September 2015
- Second stakeholder meeting on the implementation of the EMA's policy on publication of clinical data for human medicines - September 2015
- Ninth stakeholder forum on the pharmacovigilance legislation - September 2015
- Consultation meeting with industry stakeholders on new scheme to support development of innovative medicines for unmet medical needs - October 2015
- Expert meeting on paediatric development of fixed-dose combinations for the treatment of the human immunodeficiency virus (HIV) - November 2015
- Workshop on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products - November 2015

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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