The European Agency for the Evaluation of Medicinal Products
Press office

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 20-22 April 2004

This is the last meeting of the Committee for Proprietary Medicinal Products in its current form. The next meeting of the Committee will be under its new name of the Committee for Medicinal Products for Human Use (CHMP). The Committee will also welcome members from the 10 new Member States that will join the European Union on 1 May 2004.

The Committee adopted one positive opinion on the initial marketing authorisation applications for:

- **Pedea** (ibuprofen), from Orphan Europe SARL, for the treatment of patent ductus arterios. EMEA review began on 21 July 2003 and the opinion was adopted on 22 April 2004, with an active review time of 176 days.
  Pedea was designated an orphan medicinal product on 14 February 2001 and is the **seventeenth orphan medicinal product** to receive a positive CPMP opinion.

A summary of this opinion, including the full indication, is available on the EMEA web site: http://www.emea.eu.int

The Committee also gave positive opinions on the extension of indication for five medicinal products that are already authorised in the EU:

- **Herceptin** (trastuzumab), Roche Registration Limited, to extend its use in combination with docetaxel for the treatment of HER2-positive patients with metastatic breast cancer who have not received chemotherapy for their metastatic disease. Herceptin was first authorised in the European Union on 28 August 2000.
- **Humira** and **Trudexa** (adalimumab), Abbott Laboratories, to change its therapeutic indication to include reduction of the rate of progression of structural damage and improvement of physical function. Humira was first authorised in the European Union on 8 September 2003. Trudexa was first authorised in the European Union on 1 September 2003.
- **NovoMix 30** (insulin aspart), Novo Nordisk, to specify its use in combination with Metformin in patients with type 2 diabetes mellitus that are insufficiently controlled on metformin alone. NovoMix 30 was first authorised in the European Union on 1 August 2000.
- **Remicade** (infliximab), Centocor B.V., to extend its use for the treatment of methotrexate-naïve patients with early rheumatoid arthritis. Remicade was first authorised in the European Union on 13 August 1999.

Further information on these extensions will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

The Committee finalised its EU-wide review for **paroxetine** containing medicines. The review was initiated by the UK in June 2003 under Article 31 of the Community Code on human medicines. The referral was made on the basis of safety concerns relating to potential risk of emotional changes (such

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as crying, mood fluctuations, hostility, self-harm, suicidal thoughts and attempted suicide) and withdrawal reactions associated with the use of paroxetine.

The Committee concluded that the benefit-risk remains positive for these products but made the following recommendations.

The Committee recommends that paroxetine should not be used in children and adolescents as clinical trials have found paroxetine to be associated with increased risk of suicidal behaviour and hostility. In addition, trials in children and adolescents did not adequately demonstrate efficacy. The Committee noted that paroxetine is not authorised in any EU Member State for use in children.

There is a possibility of an increased risk of suicide-related behaviour in young adults. As a consequence young adults should be monitored carefully throughout treatment.

The Committee also recommends strengthened warnings concerning withdrawal symptoms. Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt and the Committee underlines that patients must not stop their treatment abruptly, except on medical advice.

A question and answer document will be published on the EMEA web site on Friday 23 April. This is in line with the Agency's new transparency policy adopted in October 2003 aimed at providing more information to patients and the general public.

The CPMP also recommended lifting the suspension of marketing authorisation for **Tasmar** (tolcapone) from Roche Registration Limited, which was approved for use in the treatment of Parkinson's disease. Tasmar was first authorised in the European Union in August 1997 and was suspended in November 1998 on the basis of concerns over hepatotoxicity and neuroleptic malignant syndrome. On the basis of new data, including a clinical trial conducted by the marketing authorisation holder during the period of the suspension, the Committee has recommended more stringent liver function monitoring and monitoring for signs and symptoms of liver disease. The CPMP also recommends that Tasmar should be contra-indicated for patients with certain medical histories, including liver disease and neuroleptic malignant syndrome. A detailed public statement will be published on the EMEA web site shortly.

A more detailed CPMP meeting report will be published shortly.

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