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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 23-26 June 2008

Positive opinions

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted three positive opinions, including one for a generic medicine, recommending the granting of a marketing authorisation, for the following medicines:

- **Intelence** (etravirine), from Janssen-Cilag International NV, for use in combination with a boosted protease inhibitor and other antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral treatment-experienced adult patients. EMEA review began on 15 August 2007 with an active review time of 178 days.
- **Oprymea** (pramipexole), from Krka D.D., for the treatment of the signs and symptoms of idiopathic Parkinson's disease in monotherapy or combination therapy. The reference product for Oprymea is Sifrol, from Boehringer Ingelheim International GmbH, which is already authorised in the European Union (EU), in the applied indication. EMEA review began on 21 November 2007 with an active review time of 177 days.
- **Vimpat** (lacosamide), from UCB Pharma S.A., for use as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older. EMEA review began on 23 May 2007 with an active review time of 209 days.

Negative opinion

The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Opgenra** (recombinant human osteogenic protein-1/eptotermin), from Howmedica International S. de R.L., Opgenra was intended to be used for posterolateral lumbar spinal fusion in adult patients with spondylolisthesis where autograft has failed, is not feasible or is unlikely to be efficacious. EMEA review began on 21 February 2007with an active review time of 202 days.

A separate question-and-answer document with more detailed information on the grounds for the negative 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:

- **Cymbalta** (duloxetine), from Eli Lilly Nederland B. V., and **Xeristar** (duloxetine), from Boehringer Ingelheim International GmbH, to extend the indication to include the treatment of generalised anxiety disorder. Cymbalta and Xeristar are currently indicated for the treatment of major depressive episodes and diabetic peripheral neuropathic pain in adults.
- **Tracleer** (bosentan), from Actelion Registration Ltd, to extend the indication to include that some improvements have also been shown in patients with Pulmonary Arterial Hypertension (PAH) functional class II. Tracleer is currently indicated for the treatment of PAH to improve exercise capacity and symptoms in patients with functional class III.

Summaries of opinions for all mentioned products, including their full indication, can be found here.

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New safety information
The CHMP has recommended a new warning for epoetin-containing medicines. These medicines are indicated for the treatment of anaemia in patients with non-myeloid tumours receiving chemotherapy and in patients with chronic renal failure. A separate press release and a question-and-answer document with more detailed information are available on the EMEA website.

Referral procedures concluded
The CHMP concluded a referral procedure for **ergot-derived dopamine agonists**, a class of medicines that is primarily used for the treatment of Parkinson's disease. A separate press release and a question-and-answer document with more detailed information are available on the EMEA website.

The CHMP concluded referral procedures for **etoricoxib-containing medicines,** intended for the treatment of osteoarthritis, rheumatoid arthritis and acute gouty arthritis. A separate press release and a question-and-answer document with more detailed information are available on the EMEA website.

The CHMP concluded a referral procedure for **Activelle,** 0.5 mg/0.1 mg, film-coated tablets (estradiol/norethisterone acetate), from Novo Nordisk A/S, indicated for Hormone Replacement Therapy for oestrogen deficiency symptoms in women more than one year after menopause and for the prevention of osteoporosis in postmenopausal women at high risk of future fractures. The Committee concluded that the benefits of the medicines outweigh their risks and, therefore, recommended the granting of a marketing authorisation. The procedure was initiated under Article 29(2) of Directive 2001/83/EC, as amended, because of concerns over the endometrial safety of Activelle 0.5 mg/0.1 mg.

The CHMP concluded a referral procedure for Rapinyl 50, 100, 200, 300, 400, 600 and 800 microgram (fentanyl citrate), from ProStrakan Ltd, indicated for the treatment of breakthrough pain in patients using opioid therapy for chronic cancer pain. The CHMP concluded that the benefits of the medicine outweigh the risks and, therefore, recommended the granting of a marketing authorisation subject to changes in the product information and follow-up measures. The procedure was initiated under Article 29(2) of Directive 2001/83/EC, as amended, because of a disagreement among some Member States whether additional data demonstrating efficacy and safety of Rapinyl in the management of breakthrough pain is required.

Procedures under Article 29(2) are initiated in cases where no agreement can be reached in the context of the mutual recognition procedure or the decentralised procedure.

The CHMP concluded two harmonisation referrals for:

- **Gemzar** (gemcitabine), from Lilly, indicated for the treatment of bladder cancer, advanced non-small cell lung cancer, advanced pancreatic cancer, breast cancer and ovarian cancer.
- **Remeron** (mirtazapine), from Organon N.V., indicated for the treatment of episodes of major depresion.

The CHMP recommended the harmonisation of the product information across the European Union for both products. The procedure was initiated under Article 30 of Directive 2001/83/EC, as amended, with a view to harmonising the product information across the EU for medicinal products authorised at level of the Member States.

Referral procedures started
The CHMP is reviewing moxifloxacin-containing medicines, intended for the treatment of acute exacerbation of chronic bronchitis, community acquired pneumonia and acute bacterial sinusitis. The procedure was triggered by the United Kingdom under Article 107 of Directive 2001/83/EC, due to new safety data which raise concerns that the benefits of the medicines do not outweigh their risks in the treatment of acute bacterial sinusitis and acute exacerbation of chronic bronchitis.
This type of procedure is initiated in cases where a Member State considers that, as a result of the evaluation of pharmacovigilance data, a medicine's marketing authorisation should be withdrawn, suspended or changed. It provides for a harmonised European approach because the CHMP is asked to

prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

The CHMP started a harmonisation referral procedure under Article 30 of Directive 2001/83/EC for **Diovan comp and associated names** (valsartan/hydrochlorothiazide), from Novartis group of companies and associated companies, intended for the treatment of hypertension.

A more detailed CHMP meeting report will be published shortly.

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