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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

- Tamiflu IV (*oseltamivir*) - closure of compassionate use programme in the EU
  Treatment of influenza

Cancer

Positive CHMP opinions on new medicines

- Imatinib medac (*imatinib*)
  Treatment of leukaemia
- Kadcyla (*trastuzumab emtansine*)
  Treatment of breast cancer
- Xofigo (*radium-223*)
  Treatment of prostate cancer

Key to symbols used

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

New medicines authorised

- Pomalidomide Celgene (*pomalidomide*)
  Treatment of multiple myeloma
- Lonquex (*lipegfilgrastim*)
  Reduction of neutropenia (low white blood cell count) with or without fever
- Stivarga (*regorafenib*)
  Treatment of colorectal cancer (cancer of the bowel and rectum)
- Tafinlar (*dabrafenib*)
  Treatment of melanoma (skin cancer)

New information on authorised medicines

- Yervoy (*ipilimumab*) - change to indication (extended use to untreated patients)
  Treatment of melanoma

Cardiovascular system

New medicines authorised

- Lojuxta (*lomitapide*)
  Treatment of homozygous familial hypercholesterolaemia (high blood levels of cholesterol)
- Cholib (*fenofibrate and simvastatin*)
  Treatment of dyslipidaemia (high blood levels of fat and cholesterol)

Safety communication update

New information on authorised medicines

- Edarbi and Ipreziv (*azilsartan medoxomil*) - new contraindication (patients with diabetes or renal impairment)
  Treatment of essential hypertension (high blood pressure)

Safety communication update

- Review of cilostazol-containing medicines - CHMP opinion
  Restricted use due to limited efficacy in increase of walking ability
- Review of substances related to nicotinic acid (acipimox) - review started
  Lack of efficacy in reducing risk of major vascular events

Diabetes

Positive CHMP opinions on new medicines

- Invokana (*canagliflozin*)
  Treatment of type-2 diabetes

Key to symbols used

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

Gastro-intestinal system

New medicines authorised

- Nexium Control (*esomeprazole*)
  Treatment of reflux symptoms (e.g. heartburn and acid regurgitation)

Gynaecology & Obstetrics

Positive CHMP opinions on new medicines

- Ovaleap (*follitropin alfa*)
  Treatment of fertility disorders

New medicines authorised

- Atosiban SUN (*atosiban*)
  Delay of premature birth

Safety communication updates

- Review of Bromocriptine-containing medicines (for prevention and suppression of lactation) - started
  Risk of side effects, particularly cardiovascular, neurological and psychiatric
- Review of Short-acting beta-agonists (for obstetric use)
  Restriction of use due to potential cardiovascular side effects
- Review of Numeta G13%E and Numeta G16%E (parenteral nutrition)
  Suspension of Numeta G13%E and new risk minimisation measures for Numeta G16%E, both due to risk of hypermagnesaemia (high blood levels of magnesium)

HIV

Positive CHMP opinions on new medicines

- Vitekta (*elvitegravir*)
  Treatment of HIV-1 infection

Arbitration procedures

- Didanosine
  Treatment of HIV-1 infection

Haematology

Positive CHMP opinions on new medicines

- NovoEight (*turoctocog alfa*)
  Treatment and prevention of bleeding in patients with haemophilia A

Safety communication update

- Kogenate Bayer and Helixate NexGen (*octocog alfa*) - review started
  Risk of reduced efficacy to treat haemophilia A due to development of antibodies

Hormone system

New medicines authorised

- Somatropin Biopartners (*somatropin*)
  Treatment of growth hormone deficiency

Safety communication update

- Review of Cyproterone- and ethinylestradiol-containing medicines - CMDh Position
  Risk minimisation measures to be included due to risk of thromboembolism (blood clots forming in blood vessels) and restricted to use in treatment of acne

Immune system

Positive CHMP opinions on new medicines

- Relvar Ellipta (*fluticasone furoate and vilanterol*)
  Treatment of asthma and chronic obstructive pulmonary disease

Metabolic system

New medicines authorised

- Pheburane (*phenylbutyrate*)
  Treatment of urea-cycle disorders

Nervous system

Positive CHMP opinions on new medicines

- Levodopa/Carbidopa/Entacapone Sandoz (*levodopa, carbidopa and entacapone*)
  Treatment of Parkinson's disease and end-of-dose motor fluctuations
- Memantine Accord (*memantine*)
  Treatment of Alzheimer's disease
- Abilify Maintena (*aripiprazole*)
  Maintenance treatment of schizophrenia

New medicines authorised

- Aubagio (*teriflunomide*)
  Treatment of multiple sclerosis
- Lemtrada (*alemtuzumab*)
  Treatment of multiple sclerosis

