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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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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.

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Information on medicines

Antivirals/anti-infectives

New medicines authorised

- Voriconazole Accord (*voriconazole*)
  Treatment of fungal infections

Cancer

Positive CHMP opinions on new medicines

- Provenge (*advanced therapy product containing autologous mononuclear cells*)
  Treatment of metastatic prostate cancer
- Stivarga (*indacaterol / glycopyrronium bromide*)
  Treatment of metastatic cancer of the colon or rectum
- Tafinlar (*dabrafenib*)
  Treatment of metastatic melanoma

Key to symbols used

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

New information on authorised medicines

- Tyverb (lapatinib) - new indication
  Treatment of breast cancer in combination with trastuzumab
- Vectibix (*panitumumab*) - change in indication
  Treatment of metastatic cancer of the colon or rectum
- Velcade (*bortezomib*) - new indication
  Treatment of multiple myeloma in combination with dexamethasone, or with dexamethasone and thalidomide

Cardiovascular system

Positive CHMP opinions on new medicines

- Cholib (*fenofibrate / simvastatine*)
  Treatment of abnormal levels of cholesterol and fat in the blood

New information on authorised medicines

- Aprovel and Karvea (*irbesartan*) - new contraindication
  Contraindicated in the treatment of high blood pressure in patients with diabetes or renal impairment in combination with aliskiren-containing medicines
- CoAprovel and Karvezide (*irbesartan / hydrochlorothiazide*) - new contraindication
  Contraindicated in the treatment of high blood pressure in patients with diabetes or renal impairment in combination with aliskiren-containing medicines
- Copalia, Dafiro, Exforge and Imprida (*amlodipine / valsartan*) - new contraindication
  Contraindicated in the treatment of high blood pressure in patients with diabetes or renal impairment in combination with aliskiren-containing medicines
- Copalia HCT, Dafiro HCT and Exforge HCT (*amlodipine / valsartan / hydrochlorothiazide*) - new contraindication
  Contraindicated in the treatment of high blood pressure in patients with diabetes or renal impairment in combination with aliskiren-containing medicines

Safety communication update

- Review of diclofenac-containing medicines (diclofenac) - CMDh Position
  Cardiovascular risk
- Review of ergot derivatives-containing medicines (*dihydroergocristine, dihydroergotamine, dihydroergotoxine, nicergoline and the combination of dihydroergocryptine with caffeine*) - CHMP Opinion
  Risk of fibrosis, spasms and obstructed blood circulation

Diabetes

New information on authorised medicines

- Onglyza (*saxagliptin*) - new indication
  Treatment as single therapy of type 2 diabetes mellitus

- Aprovel and Karvea (*irbesartan*) - new contraindication
  Contraindicated in the treatment of high blood pressure in patients with diabetes or renal impairment in combination with aliskiren-containing medicines
- CoAprovel and Karvezide (*irbesartan / hydrochlorothiazide*) - new contraindication
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- Copalia HCT, Dafiro HCT and Exforge HCT (*amlodipine / valsartan / hydrochlorothiazide*) - new contraindication
  Contraindicated in the treatment of high blood pressure in patients with diabetes or renal impairment in combination with aliskiren-containing medicines

Gastro-intestinal system

Positive CHMP opinions on new medicines

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

Haematology

Withdrawal of applications for new medicines

- Ixinity (*trenonacog alfa (recombinant human factor IX)*)
  Intended for the prevention and treatment of bleeding episodes associated with haemophilia B
- Omontys (*peginesatide*)
  Intended for the treatment of symptomatic anaemia associated with chronic kidney disease

Safety communication update

- Review of iron-containing medicines *(iron carboxymaltose, iron dextran, iron gluconate, iron isomaltoside, iron saccharose and iron sucrose)* - CHMP Opinion
  Risk of allergic reactions

Immune system

Positive CHMP opinions on new medicines

- Inflectra and Remsima (*infliximab*)
  Treatment of rheumatoid arthritis, paediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

New medicines authorised

- HyQvia (*human normal immunoglobulin*)
  Treatment of patients with low levels of antibodies

Arbitration procedures

- Sandimmun, Sandimmun Neoral and associated names (*ciclosporin*)
  Prevention of complications with transplanted organs and treatment of autoimmune diseases
- Okrido (*prednisolone sodium phosphate*)
  Treatment of a range of inflammatory and auto-immune conditions including allergies; diseases of the lungs (including asthma), upper airways (croup), blood vessels and heart, bowel or kidneys, muscles and joints (including rheumatoid arthritis) or the eye or nervous system; skin conditions; some cancers, including leukaemia, lymphoma and myeloma; organ transplantation

Nervous system

Positive CHMP opinions on new medicines

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

New medicines authorised

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

Safety communication update

- Review of ergot derivatives-containing medicines (*dihydroergocristine, dihydroergotamine, dihydroergotoxine, nicergoline and the combination of dihydroergocryptine with caffeine*) - CHMP Opinion
  Risk of fibrosis, spasms and obstructed blood circulation

Respiratory system

Arbitration procedures

- Okrido (*prednisolone sodium phosphate*)
  Treatment of a range of inflammatory and auto-immune conditions including allergies; diseases of the lungs (including asthma), upper airways (croup), blood vessels and heart, bowel or kidneys, muscles and joints (including rheumatoid arthritis) or the eye or nervous system; skin conditions; some cancers, including leukaemia, lymphoma and myeloma; organ transplantation

