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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

Withdrawal of authorised medicines

- Ribavirin BioPartners (*ribavirin*)
  Used for the treatment of hepatitis C

Arbitration procedures

- Targocid and associated names (*teicoplanin*)
  Treatment of bacterial infections and treatment of diarrhoea and colitis caused by infection with *Clostridum difficile*

Cancer

Positive CHMP opinions on new medicines

- Pomalidomide Celgene (*pomalidomide*)
  Treatment of multiple myeloma

Key to symbols used

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

- Lonquex (*lipegfilgrasim*)
  Prevention of chemotherapy-induced neutropenia

New medicines authorised

- Imatinib Actavis (*imatinib*)
  Treatment of chronic myeloid leukaemia (CML), a cancer of the white blood cells

New information on authorised medicines

- Glivec (*imatinib*) - new indication
  Treatment of Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) extended to paediatric patients

Negative CHMP opinions on extension of indication

- Lysodren (*mitotane*)
  Intended for treatment of 'non-functional' adrenal cortical carcinoma

Safety communication update

- Review of insulin glargine-containing medicines (*insulin glargine*)
  Risk of cancer with insulin glargine-containing medicines

Cardiovascular system

Positive CHMP opinions on new medicines

- Lojuxta (*lomitapide*)
  Treatment of high blood levels of cholesterol

Withdrawal of authorised medicines

- Trevaclyn (*laropiprant / nicotinic acid*)
  Used for the treatment of high levels of fat in the blood
- Tredaptive (*laropiprant / nicotinic acid*)
  Used for the treatment of high levels of fat in the blood
- Pelzont (*laropiprant / nicotinic acid*)
  Used for the treatment of high levels of fat in the blood

Safety communication update

- Review of renin-angiotensin-system (RAS)-acting agents - (*captopril, imidapril, zofenopril, candesartan, delapril, telmisartan, aliskiren, moexipril, enalapril, valsartan, fosinopril, irbesartan, perindopril, quinapril, ramipril, eprosartan, olmesartan, trandolapril, losartan, azilsartan, lisinopril, spirapril, benazepril, cilazapril)* - review started
  Risks of combining certain medicines to block separate stages of the renin-angiotensin system (RAS) in the treatment of high blood pressure and congestive heart failure
- Review of Protelos and Osseor (*strontium ranelate*) - review started
  Risk of heart problems associated with strontium ranelate

Dermatology

Safety communication update

- Review of Diane 35 and other medicines containing cyproterone acetate 2mg and ethinylestradiol 35 micrograms (*cyproterone / ethinylestradiol*) - CMDh position
  Risks of formation of blood clots in the veins or arteries

Diabetes

Safety communication update

- Review of insulin glargine-containing medicines (*insulin glargine*)
  Risk of cancer with insulin glargine-containing medicines

Gastro-intestinal system

Arbitration procedures

- Targocid and associated names (*teicoplanin*)
  Treatment of bacterial infections and treatment of diarrhoea and colitis caused by infection with *Clostridum difficile*

Haematology

Positive CHMP opinions on new medicines

- Voncento (*human coagulation factor VIII / Von Willebrand factor)*
  Prevention and treatment of bleeding in patients with haemophilia A and Von Willebrand disease
- Lonquex (*lipegfilgrasim*)
  Prevention of chemotherapy-induced neutropenia

New medicines authorised

- Imatinib Actavis (*imatinib*)
  Treatment of chronic myeloid leukaemia (CML), a cancer of the white blood cells

Hormone system

Positive CHMP opinions on new medicines

- Somatropin Biopartners (*somatropin*)
  Treatment of growth failure

Safety communication update

- Review of Diane 35 and other medicines containing cyproterone acetate 2mg and ethinylestradiol 35 micrograms (*cyproterone / ethinylestradiol*) - CMDh position
  Risks of formation of blood clots in the veins or arteries

Metabolic system

Withdrawal of applications for new medicines

- Belviq (*lorcaserin hydrochloride*)
  Intended for weight control in obese and overweight patients

Nervous system

New medicines authorised

- Maruxa (*memantine*)
  Treatment of Alzheimer's disease

New information on authorised medicines

- Tysabri (*natalizumab*) - new indication
  Treatment of multiple sclerosis in patients previously treated with glatiramer acetate

