The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 20-21 January 2004

This was the 100th meeting of the Committee for Proprietary Medicinal Products (CPMP). The Committee re-elected Dr Daniel Brasseur as its chairman and Dr Eric Abadie as vice-chairman. A separate press release is available on the EMEA web site.

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

- **Lysodren** (mitotane), from Laboratoire HRA Pharma, intended for the symptomatic treatment of advanced adrenal cortical carcinoma. EMEA review began on 18 November 2002 and the opinion was adopted on 21 January 2004, with an active review time of 182 days. Lysodren was designated an orphan medicinal product on 12 June 2002 and is the **sixteenth orphan medicinal product** to receive a positive CPMP opinion.
- **Velcade** (bortezomib), from Millenium Pharmaceuticals Ltd, intended for the treatment of relapsed and refractory multiple myeloma. EMEA review began on 24 February 2003 and the opinion was adopted on 21 January 2004, with an active review time of 173 days.

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

- **Ambirix** (inactivated hepatitis A virus hepatitis B surface antigen, rDNA), from GlaxoSmithKline Biologicals, to extend its use to children aged 1 to 5 years. Ambirix was first authorised in the European Union on 30 August 2002.
- **Paxene** (paclitaxel), from Norton HealthCare Ltd, to extend its use to include treatment of metastatic breast cancer and metastatic cancer of ovary. Paxene was first authorised in the European Union on 19 July 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 two EU-wide reviews for:

- Four generic products containing **amlodipine maleate** for which marketing authorisation applications have been made in the mutual recognition procedure. The arbitration referral was initiated by Germany in September 2003 under Article 29 of the Community Code on human medicines and related to potential differences in the quality profile between the generic products and innovator product. The Committee concluded that the apparent quality differences in the generic products did not raise safety issues and did not on balance present a risk to public health. The objections raised in the arbitration should not therefore prevent the granting of marketing authorisations in the mutual recognition procedure.
- **Zocord** (simvastatin) and associated product names from Merck Sharp & Dohme. The purpose of the referral was to harmonise the divergent marketing authorisations for these products in the European Union. The CPMP concluded that there is a positive benefit/risk balance for the product's use in hypercholesterolaemia (treatment of primary hypercholesterolaemia or mixed dyslipidaemia, as an adjunct to diet, when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate;

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treatment of homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate) and in cardiovascular prevention (reduction of cardiovascular mortality and morbidity in patients with manifest atherosclerotic cardiovascular disease or diabetes mellitus, with either normal or increased cholesterol levels, as an adjunct to correction of other risk factors and other cardioprotective therapy). The European Commission initiated the referral in November 2002 under Article 30 of the Community Code on human medicines.

A more detailed CPMP meeting report will be published shortly.

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