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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 24 to 26 June 2003

Four opinions were adopted for initial applications for marketing authorisation:

- A positive opinion for **Avandamet** (rosiglitazone/metformin), from SmithKline Beecham, intended for the treatment of type 2 diabetes mellitus patients, particularly overweight patients, who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone. EMEA review began on 21 October 2002 and the opinion was adopted on 26 June 2003, with an active review time of 176 days.
- A positive opinion for **Omnitrop** (somatropin), from Sandoz, intended for the treatment of growth hormone deficiency in children over three years of age and adolescents due to insufficient secretion of growth hormone and growth disturbance associated with Turner syndrome or chronic renal insufficiency and replacement therapy in adults with pronounced growth hormone deficiency. EMEA review began on 21 October 2002 and the opinion was adopted on 22 May 2001, with an active review time of 206 days.
- A positive opinion for **Onsenal** (celecoxib), from Pharmacia-Pfizer EEIG, intended for the treatment of familial adenomatous polyposis (FAP), as an adjunct to usual care (e.g. endoscopic surveillance, surgery). EMEA review began on 20 November 2001 and the opinion was adopted on 26 June 2003, with a total review time of 206 days.

  Onsenal was designated an orphan medicinal product on 20 November 2001 and is the **twelfth orphan medicinal product** to receive a positive CPMP opinion.
- A positive opinion for **Stalevo** (levodopa/carbidopa/entacapone), from Orion Corporation, intended for the treatment of Parkinson's disease. EMEA review began on 23 September 2002 and the opinion was adopted on 26 June 2003, with an active review time of 192 days.

Summaries of these opinions are available on the EMEA web site: http://www.emea.eu.int

The Committee began a Community-wide benefit-risk review for **paroxetine** containing medicines. The referral was made by the UK on the basis of safety concerns relating to potential risk of emotional changes (such as crying, mood fluctuations, hostility, self-harm, suicidal thoughts and attempted suicide) and withdrawal reactions associated with the use of paroxetine.

A more detailed CPMP meeting report will be published shortly.

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