European Medicines Agency
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PRESS RELEASE
European Medicines Agency: Committee for Medicinal Products for Human Use 23-26 January 2006

Initial marketing authorisation applications

The Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on an initial marketing authorisation application for **Myozyme** (recombinant human acid alpha-glucosidase), Genzyme Europe B.V. Myozyme is indicated for enzyme replacement therapy in Pompe disease. EMEA review began on 20 December 2004 with an active review time of 196 days. Myozyme is the **twenty-fourth designated orphan medicinal product** to receive a positive opinion.

Similar biological medicinal products

The CHMP adopted the first positive opinion for a similar biological medicinal product. The product, **Omnitrope** is manufactured by Sandoz GmbH and contains a DNA-recombinant growth hormone. It is indicated for the treatment of growth disturbance and growth hormone deficiency in children and adults. Omnitrope is similar to Genotropin, the reference medicinal product already authorised in the EU.

A separate press release has been published and is available here.

Extensions of indications and other recommendations

The Committee adopted positive opinions on the extension of indication of medicinal products that are already authorised in the European Union:

- **Lyrica** (pregabalin), Pfizer Limited, to extend its indication to include general anxiety disorder. Lyrica was first authorised in the European Union on 6 July 2004 and is currently approved for the treatment of peripheral neuropathic pain and epilepsy.
- **Remicade** (infliximab), Centocor B.V., to extend its indication to include treatment of moderately to severely active ulcerative colitis. Remicade was first authorised in the European Union on 13 August 1999 and is currently approved for the treatment of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis and psoriasis.
- **TachoSil** (Human fibrinogen and human thrombin), Nycomed Austria GmbH, to amend the indication by deleting the following statement: '*Efficacy has only been demonstrated in liver surgery*'. TachoSil was first authorised in the European Union on 8 June 2004 and is approved for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient.

The CHMP also recommended the approval of **Bondenza** (ibandronic acid) and **Bonviva** (ibandronic acid) 3mg/3ml solution for injection. Bondenza and Bonviva were first authorised in the European Union on 23 February 2004 and are both indicated for the treatment of osteoporosis. This strength is for intravenous administration once every 3 months compared to once daily and once monthly oral administrations previously authorised.

Summaries of opinions for all these products are available and can be found here.

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Re-examination procedure concluded

Following the re-examination of the negative opinion adopted on 13 October 2005, the Committee adopted a final positive opinion to recommend the extension of indication for **Exelon** and **Prometax**, from Novartis Europharm Ltd, to add the symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Exelon and Prometax are currently indicated for symptomatic treatment of mild to moderately severe Alzheimer's dementia.

A summary of opinion with more information about the re-examination procedure has been published and can be found **here**.

Safety updates

Following a preliminary review of cases of serious liver injury associated with the use of **Ketek** (telithromycin), the CHMP has asked the marketing authorisation holder (Aventis Pharma S.A.) to change the product information to include stronger warnings relating to liver disorders. This is a precautionary measure, pending the outcome of a full benefit/risk assessment of the product in the context of the ongoing renewal procedure for the marketing authorisation.

A separate press release has been published and can be found here.

Referral procedure concluded

The Committee concluded a referral procedure for **Nifedipine Pharmamatch retard 30 and 60 mg** (nifedipine), from Pharmamatch BV, with a recommendation to grant a marketing authorisation. The referral was initiated by the United Kingdom under Article 29(2) of Directive 2001/83/EC as amended, because of differences between the summaries of product characteristics of the reference product and the generic product regarding contraindications in women capable of child bearing and nursing mothers.

Concluding a referral procedure for **Prograf / Prograft** (tacrolimus) hard capsules and concentrate for solution for infusion from Astellas Pharma GmbH (formerly Fujisawa GmbH), the Committee recommended that the product information be harmonised across EU Member States. The procedure was initiated by the marketing authorisation holder under Article 30 of the Community code on human medicines (Directive 2001/83/EC, as amended). The products are authorised in most EU Member States for the prevention and treatment of rejection after various types of organ transplantations.

A more detailed CHMP meeting report will be published shortly.

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