The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE (revised)
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 18 to 20 February 2003

- The Agency's scientific committee, the CPMP, adopted a positive opinion on initial marketing authorisation applications at this meeting for **Aldurazyme** (laronidase), from Genzyme, which is intended for enzyme replacement therapy in mucopolysaccharidosis I (formerly known as Hurler, Hurler-Scheie, Scheie). EMEA review began on 26 March 2002 and the opinion was adopted on 20 February 2003, with an active review time of 209 days.

  Aldurazyme was designated an orphan medicinal product on 14 February 2001 and is the **ninth** orphan medicinal product to receive a CPMP positive opinion for marketing authorisation. A summary of this opinion is available on the EMEA web site: http://www.emea.eu.int

- The Committee extended the indication for **Viread** (tenofovir disoproxil fumarate), from Gilead, to include the treatment of previously untreated adult patients with HIV infection. Viread is currently indicated in combination with other antiretroviral agents in pre-treated HIV infected adults experiencing virological failure. Viread was first authorised in the European Union in February 2002. Further information on this extension will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

- The Committee also extended the indication for **Remicade** (infliximab), from Centocor, to include the treatment of ankylosing spondylitis. Remicade is currently indicated in the treatment of rheumatoid arthritis and in Crohn's disease. Remicade was first authorised in the European Union in August 1999. Further information on this extension will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

- A Community-wide review for **Botox** (clostridium botulinum type A neurotoxin complex) was completed. The product is already licensed in a number of EU Member States and the review relates only to an application for a new indication for the treatment of primary axillary hyperhidrosis (excessive sweating). The CPMP considers that there is a positive benefit-risk balance based on currently available information and recommended the approval of the new indication. The referral was made by Germany and Italy to the EMEA in October 2002.

A more detailed CPMP meeting report will be published shortly.

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