London, 28 April 2003
Doc. Ref: EMEA/CPMP/2376/03/Final

PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 23 to 25 April 2003

- The Agency's scientific committee, the CPMP, adopted a negative opinion on the initial marketing authorisation application for **Serostim** (somatropin), from Ares Serono, intended for the treatment of AIDS-related wasting syndrome. EMEA review began on 17 July 2001 and the opinion was adopted on 25 April 2003, with an active review time of 177 days.

  Serostim was designated an orphan medicinal product on 8 August 2000. The criteria for orphan designation mainly focus on the very low prevalence of a disease and are not the same as the criteria (quality, safety, efficacy) used in deciding whether a product should be granted a 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 **Travatan** (travoprost), from Alcon Laboratories, for its use as first line therapy in patients with ocular hypertension or open-angle glaucoma. Travatan is currently indicated as second line treatment. Travatan was first authorised in the European Union in November 2001. Further information on this extension will be included in the public assessment report (EPAR) once the European Commission has taken its decision.

- The Committee concluded its Community-wide reviews for **Roaccutane** and associated trade names (isotretinoin) from Roche and generic products containing **isotretinoin** from Schering Health Care (Isotretinoin, Trivane, Scheritonin, Rexidal and Lurantal). The purpose of the referral was to harmonise the product information for these products in all EU Member States, in order to avoid disharmony between the pregnancy prevention measures in place for the brand leader product (Roaccutane) and those proposed for the generic products. France made the referral to the EMEA in May 2002.

  The harmonised indications recommended by the Committee are for the products' use in severe forms of acne (i.e. nodular or conglobate acne or acne at risk of permanent scaring) that is resistant to standard therapy. Due to the risk of congenital defects, the Committee recommended a harmonised set of elements that should be included in all the nationally agreed risk management programmes. These should include measures to avoid risk of pregnancy exposure in women of child bearing potential.

- The CPMP reviewed the safety of the centrally authorised hexavalent vaccines, Hexavac and Infanrix Hexa. The CPMP concluded that there was no change in the benefit/risk profile of these products and therefore did not recommend any changes to the present conditions of use. A separate Public Statement (EMEA/8519/03) is available on the EMEA web site (http://www.emea.eu.int).

A more detailed CPMP meeting report will be published shortly.

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Media enquiries only please contact Martin Harvey Allchurch EMEA press officer, Tel. (44-20) 74 18 84 27, E-mail: martin.harvey-allchurch@emea.eu.int

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int