New information on authorised medicines

- Thymanax (*agomelatine*) - new contraindication (hepatic impairment)
  Treatment of major depression
- Valdoxan (*agomelatine*) - new contraindication (hepatic impairment)
  Treatment of major depression

Respiratory system

Positive CHMP opinions on new medicines

- Relvar Ellipta (*fluticasone furoate and vilanterol*)
  Treatment of asthma and chronic obstructive pulmonary disease

Rheumatology

New information on authorised medicines

- Kineret (*anakinra*) - addition of a new strength for a new indication
  Treatment of cryopyrin-associated periodic syndromes (auto inflammatory syndromes) and arthritis
- Cimzia (*certolizumab pegol*) - addition of a new indication
  Treatment of axial spondyloarthritis (inflammatory arthritis)

Vaccines

Positive CHMP opinions on new medicines

- Fluenz Tetra (*influenza vaccine*)
  Prophylaxis of influenza

New medicines authorised

- Imvanex (*vaccinia Ankara*)
  vaccination against smallpox

Other medicines

Positive CHMP opinions on new medicines

- Lidocaine/Prilocaine Plethora (*lidocaine and prilocaine*)
  Treatment of premature ejaculation
- Votubia (*everolimus*)- change in indication (extended to younger children)
  Treatment of subependymal giant cell astrocytoma

Safety communication update

- Review of Numeta G13%E and Numeta G16%E - CMDh position
  Suspension of Numeta G13%E and new risk minimisation measures for Numeta G16%E due to risk of hypermagnesaemia (high blood levels of magnesium)

Medicines under additional monitoring

- List of medicinal products under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Concept paper on development of product-specific guidance on demonstration of bioequivalence released for a two-month public consultation
  Deadline for comments: 30 September 2013
- Concept paper on the development of product-specific guidance on demonstration of bioequivalence
  Deadline for comments: 30 September 2013
- Explanatory note on the withdrawal of the note for guidance on harmonisation of requirements for influenza vaccines and of the core summary of product characteristics and package leaflet for inactivated seasonal-influenza vaccines
  Deadline for comments: 31 October 2013
- Guideline on medicines for the treatment of amyotrophic lateral sclerosis released for a six-month public consultation
  Deadline for comments: 31 January 2014
- Draft paediatric addendum to the note for guidance on the clinical investigation on medicinal products in the treatment of hypertension
  Deadline for comments: 31 March 2014
- Draft guideline on the clinical development of medicinal products for the treatment of HIV infection (Rev.3)
  Deadline for comments: 31 March 2014

Adopted guidelines

- Reflection paper on management of clinical risks deriving from insertional mutagenesis
- Reflection paper on general issues for consideration regarding coated nanomedicines
- Points to consider on the identification of triggers for the selection of applications for 'routine' and 'for-cause' inspections, their investigation and the scope of such inspections

Scientific committee and working party activities

- CAT monthly report - September
- CHMP highlights - September
- CHMP applications for new human medicines under evaluation - September
- CHMP Opinions on safety variations / periodic safety update reports - September
- CHMP Opinions on safety variations / periodic safety update reports - July
- COMP Agenda - October
- COMP meeting report - September

- PDCO monthly report - September
- PDCO monthly report - August
- PDCO minutes - August
- PRAC highlights - September
- PRAC minutes - July
- HMPC publishes its meeting agenda for the first time
- Scientific advice and protocol assistance - September
- Working parties for healthcare professionals and for patients and consumers elect new co-chairs

Other publications

- Minutes of the 80th meeting of the Management Board
- European Medicines Agency reveals new structure
- European Medicines Agency hears views from stakeholders on its conflicts-of-interests policy for scientific experts
- Call for expressions of interest for patient and healthcare professional representatives as members of Paediatric Committee
- Medicines for human use: Monthly figures - August 2013
- Scientific guidelines with summary-of-product-characteristics recommendations
- The joint European Union Telematics governance model
- EMA and US FDA release first conclusions of parallel assessment of quality-by-design applications
- Report on annual workshop of the EU Network of Paediatric Research at the EMA, 27-28 June 2013
- Communication on reporting of suspected adverse reactions occurring in the EU by Competent Authorities in MS to the WHO
- First information day on the use of the Medical Dictionary for Regulatory Activities (MedDRA) including medication errors - London 22 Oct 2013
- Report - Workshop on development of new antibacterial medicines
- Joint EMA / EU Directorate for Quality of Medicines and Healthcare workshop on characterisation of new clotting-factor concentrates (factor VIII and factor IX) - London, 28-29 Nov 2013
- EMA organising workshop on biosimilars - London, 31 Oct 2013
- EMA to host workshop on regulatory options in the fight against antimicrobial resistance - London, 8-Nov 2013
- World Alzheimer's Month - Supporting development of medicines by qualification of biomarkers
- World Heart Day – more guidance for medicines developers

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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