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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

- Incivo (*telaprevir*)
  Treatment of hepatitis C

Cancer

Positive CHMP opinions on new medicines

- Zytiga (*abiraterone*)
  Treatment of prostate cancer
- Mercaptopurine Nova Laboratories (*mercaptopurine*) O
  Treatment of leukaemia

New marketing authorisations

- Yervoy (*ipilimumab*)
  Treatment of melanoma (type of skin cancer)

Key to symbols used

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

Withdrawal of marketing authorisation applications

- Doxorubicin Sun (*doxorubicin*)
  Intended for the treatment of breast cancer, ovarian cancer, progressive myeloma and AIDS-related Kaposi's sarcoma
- Ibandronic acid Hexal (*ibandronic acid*)
  Intended for the prevention of skeletal events in patients with breast cancer and bone metastases

New information on authorised medicines

- Afinitor (*everolimos*) - new indication
  Treatment of pancreatic tumours
- Tarceva (*erlotinib*) - new indication
  Treatment of non-small cell lung cancer

Cardiovascular system

Positive CHMP opinions on new medicines

- Telmisartan Teva Pharma (*telmisartan*)
  Treatment of essential hypertension (high blood pressure)

Arbitration procedures

- Norvasc (*amlodipine*)
  Treatment of cardiovascular problems such as hypertension and angina

Safety communication update

- Multaq (*dronedarone*)
  Prevention of atrial fibrillation (abnormal heart rhythm)

Dermatology

New information on authorised medicines

- Enbrel (*etanercept*) - change to an indication
  Treatment of plaque psoriasis in children and adolescents from the age of **6** years

Diabetes

Positive CHMP opinions on new medicines

- Pioglitazone ratiopharm GmbH/Pioglitazone ratio/Pioglitazone ratiopharm (*pioglitazone*)
  Treatment of type 2 diabetes mellitus
- Pioglitazone Accord (*pioglitazone*)
  Treatment of type 2 diabetes mellitus
- Paglitaz and Pioglitazone Krka (*pioglitazone*)
  Treatment of type 2 diabetes mellitus

New marketing authorisations

- Bydureon (*exenatide*)
  Treatment of type 2 diabetes mellitus

Safety communication update

- Pioglitazone-containing medicines (Actos, Glustin, Competact, Glubrava and Tandemact)
  Treatment of type 2 diabetes mellitus

Hormone diseases

Positive CHMP opinions on new medicines

- Plenadren (*hydrocortisone*)
  Treatment of adrenal insufficiency

Immune disorders

New marketing authorisations

- Cinryze (*C1 inhibitor*)
  Treatment and prevention of hereditary angioedema
- Nulojix (*belatacept*)
  Prevention of transplanted kidney rejection

Arbitration procedures

- Dexamethasone Alapis (*dexamethasone*)
  Treatment of inflammation and swelling

Musculoskeletal

New information on authorised medicines

- Enbrel (*etanercept*) - change to indication
  Treatment of arthritis in children and adolescents from the age of **2** years

Nervous system

Positive CHMP opinions on new medicines

- Levetiracetam Accord (*levetiracetam*)
  Treatment of epilepsy
- Levetiracetam Actavis (*levetiracetam*)
  Treatment of epilepsy
- Matever (*levetiracetam*)
  Treatment of epilepsy
- Pramipexole Accord (*pramipexole*)
  Treatment of Parkinson's disease and restless leg syndrome

- Dexdor (*dexmedetomidine*)
  Sedation of adult patients in intensive care units
- Vyndaqel (*tafamidis*)
  Treatment of transthyretin amyloidosis (to delay neurological impairment)

New marketing authorisations

- Rivastigmine Actavis (*rivastigmine*)
  Treatment of Alzheimer's dementia

Negative CHMP opinions on extension of indication

- Ariclaim, Cymbalta and Xeristar (*duloxetine*)
  Intended for the treatment of chronic somatic pain

Negative CHMP opinions on new medicines

- Sumatriptan Galpharm (*sumatriptan*)
  Intended for the treatment of migraine attacks

Safety communication update

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

Ophthalmology

Withdrawal of marketing authorisation applications for extension of indication

- Macugen (*pegaptanib*)
  Intended to add the treatment of visual impairment due to diabetic macular oedema

Vaccines

Safety communication update

- Pandemrix - restricted use
  Vaccination for prevention of influenza

Other medicines

New marketing authorisations

Safety communication update

- Champix (*varenicline*)
  Smoking cessation

Other information

Guidelines

Guidelines open for consultation

- Reflection paper on methodological issues associated with pharmacogenomic biomarkers in relation to clinical development and patient selection
  Deadline for comments: 25 November 2011
- Reflection paper on the data requirements for intravenous liposomal products developed with reference to an innovator liposomal product
  Deadline for comments: 31 January 2012
- Concept paper on the need for a guideline on the treatment of Duchenne and Becker muscular dystrophy
  Deadline for comments: 30 September 2011
- Concept paper on the need for revision of guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis
  Deadline for comments: 30 September 2011
- Concept paper on the need for revision of the guideline on non-clinical local tolerance testing of medicinal products
  Deadline for comments: 30 October 2011
- Concept paper on the revision of the guideline on nonclinical and clinical development of similar biological medicinal products containing recombinant human insulin
  Deadline for comments: 30 September 2011
- Concept paper on the revision of the guideline on nonclinical and clinical development of similar biological medicinal products containing low-molecular-weight heparins
  Deadline for comments: 30 September 2011
- Draft guideline on stability testing for applications for variations to a marketing authorisation
  Deadline for comments: 31 January 2012

Scientific committee activities

- CHMP monthly report from the June meeting
- CHMP meeting highlights from the July meeting
- COMP monthly report from the July meeting
- CAT monthly report from the June meeting
- CAT monthly report from the July meeting
- PDCO monthly report from the June meeting
- PDCO monthly report from the July meeting
- HMPC monthly report from the July meeting

Other publications

- Guide to the European Medicines Agency
- Organisation chart of the European Medicines Agency
- Report on budgetary and financial management: Financial year 2010
- Medicinal products for human use: Monthly figures - December 2010
- Guidance for submission of electronic declaration of interests
- European Medicines Agency publishes format for submission of information on medicines
- Creating electronic drug information for prescribing in the European Union
- European Medicines Agency welcomes new rules on falsified medicines
- European Medicines Agency plans public access to information on side effects
- European Medicines Agency seeks views on genomic markers in medicine development
- European Medicines Agency improves package leaflets
- Public consultation opens on the revised guideline on good distribution practice of medicinal products for human use
- Report from Committee for Advanced Therapies Interested Parties Focus Groups (CATIPs FG) on system to navigate guidelines for advanced-therapy medicinal products
- High-grade glioma expert group
- Benefit-risk methodology project
- Ethical considerations for paediatric trials - how can ethics committees in the European Member States and the Paediatric Committee at the European Medicines Agency work together?
- Transatlantic workshop: drug-related progressive multifocal leukoencephalopathy
- European Medicines Agency hosts meeting with European Parliament representatives
- Expert meeting on clinical investigation of new drugs for the treatment of chronic hepatitis C in the paediatric population
- Committee for Advanced Therapies-European Society for Gene and Cell Therapy satellite workshop - Advanced-therapy medicinal products
- European Medicines Agency-European Federation of Pharmaceutical Industries and Associations modelling and simulation workshop
- Identifying research priorities for the study of drug-related progressive multifocal leukoencephalopathy (PML)
- European Medicines Agency invites expressions of interest for ophthalmology workshop
- Expressions of interest invited for workshop on ethics of clinical trials in children
- Registration open for conference on advanced therapies

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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