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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
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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

- Sirturo (*bedaquiline*) O
  Treatment of multidrug-resistant tuberculosis

Other information

- Sofosbuvir Gilead and Sofosbuvir - compassionate use
  Treatment of hepatitis C virus infection

Cancer

Positive CHMP opinions on new medicines

- Cometriq (*cabozantinib*) O C
  Treatment of medullary thyroid cancer

Key to symbols used

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

New medicines authorised

- Kadcyla (*trastuzumab emtansine*)
  Treatment of advanced or metastatic breast cancer

Arbitration procedures

- Nanotop and associated names (*human albumin, denatured*)
  Diagnostic agent to detect tumours in lymph nodes of patients with breast cancer or malignant melanoma (a type of skin cancer)

Safety communication update

- Review of Iclusig (*ponatinib*) - review started due to risk of blood clots or blockages in arteries or veins
  Treatment of leukaemia

Cardiovascular system

Withdrawal of authorised medicines

- Clopidogrel ratiopharm (*clopidogrel*)
  Prevention of blood clots and hardening of the arteries

Safety communication update

- Review of substances related to nicotinic acid (acipimox) - changes in use to reduce risk of muscle damage when used together with a statin
  Treatment of dyslipidaemia (high blood levels of fats such as triglycerides and cholesterol)
- Review of Iclusig (*ponatinib*) - review started due to risk of blood clots or blockages in arteries or veins
  Treatment of leukaemia

Dermatology

Positive CHMP opinions on new medicines

- Mirvaso (*brimonidine*)
  Symptomatic treatment of facial erythema of rosacea

Diabetes

New information on authorised medicines

- Jentadueto (*linagliptin and metformin hydrochloride*) - new indication (to be used in combination with insulin)
  Treatment of type 2 diabetes

Gynaecology & Obstetrics

Arbitration procedures

- Tibolona Aristo and Tibocina and associated names (*tibolone*)
  Used to alleviate symptoms of menopause

Safety communication update

- Review of Linoladiol N and Linoladiol HN (*estradiol*) - changes in use to reduce potential risk of blood clots, stroke and endometrial cancer
  Topical treatment of diseases of the genital area in women after menopause

Haematology

New medicines authorised

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

Safety communication update

- Review of Iclusig (*ponatinib*) - review started due to risk of blood clots or blockages in arteries or veins
  Treatment of leukaemia
- Review of Kogenate Bayer and Helixate NexGen (octocog alpha) - Benefits continue to outweigh risk of developing antibodies (factor VIII inhibitors) against these medicines in previously untreated patients
  Treatment of haemophilia A (a bleeding disorder)

Hormone system

Supply shortages

- Increlex (*mecasermin*) - shortage resolution
  Treatment of deficiency of insulin-like growth factor

Metabolic system

Safety communication update

- Review of substances related to nicotinic acid (acipimox) - changes in use to reduce risk of muscle damage when used together with a statin
  Treatment of dyslipidaemia (high blood levels of fats such as triglycerides and cholesterol)

Nephrology

Negative CHMP opinions on new medicines

- Winfuran (*nalfurafine*)
  Intended for the treatment of severe uraemic pruritus (itching occurring due to kidneys malfunctioning)

Nervous system

Positive CHMP opinions on new medicines

- Neuraceq (*florbetaben (^{18}F)*)
  Diagnostic agent for Alzheimer's disease (AD) and other cognitive impairments

New medicines authorised

- Memantine Accord (*memantine*)
  Treatment of Alzheimer's disease

Withdrawal of applications for extension of indication

- Exelon and Prometax (*rivastigmine*)
  Intended to treat severe Alzheimer's dementia in the same way as mild to moderate Alzheimer's dementia

Arbitration procedures

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

Ophthalmology

Positive CHMP opinions on new medicines

- Izba (*travoprost*)
  Used to reduce intraocular pressure in ocular hypertension or open angle glaucoma

