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

The Agency's scientific committee, the CPMP, adopted 4 opinions on initial marketing authorisation applications at this meeting:

- A positive opinion for **Hepsera** (adefovir dipivoxil) from Gilead Science International, which is intended for the treatment of chronic hepatitis B in adults. EMEA review began on 22 April 2002 and the opinion was adopted on 21 November 2002, with an active review time of 152 days.
- Positive opinions for **Levitra** and **Vivanza** (vardenafil) from Bayer. The products are indicated for the treatment of erectile dysfunction. EMEA review began on 28 January 2002 and 22 April 2002. The opinions were adopted on 21 November 2002, with an active review time of 180 and 95 days.
- A positive opinion for **Ytracis** (yttrium(Y-90)) from CIS bio International. It is a radiopharmaceutical precursor solution intended for the radiolabelling of carrier molecules. EMEA review began on 22 October 2001 and the opinion was adopted on 21 November 2002, with an active review time of 176 days.

A summary of these opinions is available on the EMEA web site: http://www.emea.eu.int

The Committee also gave positive opinions for a number of new indications for already authorised medicinal products, including:

- Extension of the indication for **Caspofungin MSD** (caspofungin) from Merck Sharp & Dohme to include treatment of invasive candidiasis in non-neutropenic adult patients. Caspofungin MSD was first authorised in the European Union in October 2001.
- Extension of the indication for **Lantus** (insulin glargine) from Aventis Pharma to include the treatment in children of 6 years or above with diabetes mellitus. Lantus was first authorised in the European Union in June 2000.

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

The Committee began a Community-wide review for:

- **Pravachol** (pravastatin) and associated product names from Bristol-Myers Squibb. The referral is part of the first wave of referrals arising from the concerted action by EU regulatory authorities to harmonise the marketing conditions of a number of European brand leaders in major therapeutic areas. The referral is made by the European Commission under Article 30 of the Community Code on human medicines (ex-Article 11 of Council Directive 75/319/EEC). The referral was not initiated as a result of any established safety or efficacy concern with this product.
- **Zocord** (simvastatin) and associated product names from Merck Sharp & Dohme. The referral is part of the first wave of referrals arising from the concerted action by EU regulatory authorities to harmonise the marketing conditions of a number of European brand leaders in major therapeutic areas. The referral is made by the European Commission under Article 30 of the Community Code on human medicines (ex-Article 11 of Council Directive 75/319/EEC). The referral was not initiated as a result of any established safety or efficacy concern with this product.

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- **Laurina** and **Laurina 28** (containing desogestrel and ethinylestrodial) from Organon. These combined oral contraceptives are currently licensed in a number of Member States. The arbitration referral relates to proposed changes to the wording of the product information that is not fully in line with the September 2001 CPMP assessment report on combined oral contraceptives. The referral is made by Germany under Article 7(5) of the Variations Regulation (Commission Regulation (EC) No 541/95).
- **Mononine** containing medicinal products from Aventis Behring. The product is currently licensed in a number of Member States for the treatment and prophylaxis of patients with haemophilia B and the arbitration referral only relates to an application to include a new mode of administration by continuous infusion. The referral is made by Sweden under Article 7(5) of the Variations Regulation (Commission Regulation (EC) No 541/95) and relates to the efficacy of monomine in this new mode of administration only.

The Committee concluded its Community-wide reviews for:

- Medicinal products containing **calcitonin**. These products are marketed by a large number of companies throughout the European Union. The CPMP recommended revisions to and harmonisation of the authorised indications of these products. The harmonised indications for the injectable form recommended by the Committee are for the products' use in prevention of acute bone loss due to sudden immobilisation (such as patients with recent bone fractures), Paget's disease (a bone disorder) and hypercalcaemia of malignancy. The harmonised indication for the intranasal form recommended by the Committee is for the products' use in the treatment of established post-menopausal osteoporosis to prevent vertebral fractures. The procedure began in April 2000 following a referral by The Netherlands under Article 31 of the Community Code on human medicines (ex-Article 12 of Council Directive 75/319/EEC).

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

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