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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

Negative CHMP opinions on new medicines

- Delamanid (*delamanid*)
  Intended for the treatment of multidrug-resistant tuberculosis

Safety communication update

- Review of ketoconazole-containing medicines - CHMP Opinion
  Risk of liver injury with oral ketokonazole

Cancer

Positive CHMP opinions on new medicines

- Giotrif (*afatinib*)
  Treatment of non-small cell lung cancer

Key to symbols used

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

New medicines authorised

- Capecitabine SUN (*capecitabine*)
  Treatment of colon, colorectal, gastric and breast cancer
- Erivedge (*vismodegib*)
  Treatment of basal cell carcinoma
- Iclusig (*ponatinib*)
  Treatment of leukaemia
- Imatinib Accord (*imatinib*)
  Treatment of leukaemia
- Xtandi (*enzalutamide*)
  Treatment of prostate cancer

Cardiovascular system

New medicines authorised

- Stayveer (*bosentan monohydrate*)
  Treatment of pulmonary arterial hypertension

Diabetes

Positive CHMP opinions on new medicines

- Incresync (*alogliptin / pioglitazone*)
  Treatment of type 2 diabetes mellitus
- Vipidia (*alogliptin*)
  Treatment of type 2 diabetes mellitus

New information on authorised medicines

- Insuman (*insulin human*) - new formulation
  Treatment of type 1 diabetes mellitus

Withdrawal of authorised medicines

- Sepioglin (*pioglitazone*)
  Used for the treatment of type 2 diabetes mellitus

Safety communication update

- Review of GLP-1 based diabetes therapies (*exenatide, liraglutide, lixisenatide, sitagliptin, saxagliptin, linagliptin, and vildagliptin*) - CHMP Opinion
  Risk of pancreatic adverse events

Gastro-intestinal system

New information on authorised medicines

- Simponi (*golimumab*) - new indication
  Treatment of ulcerative colitis

Safety communication update

- Review of metoclopramide-containing medicines - CHMP Opinion
  Risk of neurological side effects

HIV

Positive CHMP opinions on new medicines

- Tybost (*cobicistat*)
  Treatment of HIV-1 infection in combination with atazanavir and darunavir

New information on authorised medicines

- Prezista (*darunavir*) - new indication
  Treatment of HIV infection in previously-untreated paediatric patients

Withdrawal of applications for extension of indication

- Eviplera (*INN*)
  Intended for treatment of HIV-1 in previously untreated patients with a viral load of between 100,000 and 500,000 copies/ml

Haematology

Positive CHMP opinions on new medicines

- Grastofil (*filgrastim*)
  Treatment of neutropenia, an abnormal low number of white blood cells

New medicines authorised

- Iclusig (*ponatinib*)
  Treatment of leukaemia
- Imatinib Accord (*imatinib*)
  Treatment of leukaemia

Immune system

New information on authorised medicines

- Simponi (*golimumab*) - new indication
  Treatment of ulcerative colitis

Musculoskeletal system

New medicines authorised

- Maci (*autologous cultured chondrocytes*)
  Treatment of defects in cartilage of the knee

Nervous system

New medicines authorised

- Nuedexta (*dextromethorphan hydrobromide / quinidine sulfate*)
  Treatment of pseudobulbar effect (sudden and uncontrollable bouts of laughing or crying unrelated or disproportionate to their emotional state)

New information on authorised medicines

- Zonegran (*zonisamide*) - new indication
  Treatment of partial seizures in adolescents and children aged 6 years and above

Arbitration procedures

- Methylphenidate Hexal and Methylphenidate Sandoz (*methylphenidate hydrochloride*)
  Treatment of attention deficit/hyperactivity disorder

Safety communication update

- Review of zolpidem-containing medicines (zolpidem) - review started
  Risk of accidents due to reduced alertness
- Review of metoclopramide-containing medicines - CHMP Opinion
  Risk of neurological (brain and nerve) side effects

Ophthalmology

New information on authorised medicines

- Eylea (*aflibercept*) - new indication
  Treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

Respiratory system

Positive CHMP opinions on new medicines

- Xoterna Breezhaler and Ultibro Breezhaler (*indacaterol / glycopyrronium bromide*)
  Treatment to relieve symptoms of chronic obstructive pulmonary disease (COPD)

Negative CHMP opinions on new medicines

- Delamanid (*delamanid*)
  Intended for the treatment of multidrug-resistant tuberculosis