Respiratory system

New medicines authorised

- Relvar Ellipta (*fluticasone furoate and vilanterol*)
  Treatment of asthma and used to relieve the symptoms of chronic obstructive pulmonary disease (COPD)

Rheumatology

Arbitration procedures

- Valebo and associated names (*alendronic acid and alfacalcidol*)
  Treatment of osteoporosis

Vaccines

New medicines authorised

- Fluenz Tetra (*influenza vaccine*)
  Immunisation against influenza
- Tritanrix HB H-W-3838 (*diphtheria (D), tetanus (T), pertussis (whole cell) (Pw) and hepatitis B (rDNA) (HBV) vaccine (adsorbed)*)
  Immunisation against diphtheria, tetanus, pertussis and hepatitis B

Other medicines

Positive CHMP opinions on new medicines

- Neuraceq (*florbetaben (^{18}F)*)
  Diagnostic agent for Alzheimer's disease (AD) and other cognitive impairments

Arbitration procedures

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Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Other information

Guidelines

Guidelines open for consultation

- Draft sunitinib product-specific bioequivalence guidance
  Deadline for comments: 3 March 2014
- Concept paper on the second revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products
  Deadline for comments: 15 March 2014
- Draft guideline on core summary of product characteristics for plasma-derived fibrin sealant / haemostatic products
  Deadline for comments: 31 March 2014

Adopted guidelines

- Guideline on good pharmacovigilance practices (GVP): Product- or population-specific considerations I: Vaccines for prophylaxis against infectious diseases
- Guideline on core summary of product characteristics and package leaflet for technetium (99mTc) sestamibi
- Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report
- Reflection paper on the use of recovered/recycled solvents in the manufacture of herbal preparations for use in herbal medicinal products / traditional herbal medicinal products
- Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials, with particular emphasis on the handling of expiry dates

Scientific committee and working party activities

- European Medicines Agency now publishing meeting agendas for all scientific committees
- Principles for publication of agendas and minutes of EMA scientific committees
- CAT - agendas, minutes and reports
- CAT - procedural advice on the provision of scientific recommendation on classification of advanced therapy medicinal products in accordance with Article 17 of Regulation (EC) No 1394/2007
- CHMP - agendas, minutes and highlights
- COMP - agendas, minutes and meeting reports
- HCMP - agendas, minutes and meeting reports
- PDCO - agendas, minutes and meeting reports
- PRAC - agendas, minutes and highlights
- PRAC - recommendations on safety signals
- PCWP and HCPWP joint meeting - 25 September
- PCWP minutes: Election of co-chair - 25 September
- HCPWP minutes: Election of co-chair - 25 September
- EMA Human Scientific Committees' PCWP meeting with all eligible organisations - agenda

Other publications

- Looking back at 2013 - from Guido Rasi, Executive Director
- Agenda - Training session for patients and consumers involved in European Medicines Agency activities
- Training and support for patients and consumers
- Sixth annual report on the interaction with patients' and consumers' organisations (2012)
- Minutes of the 81st meeting of the Management Board
- Agenda of the 82nd meeting of the Management Board
- European Medicines Agency's Management Board endorses work programme 2014
- European Medicines Agency to push ahead in 2014 towards publication and access to clinical trial data
- European Medicines Agency applies greater fee-reduction rates for orphan medicines in 2014
- List of details of the national reporting systems to communicate adverse reactions (side effects)
- EMA publishes report on workshop on regulatory options in the fight against antimicrobial resistance
- Consultation meeting with stakeholders: Request from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals
- European Medicines Agency post-authorisation procedural advice for users of the centralised procedure
- Explanatory note on fees payable to the European Medicines Agency

- Statements of non-compliance with GMP now publicly available in EudraGMDP
- EMA and FDA announce launch of generic medicines application inspections initiative
- Joint European Medicines Agency/Parenteral Drug Association quality-by-design workshop - 28-29 Jan 2014, EMA, London

Key to symbols used

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

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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