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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.

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Information on medicines

Cancer

Positive CHMP opinions on new medicines

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

New medicines authorised

- Bosulif (*bostinib*) O C
  Treatment of myeloid leukaemia

Key to symbols used

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

Other information

- Questions and answers on the supply situation of Caelyx (*doxorubicin*)
  Treatment of breast cancer, cancer of the ovary, AIDS-related Kaposi's sarcoma and multiple myeloma

Cardiovascular system

New medicines authorised

- Tolucombi (*telmisartan / hydrochlorothiazide*)
  Treatment of hypertension

New information on authorised medicines

- Pradaxa (*dabigatran etexilate*) - new contraindication
  Prevention of blood clots in veins after hip or knee surgery
- Kinzalkomb (previously BolusacPlus) and PriotorPlus (*telmisartan / hydrochlorothiazide*) - new contraindication
  Treatment of high blood pressure
- MicardisPlus (*telmisartan / hydrochlorothiazide*) - new contraindication
  Treatment of high blood pressure
- Twynsta and Onduarp (*telmisartan / amlodipine*) - new contraindication
  Treatment of high blood pressure
- Kinzalmono (previously Telmisartan Boehringer Ingelheim Pharma KG) and Pritor (*telmisartan*) - new contraindication
  Treatment of high blood pressure
- Micardis (*telmisartan*) - new contraindication
  Treatment of high blood pressure

Arbitration procedures

- Questions and answers on the referral for Simvastatin Vale and associated names (*simvastatin*)
  Treatment of cholesterol and prevention of heart disease

HIV

Other information

- Questions and answers on the supply situation of Caelyx (*doxorubicin*)
  Treatment of breast cancer, cancer of the ovary, AIDS-related Kaposi's sarcoma and multiple myeloma

Haematology

New information on authorised medicines

- Revlimid (*lenalidomide*) - new indication
  Treatment of anaemia (low red blood cell counts) due to myelodysplastic syndromes

Other information

- Questions and answers on the outcome of extension of indication application for Exjade (*deferasirox*)
  Treatment of excess iron in the body

Hormone system

Other information

- Questions and answers on the shortage of Increlex (*mecasermin*)
  Treatment of deficiency of insulin-like growth factor

Musculoskeletal system

Positive CHMP opinions on new medicines

- 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)

Other information

- European Medicines Agency recommends approval of first treatment for pseudobulbar affect

Ophthalmology

New medicines authorised

- Jetrea (*ocriplasmin*)
  Treatment of vitreomacular traction

Withdrawal of applications for new medicines

- Raxone (*idebenone*) O
  Intended for the treatment of Leber's hereditary optic neuropathy, a condition that causes loss of vision

Rheumatology

New information on authorised medicines

- RoActermra (*tocilizumab*) - new indication
  Treatment of polyarthritis

Negative CHMP opinions on new medicines

- Xeljanz (*tofacitinib citrate*)
  Intended for the treatment of arthritis

Safety update

- Review of tetrazepam-containing medicines (*tetrazepam*) - recommendation
  Treatment of muscle spasms

Key to symbols used

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- Recommendation to restrict the use of Protelos/Osseor (*strontium ranelate*)
  Treatment of osteoporosis

Vaccines

Other information

- Questions and answers on the outcome of application to extend use of Menveo in children less than 2 years (*N. meningitidis*)
  Prevention of disease caused by bacterium N. meningitidis

Other medicines

Positive CHMP opinions on new medicines

- Spedra (*avanafil*)
  Treatment of erectile dysfunction

Other information

Guidelines

Guidelines open for consultation

- Concept paper on the need for a reflection paper on quality aspects of medicines for older people
  Deadline for comments: 30/06/2013
- Concept paper on the development of medicinal products for the treatment of autism spectrum disorder
  Deadline for comments: 04/07/2013

Adopted guidelines

- Concept paper on extrapolation of efficacy and safety in medicine development

Scientific committee activities

- CHMP April meeting highlights
- CHMP adopted opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures
- CHMP adopted opinions on safety variations
- CAT April meeting monthly report
- PDCO March meeting minutes
- PDCO April report of PIP opinions and other activities
- PRAC April meeting highlights

- PRAC March meeting minutes

Other publications

- EMA receives interim decisions of the General Court of the EU on access to clinical and non-clinical information
- EMA publishes initial list of medicines under additional monitoring
- EU agencies consider phenylbutazone detected in horsemeat of low concern for consumers; recommend improved horse traceability and monitoring of veterinary medicinal residues
- EMA publishes 2012 annual report
- EMA publishes report on patient recruitment and geographical location of clinical trials
- EMA recommends approval of combined advanced-therapy product
- Report on annual workshop of the European Network of Paediatric Research at the EMA (Enpr-EMA), EMA, London, UK, 22 - 23 Mar 2012
- Training session on the new pharmaceutical legislation, 29 Nov 2012, EMA, London, UK
- 7 April 2013: World Health Day: focus on high blood pressure
- 14th EudraVigilance information day: Adverse-drug-reaction reporting in the European Union and highlights of the new pharmacovigilance legislation, EMA, London, UK, 23 May 2013
- Annual workshop on the European Network of Paediatric Research at the European Medicines Agency, EMA, London, UK, 27-28 Jun 2013
- Medicinal products for human use: March figures
- EudraGMDP database
- Glossary of frequently used terms on the EMA website
- Falsified medicines
- Stem cell therapy treatments
- Documents from advisory groups on clinical-trial data

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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