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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 19 to 21 March 2002

The Agency's scientific committee, the CPMP, adopted 2 opinions on initial marketing authorisation applications at this meeting:

- A positive opinion for **Pegasys** (peginterferon alfa-2a) from Roche Registration Ltd. indicated for the treatment of chronic hepatitis C in adult patients. EMEA review began on 30 January 2001 and the opinion was adopted on 21 March 2002, with an active review time of 206 days.

- A positive opinion for **Tamiflu** (oseltamivir) from Roche Registration Ltd. indicated for the treatment and prophylaxis of influenza in adults and children one year of age or older. Tamiflu is not a substitute for influenza vaccination. EMEA review began on 27 February 2001 and the opinion was adopted on 21 March 2002, with an active review time of 203 days.

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

The CPMP initiated a Community-level review on the risk-benefit of **sibutramine** containing medicinal products (Reductil and associated product names), following a referral by Italy under Article 31 of the Community Code on human medicines (ex-Article 12 of Council Directive 75/319/EEC).

The Committee completed its review of **cerivastatin** containing medicinal products (Lipobay and associated product names). The CPMP opinion recommends that marketing authorisations for cerivastatin containing medicinal products should be withdrawn. The review was initiated in September 2001 by Portugal following safety concerns related to the increased risk of rhabdomyolysis. The Committee was informed that the class review of statins at the level of the national competent authorities is still continuing and is expected to be completed shortly.

The Agency also announced the appointment of Dr Panos Tsintis as the new head of sector whose responsibilities include the post-marketing surveillance of medicines, with effect from 18 March 2002.

The appointment comes at a time when the EMEA is seeking to strengthen pharmacovigilance in the European Union. Following the implementation of the EudraVigilance database and data-processing network in December 2001, the Agency is working towards introducing rapid electronic exchange of safety information between national authorities and marketing authorisation holders. This is described in the 'Policy Paper on the Implementation of the Electronic Transmission of Individual Case Safety Reports for Medicinal Products Authorised in the European Union' that will shortly be available on the EMEA web site.

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The Committee began discussions on Agency proposals for a risk management strategy. The strategy aims at measures to minimise the risks associated with the placing on the market of new medicines reviewed by the CPMP in accordance with the centralised procedure. The proposals cover four elements: risk detection, risk assessment, risk minimisation and risk communication.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 18 March 2002.

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