The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 18 – 20 November 2003

The Committee gave four positive opinions on the initial marketing authorisation applications for:

- **Cholestagel** (colesevelam hydrochloride), from Genzyme Europe BV, intended for the reduction of elevated total and LDL cholesterol in patients with primary hypercholesterolaemia. EMEA review began on 23 September 2002 and the opinion was adopted on 20 November 2003, with an active review time of 201 days.
- **Faslodex** (fulvestrant), from AstraZeneca, intended for the treatment of locally advanced or metastatic breast cancer. EMEA review began on 24 February 2003 and the opinion was adopted on 20 November 2003, with an active review time of 176 days.
- **Oxybutynin Nicobrand** (oxybutynin), from Nicobrand Ltd, symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with unstable bladder. EMEA review began on 24 February 2003 and the opinion was adopted on 20 November 2003, with an active review time of 180 days.
- **Reyataz** (atazanavir sulphate), from Bristol-Myers Squibb Pharma EEIG, intended for the treatment of HIV-1infected, antiretroviral treatment experienced adults, in combination with other antiretroviral medicinal products EMEA review began on 20 May 2002 and the opinion was adopted on 20 November 2003, with an active review time of 200 days.

The CPMP concluded the appeal process for **Yondelis** (trabectedin), from PharmaMar SA, intended for the treatment of advanced soft tissue sarcoma. The initial opinion was adopted in July 2003. This final opinion followed an oral hearing from the applicant and considered the grounds for appeal.

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

The Committee finalised two EU-wide reviews for the following substances:

- The 'COX-2 inhibitor' substances **celecoxib**, **etoricoxib**, **parecoxib**, **rofecoxib** and **valdecoxib**. The review was initiated by France under Article 31 of the Community Code on human medicines in July 2002 because of gastrointestinal and cardiovascular safety concerns. The CPMP concluded that the benefit-risk balance for these products remains positive for the target patient populations. However to promote the safe use of the products, the Committee recommends adding or strengthening warnings, in particular recommending caution for patients with underlying gastrointestinal and cardiovascular risks. The Committee also recommends adding (or modifying) warnings concerning the risk of severe skin and hypersensitivity reactions. The recommendations apply to all these substances whether authorised through the European centralised procedure or through mutual recognition procedures.
- **Loratadine** containing medicinal products, including combinations of loratadine and pseudoephedrine. The review was initiated by Sweden under Article 31 of the Community Code on human medicines in April 2002 because of safety concerns relating to hypospadias in new-born boys following use of loratadine during pregnancy. The Committee concluded that a causal relationship could neither be confirmed nor excluded and as a precautionary measure

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

the product information for loratadine was revised to state that the use of loratadine during pregnancy is not recommended. Furthermore the Committee recommended that use of combinations of loratadine and pseudoephedrine should be contra-indicated in pregnancy because pseudoephedrine decreases maternal uterine blood flow.

A parallel review for desloratadine containing medicines (desloratadine is the major metabolite of loratadine) was finalised in December 2002. The Committee also concluded that a causal relationship could neither be confirmed nor excluded and as a precautionary measure the product information for desloratadine was revised to state that the use of desloratadine during pregnancy is not recommended.

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