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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.

To receive an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Dificlir (*fidaxomicin*)
  Treatment of *Clostridium difficile* infections
- Colobreathe (*colistimethate sodium*) O
  Treatment of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged 6 years and older

Arbitration procedures

- Famvir (*famciclovir*)
  Treatment of infection with herpes viruses
- Valtrex (*valaciclovir*)
  Treatment of infections with herpes viruses and with cytomegalovirus

Key to symbols used

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

Cancer

New marketing authorisations

- Votubia (*everolimus*)
  Treatment of subependymal giant cell astrocytoma

Withdrawal of marketing authorisation applications

- Doxorubicin SUN (*doxorubicin*)
  Intended for the treatment of breast cancer, ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma

New information on authorised medicines

- Avastin (*bevacizumab*) - new indication
  Treatment of ovarian, fallopian tube or peritoneal cancer
- Alimta (*pemetrexed*)
  Treatment of non-small cell lung cancer

Arbitration procedures

- Levact (*bendamustine*)
  Treatment of lymphocytic leukaemia, non-Hodgkin's lymphoma (lymph tissue cancer) and multiple myeloma

Safety communication update

- Caelyx (*doxorubicin*)
  Treatment of breast cancer, ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma
- Revlimid (*lenalidomide*)
  Treatment of multiple myeloma

Cardiovascular system

Positive CHMP opinions on new medicines

- Ipreziv (*azilsartan medoxomil*)
  Treatment of essential hypertension
- Edarbi (*azilsartan medoxomil*)
  Treatment of essential hypertension
- Rasitrio (*aliskiren, amlodipine and hydrochlorothiazide*)
  Treatment of essential hypertension
- Onduarp (*amlodipine and telmisartan*)
  Treatment of essential hypertension

New marketing authorisations

- Sprimeo HCT (*aliskiren and hydrochlorothiazide*)
  Treatment of essential hypertension

New information on authorised medicines

- Xarelto (*rivaroxaban*) - new indications
  Treatment of deep vein thrombosis (DVT), prevention of recurrent DVT, pulmonary and systemic embolism and stroke

Arbitration procedures (non-safety related)

- Clopidogrel Orion and Clopidogrel Teva (*clopidogrel*)
  Prevention of atherothrombotic events such as heart attack and stroke
- Lescol (*fluvastatin*)
  Treatment of dyslipidaemia (abnormal levels of cholesterol in the blood)
- Atacand Plus (*candesartan cilexetil and hydrochlorothiazide*)
  Treatment of essential hypertension

Safety communication update

- Multaq (*dronedarone*)
  Treatment of atrial fibrillation

Diabetes

Positive CHMP opinions on new medicines

- Pioglitazone Actavis and Pioglitazone Actavis Group (*pioglitazone*)
  Treatment of type 2 diabetes mellitus
- Pioglitazone Teva Pharma, Pioglitazone Teva Generics and Pioglitazone Teva (*pioglitazone*)
  Treatment of type 2 diabetes mellitus
- Sepioglin (*pioglitazone*)
  Treatment of type 2 diabetes mellitus
- Komboglyze (*saxagliptin / metformin hydrochloride*)
  Treatment of type 2 diabetes mellitus

New information on authorised medicines

- Levemir (*detemir*) - extended indication
  Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above

Safety communication update

- Apidra (*glulisine*)
  Treatment of diabetes

Gastro-intestinal diseases

Arbitration procedures (non-safety related)

- Kytril (*granisetron*)
  Prevention of nausea and vomiting following chemotherapy / radiotherapy treatment
- Losec *(omeprazole)*
  Treatment of reflux disease, (heartburn), reflux oesophagitis (inflammation of the gullet), stomach or duodenal ulcer and Zollinger-Ellison syndrome (oversecretion of acid in the stomach)

Haematology

New information on authorised medicines

- Soliris (*eculizumab*) - new indication
  Treatment of atypical hemolytic uremic syndrome

HIV

Positive CHMP opinions on new medicines

- Eviplera (*emtricitabine, rilpivirine and tenofovir disoproxil*)
  Treatment of HIV infection
- Edurant (*rilpivirine*)
  Treatment of HIV infection

