



European Medicines Agency
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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 20-23 October 2008

Positive opinions

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions for the following medicines:

- **Lunivia** (eszopiclone), from Sepracor Pharmaceuticals Ltd, for the treatment of insomnia, including difficulty falling asleep, nocturnal awakening or early awakening, in adults, usually for short-term duration. EMA review began on 18 August 2007 with an active review time of 205 days.
- **Vidaza** (azacitidine), from Celgene Europe Ltd, for the treatment of myelodysplastic syndromes and acute myeloid leukaemia in adults who are not eligible for haematopoietic stem-cell transplantation. Vidaza is the 50th orphan medicine to receive a positive opinion by the CHMP. EMA review began on 30 January 2008 with an active review time of 198 days.

Generic medicinal product

The Committee adopted a positive opinion for **Pramipexole Teva** (pramipexole), from Teva Pharma B.V., for the treatment of signs and symptoms of idiopathic Parkinson's disease, alone or in combination with levodopa. EMA review began on 21 November 2007 with an active review time of 196 days. The reference product for Pramipexole Teva is Sifrol, which is already authorised in the European Union, in the indication applied for.

Re-examination procedure concluded

Following a re-examination of a negative opinion adopted in June 2008, the CHMP adopted a final positive opinion for **Opgenra** (recombinant human osteogenic protein-1/eptoterminal alfa), from Howmedica International S. de R.L. Opgenra is indicated for posterolateral lumbar spinal fusion in adult patients with spondylolisthesis where autograft has failed or is contraindicated.

A separate question-and-answer document with more detailed information on the grounds for the final positive opinion is available [here](#).

Extensions of indication

The CHMP gave positive opinions for applications for extension of indication, adding new treatment options for the following previously approved medicines:

- **Binocrit** (epoetin alfa), from Sandoz GmbH, **Abseamed** (epoetin alfa), from Medice Arzneimittel Putter GmbH & Co. KG, and **Epoetin Alfa Hexal** (epoetin alfa), from Hexal Biotech Forschungs GmbH, to add the indication of increasing the yield of autologous blood from patients in a pre-donation programme. Binocrit, Abseamed and Epoetin Alfa Hexal are currently indicated in the treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients.
- **Erbix** (cetuximab), from Merck KGaA, to extend the indication to the treatment of patients with squamous cell cancer of the head and neck in combination with platinum-based

* Rev. 1 The indication for Avalox and Octegra (page 3) has been corrected.
Rev. 2 The indication for Opgenra has been corrected.

chemotherapy for recurrent and/or metastatic disease. Erbitux is currently indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer in combination with chemotherapy or as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. In combination with radiation therapy, Erbitux is also indicated for the treatment of patients with locally advanced squamous cell cancer of the head and neck.

- **Prezista** (darunavir), from Tibotec, to extend the indication to the treatment of human immunodeficiency virus (HIV-1) infection to include treatment-experienced adult patients. Prezista is currently indicated for the treatment of HIV-1 in combination with other antiretroviral medicines in highly pre-treated adult patients who failed more than one regimen containing a protease inhibitor.
- **Pegasys** (peginterferon alfa-2a), from Roche Registration Ltd, to extend the indication in combination with ribavirin to the treatment of hepatitis C in adults patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) in combination therapy with ribavirin. Pegasys is currently indicated for the treatment of chronic hepatitis C in adult patients who are positive for serum hepatitis C virus RNA, including patients with compensated cirrhosis and/or co-infected with clinically stable HIV. In this indication peginterferon alfa-2a can be used in combination with ribavirin or in monotherapy. It is also indicated for the treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased alanine aminotransferase (ALT) and histologically verified liver inflammation and/or fibrosis.

First positive opinion for switch from prescription-only to non-prescription for a centrally authorised medicine

The CHMP has recommended for the first time that the status for supply of a centrally authorised medicine in the European Union be switched from prescription-only to non-prescription. The medicine concerned is **Alli** (orlistat), from Glaxo Group Ltd. This will enable patients to buy the medicine over-the-counter. A separate press release is available [here](#).

First positive opinion on paediatric extension according to Article 29 of the Paediatric Regulation (1901/2006)

The CHMP gave a positive opinion for a line-extension of **Cozaar** and associated names (losartan potassium), from Merck Sharp & Dohme BV, to add a paediatric formulation of powder and solvent for oral suspension. Cozaar and associated names are authorised at the level of the Member States. This is the first recommendation for a line-extension relating to a new pharmaceutical form for use in the paediatric population on the basis of data generated in accordance with an agreed paediatric investigation plan (PIP). The paediatric formulation has been developed for the treatment of essential hypertension in children and adolescents 6-16 years of age.

Once the CHMP opinion has been transformed into a decision by the European Commission, the company will be able to obtain approval for the paediatric formulation in all EU Member States where the medicine is authorised.

Article 29 of the Paediatric Regulation allows companies to submit to the EMEA an application for a new indication, a new pharmaceutical form or a new route of administration for medicines that are already authorised at the level of the Member States. Data supporting such applications have to be generated in accordance with an agreed PIP.

This recommendation follows the CHMP opinion adopted at its September 2008 meeting recommending for the first time the use of a centrally-authorised medicine in children based on PIP data. A separate press release is available.

PIPs are drug-development plans that set out measures ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of the medicine for children. PIPs must be agreed in advance by the Agency's Paediatric Committee (PDCO), and are legally binding for companies developing medicines for use in the European Union.

Negative opinion for extension of indication

The CHMP adopted a negative opinion for an extension of indication for **Cymbalta** (duloxetine hydrochloride), from Eli Lilly Nederland B.V., and **Xeristar** (duloxetine hydrochloride), from Boehringer Ingelheim International GmbH. The indication applied for related to the treatment of fibromyalgia with or without depression. Cymbalta and Xeristar are currently approved for the treatment of major depressive episodes, diabetic peripheral neuropathic pain in adults and generalised anxiety disorder. A separate [question-and-answer document](#) explaining the grounds for the negative opinion for the extension of indication is available on the EMEA website.

Summaries of opinions for all mentioned products, including their full indications, can be found [here](#).

Suspension of marketing authorisation

The CHMP recommended the suspension of the marketing authorisation for **Acomplia** (rimonabant), from Sanofi-Aventis. A separate [press release](#) and a [question-and-answer](#) document are available.

Referral procedure started

The CHMP started a number of referral procedures under Article 29 of Directive 2001/83/EC, as amended. This type of procedure is initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure. The medicines concerned are:

- **Avalox** (moxifloxacin hydrochloride) 400mg solution for infusion, from Bayer HealthCare/Bayer Vital GmbH, an antibiotic agent.
- **Octegra** (moxifloxacin hydrochloride) 400mg solution for infusion, from Bayer HealthCare/Bayer Vital GmbH, an antibiotic agent.
- **Implanon** (etonogestrel) 68mg Subdermal implant, from N.V. Organon/Organon B.V., indicated for contraception.
- **Teicoplanin Hospira** (teicoplanin) 200 and 400mg powder and solvent for injection or infusion, from Hospira UK Limited, indicated for the treatment of specific bacterial infections.

In addition, the Committee started one referral under Article 30 of Directive 2001/83/EC as amended, for **Meropenem** and associated names (meropenem), from AstraZeneca BV, used in the treatment of respiratory-tract infections. This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level.

A more detailed CHMP meeting report will be published shortly.

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