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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 15 to 17 October 2002

The Agency's scientific committee, the CPMP, adopted 1 opinion on initial marketing authorisation applications for an orphan drug at this meeting:

- A positive opinion for **Carbaglu** (N-carbamoyl-L-glutamic acid) from Orphan Europe, which is intended for the treatment of hyperammonaemia associated with N-acetyl-glutamate synthase (NAGS) deficiency. EMEA review began on 22 October 2001 and the opinion was adopted on 17 October 2002, with an active review time of 148 days.

  Carbaglu was designated an orphan medicinal product on 18 October 2000 and is the eighth orphan medicinal product to receive a CPMP positive opinion for marketing authorisation.

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

The Committee also gave a positive opinion for an extension of the indication for **Caelyx** (doxorubicin hydrochloride) from Schering-Plough Europe to include monotherapy treatment of metastatic breast cancer in women where there is an increased cardiac risk. Caelyx was first authorised in the European Union in June 1996. Further information on the extension 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:

- **Botox** (clostridium botulinum type A neurotoxin complex) from Allergan Pharmaceuticals. The product is already licensed in a number of Member States and the arbitration referral only relates to an application for a new indication for the treatment of primary axillary hyperhidrosis (excessive sweating). The referral is made by Germany and Italy under Article 29(2) of the Community Code on human medicines and relates to safety and efficacy concerns of Botox in this new indication only.

The Committee concluded its Community-wide reviews for:

- **Beriate P** (human coagulation factor VIII) from Aventis Behring. The CPMP recommended that the summary of product characteristics, in particular the warning on transmissible agents, was brought in line with the June 2000 core SPC for human plasma derived factor VIII products. The procedure began in September 2001, following a referral by the marketing authorisation holder under Article 31 of the Community Code on human medicines.
- The CPMP recommended the revocation of national authorisations granted through the mutual recognition procedure for a number of generic medicines containing **felodipine**. This follows a GCP inspection that identified irregularities in the conduct and reporting of clinical trials supporting these authorisations. The review began in September 2002, following a referral by Germany under Article 36 of the Community Code on human medicines. The recommendation does not relate to originator (non-generic) products containing felodipine.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 14 October 2002.

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