Rheumatology

New information on authorised medicines

- Stelara (*ustekinumab*) - new indication
  Treatment of psoriatic arthritis
- Ilaris (*canakinumab*) - new indication
  Treatment of systemic juvenile idiopathic arthritis

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Vaccines

New medicines authorised

- Hexacima and Hexyon
  Immunisation against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases (such as meningitis) caused by H. influenzae type b bacteria

Other information

- Daronrix (*pandemic influenza vaccine (H5N1) (whole virion, inactivated, adsorbed)*)
  Immunisation against pandemic influenza
- Infanrix Penta
  Immunisation against diphtheria, tetanus, pertussis, hepatitis B and poliomyelitis

Other medicines

New medicines authorised

- Spedra (*avanafil*)
  Treatment of erectile dysfunction

Withdrawal of applications for new indication

- Effentora (*fentanyl*)
  Intended for the treatment of breakthrough pain in adults with long-term persistent pain from causes other than cancer

Safety communication update

- Review of hydroxyethyl starch-containing medicines (HES) (*hydroxyethyl startch*) - review started
  Risk of kidney injury and death
- Review of metoclopramide-containing medicines - CHMP Opinion
  Risk of neurological (brain and nerve) side effects

Medicines under additional monitoring

- Updated list of medicine under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Qualification opinion of a novel data driven model of disease progression and trial evaluation in mild and moderate Alzheimer's disease
  Deadline for comments: 27 August 2013

- Concept paper on the need to revise condition-specific guidance, Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man
  Deadline for comments: 31 October 2013
- Draft note for guidance on clinical investigation of medicinal products for treatment of asthma
  Deadline for comments: 31 December 2013
- Draft concept paper on the need for revision of the note for guidance on manufacture of the finished dosage form
  Deadline for comments: 31 December 2013
- Draft guideline on the evaluation of medicinal products for the treatment of irritable bowel syndrome
  Deadline for comments: 15 January 2014
- Draft guideline on clinical investigation of medicinal products in the treatment of hypertension
  Deadline for comments: 31 January 2014

Adopted guidelines

- Guideline on the use of starting materials and intermediates collected from different sources in the manufacturing of non-recombinant biological medicinal products
- Guideline on the clinical investigation of medicinal products for the treatment of urinary incontinence
- Guideline on pharmaceutical development of medicines for paediatric use

Scientific committee and working party activities

- CAT June meeting report
- CAT July meeting report
- CHMP June adopted opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures
- CHMP June adopted opinions on safety variations / PSURs
- CHMP June organisational matters
- CHMP July meeting highlights
- COMP May meeting minutes
- COMP June meeting minutes
- COMP July report on the review of applications for orphan designation
- PDCO June meeting minutes
- PDCO July report of PIP opinions and other activities
- PRAC June meeting minutes
- PRAC July meeting highlights
- HCPWP mandate, objectives and rules of procedure
- HCPWP June meeting minutes and presentations
- PCWP mandate, objectives and rules of procedure

- PCWP June meeting minutes and presentations
- PCWP / HCPWP June joint meeting minutes and presentations
- Pharmacovigilance Inspectors Working Group annual report 2012
- Working Party on Community Monographs and Community List report on the Hearing of the Association of the European Self-Medication Industry

Other publications

- EMA recommends approval of 44 medicines for human use and six medicines for veterinary use in first half 2013
- Antimicrobial resistance: EMA provides advice on use of colistin and tigecycline in animals
- Falsified Medicines Directive: imported active substances need written confirmation to guarantee GMP standards
- Croatia becomes a new member of the European medicines network
- PRAC: one year of public health promotion and protection
- EMA Healthcare Professionals' Working Party (HCPWP) formally established
- 2012 annual report on EudraVigilance published
- ENCePP guide on methodological standards in pharmacoepidemiology revised
- EMA budgetary and financial management report 2012
- EMA annual accounts 2012
- Registration opens for EMA workshop on conflicts of interests, London, UK, 6 Sep 2013
- Report from the EMA paediatric anticoagulation therapy expert meeting
- EMA supports the World Hepatitis Day: 28 July 2103
- EMA revises rules on fees
- EMA welcomes new Head of Legal Service
- EMA's Head of Human Medicines Development and Evaluation Patrick Le Courtois retires after 16 years of service
- EMA meeting and holiday dates 2014

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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