Withdrawal of applications for extension of indication

- Tysabri (*natalizumab*)
  Intended for the treatment of non-highly active relapsing-remitting multiple sclerosis

Safety communication update

- Review of Trobalt (retigabine) - CHMP opinion
  Risk of abnormal colouring of the skin, nails, lips and eye tissues, including the retina

Ophthalmology

New information on authorised medicines

- Lucentis (*ranibizumab*) - new indication
  Treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM)

Respiratory system

Arbitration procedures

- Kantos Master (*beclomethasone dipropionate / formoterol fumarate*)
  Treatment of asthma

Safety communication update

- Review of almitrine-containing medicines (*almitrine*) - CMDh position
  Risk of weight loss and nerve damage in the hands and feet when taking oral almitrine-containing medicines

Rheumatology

Withdrawal of authorised medicines

- Bondenza (previously Ibandronic Acid Roche) (*ibandronic acid*)
  Used for the treatment of osteoporosis

Safety communication update

- Review of Protelos and Osseor (*strontium ranelate*) - review started
  Risk of heart problems associated with strontium ranelate

Vaccines

Positive CHMP opinions on new medicines

- Imvanex (*modified vaccinia Ankara virus)*
  Immunisation against smallpox

New information on authorised medicines

- Prevenar 13 (pneumococcal polysaccharide conjugate vaccine(13-valent, adsorbed)) - change in indication
  Prevention of invasive disease caused by *Streptococcus pneumoniae,* including adults ≥18 years of age

Other medicines

Positive CHMP opinions on new medicines

- Atosiban Sun (*atosiban*)
  Delay of imminent pre-term birth

Withdrawal of applications for new medicines

- Belviq (*lorcaserin hydrochloride*)
  Intended for weight control in obese and overweight patients

Safety communication update

- Review of Diane 35 and other medicines containing cyproterone acetate 2mg and ethinylestradiol 35 micrograms (*cyproterone / ethinylestradiol*) - CMDh position
  Risks of formation of blood clots in the veins or arteries

Other information

Guidelines

Guidelines open for consultation

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline M7 on assessment and control of DNA reactive

(mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk - Step 3
Deadline for comments: 30 June 2013

- Draft inventory of paediatric medicines - Infectious diseases
  Deadline for comments: 15 July 2013
- Draft guideline on similar biological medicinal products
  Deadline for comments: 31 October 2013
- Draft reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use Deadline for comments: 31 October 2013
- Draft guideline on the use of phthalates as excipients in human medicinal products
  Deadline for comments: 31 October 2013
- Draft guideline on the clinical development of medicinal products intended for the treatment of pain
  Deadline for comments: 30 November 2013

Adopted guidelines

- Guideline on clinical investigation of medicinal products in the treatment of depression
- Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in patients undergoing high VTE-risk surgery (EMA/CHMP/325170/2012) (former CPMP/EWP/707/98 Rev.1 corr)

Scientific committee and working party activities

- CAT May meeting monthly report
- CHMP April organisational matters
- CHMP April adopted opinions on safety variations
- CHMP April adopted opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures
- CHMP May meeting highlights
- COMP March meeting minutes
- COMP April meeting minutes
- COMP May report on the review of applications for orphan designation
- PDCO April meeting minutes
- PDCO May report of PIP opinions and other activities
- PRAC May meeting highlights
- PCWP/HCPWG February joint meeting minutes
- HCPWG February meeting minutes
- Summary of Product Characteristics Advisory Group two-year activity report (April 2011-November 2012)

Other publications

- European Medicines Agency reorganisation
- Frequently asked questions about parallel distribution
- Report and presentations from EMA workshop on medication errors
- European Medicines Agency issues six key recommendations to tackle the issue of medication errors
- Report and presentations from EMA workshop on paediatric investigation plans in type-2 diabetes mellitus
- Presentations from the EMA workshop for micro, small and medium-sized enterprises (SMEs)
- Presentations from the EMA/HALMED conference in view of the accession of Croatia to the European Union
- European Medicines Agency simplifies processing of fee reductions for orphan medicines
- First information day on periodic safety update reports (agenda and registration form) - 19 June 2013, EMA, London
- European Medicines Agency supports the International Clinical Trials Day (20 May 2013)
- European Medicines Agency supports the World Hypertension Day (17 May 2013)

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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