Safety communication update

- Review of codeine-containing medicines (*codeine*) - CMDh Position
  Risk of serious and fatal respiratory depression in children

Rheumatology

Positive CHMP opinions on new medicines

- Inflectra and Remsima (*infliximab*)
  Treatment of rheumatoid arthritis, paediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis

Safety communication update

- Review of diclofenac-containing medicines (diclofenac) - CMDh Position
  Cardiovascular risk

Other medicines

Positive CHMP opinions on new medicines

- Evarrest (*human fibrinogen / human thrombin*)
  Prevention of excessive blood loss during surgery
- Procysbi (*mercaptamine*)
  Treatment of nephropathic cystinosis

New information on authorised medicines

- Evicel (*human fibrinogen / human thrombin*) - new indication
  To be used in surgery to seal cuts in the protective layer surrounding the brain and spinal cord

Arbitration procedures

- Okrido (*prednisolone sodium phosphate*)
  Treatment of a range of inflammatory and auto-immune conditions including allergies; diseases of the lungs (including asthma), upper airways (croup), blood vessels and heart, bowel or kidneys, muscles and joints (including rheumatoid arthritis) or the eye or nervous system; skin conditions; some cancers, including leukaemia, lymphoma and myeloma; organ transplantation

Safety communication update

- Review of ergot derivatives-containing medicines (*dihydroergocristine, dihydroergotamine, dihydroergotoxine, nicergoline and the combination of dihydroergocryptine with caffeine*) - CHMP Opinion
  Risk of fibrosis, spasms and obstructed blood circulation
- Review of flupirtine-containing medicines (*flupirtine*) - CMDh Position
  Risk of liver problems
- Review of hydroxyethyl starch-containing (HES) - PRAC recommendation
  Risk of kidney injury and death
- Review of iron-containing medicines *(iron carboxymaltose, iron dextran, iron gluconate, iron isomaltoside, iron saccharose and iron sucrose)* - CHMP Opinion
  Risk of allergic reactions
- Review of Numeta G13%E and Numeta G16%E emulsion for infusion (*glucose, lipids, amino acids and electrolytes)* - review started
  Risk of high blood levels of magnesium in premature babies

Medicines under additional monitoring

- Updated list of medicines under additional monitoring

Key to symbols used

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Other information

Guidelines

Guidelines open for consultation

- Guideline on good pharmacovigilance practices: Module XVI – Risk-minimisation measures: selection of tools and effectiveness indicators
  Deadline for comments: 5 August 2013
- Guideline on good pharmacovigilance practices: Module VI – Management and reporting of adverse reactions to medicinal products
  Deadline for comments: 5 August 2013
- Draft guideline on the acceptability of names for human medicinal products processed through the centralised procedure
  Deadline for comments: 30 August 2013
- Concept paper on the need for revision of the guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease
  Deadline for comments: 1 September 2013
- Draft concept paper on the need for a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development
  Deadline for comments: 30 September 2013
- Draft guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues
  Deadline for comments: 30 November 2013
- Draft guideline on adjustment for baseline covariates
  Deadline for comments: 31 December 2013

Adopted guidelines

- Guideline on quality of biological active substances produced by transgene expression in animals
- Guideline on the use of bovine serum in the manufacture of human biological medicinal products
- Position paper on potential medication errors in the context of benefit-risk balance and risk-minimisation measures
- Table of relevant scientific guidance for summaries of product characteristics
- The dates of 2014 Scientific Advice Working Party meetings and deadlines for submission of scientific advice, protocol assistance, qualification of biomarkers and parallel European Medicines Agency-health-technology-assessment requests

Scientific committee and working party activities

- CHMP June meeting highlights

- CHMP May adopted opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures
- CHMP May adopted opinions on safety variations
- CHMP May organisational matters
- PDCO June report of PIP opinions and other activities
- PDCO May meeting minutes
- PRAC June meeting highlights
- PRAC May meeting minutes
- PRAC April meeting minutes
- Good Clinical Practice Inspectors Working Group annual report 2012
- CHMP Geriatric Expert Group mandate, objectives and rules of procedure
- Proposal for the development of points to consider for baseline characterisation of frailty status
- Vaccines Working Party report on closed workshop on correlates for the protection and serological assays for influenza vaccines

Other publications

- EMA's Management Board endorses revised EMA code of conduct
- EMA releases for public consultation its draft policy on the publication and access to clinical-trial data
- European Commission report highlights successes of the first five years of the EU Paediatric Regulation
- Registration open for workshop on the clinical investigation of medicines for the treatment of multiple sclerosis EMA, London, UK, 17 Oct 2013
- Registration opens for workshop on EMA-HTA parallel scientific advice in drug development EMA, London, UK, 26 Nov 2013
- Workshop on patient-support programmes (PSPs) and market-research programmes (MSPs) – Understanding the diversity of such programmes and the management of safety information
- Amendments to the pharmacovigilance legislation: new notification requirements for marketing-authorisation holders
- Guidance on submission of single assessment PSURs published
- 2011 EudraVigilance Human annual report and Explanatory note
- Analysis and assessment of the Executive Director's annual activity report 2012
- Minutes of the 79th meeting of the Management Board
- Agenda of the 80th meeting of the Management Board
- Management Board meeting dates 2014
- EMA and EUnetHTA review progress of their cooperation
- EMA and European Network for Health Technology Assessment May meeting minutes

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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