Immune diseases

Positive CHMP opinions on new medicines

- Desloratadine Krka and Dasselta (*desloratadine*)
  Treatment of allergic rhinitis and urticaria
- Desloratadine Teva (*desloratadine*)
  Treatment of allergic rhinitis and urticaria

Nervous system

Positive CHMP opinions on new medicines

- Levetiracetam Actavis Group (*levetiracetam*)
  Treatment of epilepsy

New marketing authorisations

- Levetiracetam ratiopharm (*levetiracetam*)
  Treatment of epilepsy
- Levetiracetam Teva (*levetiracetam*)
  Treatment of epilepsy
- Buccolam (*midazolam*)
  Treatment of convulsive seizures in children and adolescents
- Levodopa/Carbidopa/Entacapone Orion (*levodopa / carbidopa / entacapone*)
  Treatment of Parkinson's disease

Safety communication update

- Vimpat (*lacosamide*)
  Treatment of partial-onset seizures

Respiratory system

Safety communication update

- Suppositories containing terpenic derivatives
  Treatment of bronchial disorders

Rheumatology

Arbitration procedures

- Fortipan Combi D and Norsed Combi D (*risedronate sodium, calcium carbonate and colecalciferol*)
  Treatment of osteoporosis

Nephrology

Safety communication update

- Baxter's dialysis solutions
  Peritoneal dialysis and haemodialysis

Vaccines

Positive CHMP opinions on new medicines

- Prevenar 13 (*pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed*))
  Active immunisation for the prevention of invasive disease caused by *Streptococcus pneumoniae* in adults aged 50 years and older

Safety communication update

- Gardasil (*Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed*))
  Prevention of premalignant genital lesions, cervical cancer and external genital warts caused by human papillomavirus (HPV)

Other medicines

Arbitration procedures

- Prevora (*chlorhexidine*)
  Reduction of dental caries (tooth decay)

Other information

- Orlistat-containing medicines
  To aid weight loss

Other information

Guidelines

Guidelines open for consultation

- Concept paper on pharmacovigilance implementing measures released for consultation
  Deadline for comments: 7 November 2011
- Concept paper on the need for revision of Note for Guidance on Clinical Medicinal Products for Treatment of Nociceptive Pain and Guideline on clinical investigation of products intended for the treatment of neuropathic pain
  Deadline for comments: 31 December 2011
- Draft guideline on core summary of product characteristics for plasma-derived fibrin sealant / haemostatic products
  Deadline for comments: 31 December 2011

Adopted guidelines

- Guideline on specifications test procedures and acceptance criteria for herbal substances herbal preparations and herbal medicinal products traditional herbal medicinal products
- Guideline on quality of herbal medicinal products traditional herbal medicinal products

Scientific committee activities

- CHMP highlights from the September meeting
- COMP report from the September meeting
- PDCO report from the September meeting
- PhVWP report from the September meeting
- HMPC report from the September meeting

Other publications

- European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting
- European Medicines Agency provides update on electronic submission of information on medicines
- European Medicines Agency launches new database of European experts
- Annual Report of the Pharmacovigilance Inspectors Working Group (PhV IWG) for 2010
- Report on the implementation of the European Medicines Agency/Committee for Medicinal Products for Human Use think-tank recommendations
- Thalidomide - Follow-up meeting with patients' and victims' organisations
- Transatlantic workshop on drug-related progressive multifocal leukoencephalopathy (PML)
- Questions and answers on the paediatric use marketing authorisation (PUMA)

- News bulletin for small and medium-sized enterprises - Issue 17
- EU Clinical Trials Register recognised as 'primary registry' of WHO's International Clinical Trials Registry Platform
- 2nd Joint DIA/EMA ENCePP Information Day EMA, London, UK, 7-Nov-2011
- EUCERD/EMA Workshop: Towards a public-private partnership for registries in the field of rare disease, EMA, London, UK, 04-Oct-2011
- Ethical considerations for paediatric trials - how can ethics committees in the European Member States and the Paediatric Committee at the EMA work together?, 29-30 Nov-2011
- World Alzheimer's Day: 21 September 2011
- World Heart Day: 29 September 2011

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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