The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 17 to 19 September 2002

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

- A positive opinion for **Theryttrex** (yttrium(^{90}Y) chloride) from MSD Nordion, which is a radionuclide intended for the radiolabelling of carrier molecules. EMEA review began on 17 September 2001 and the opinion was adopted on 19 September 2002, with an active review time of 177 days.

A summary of this opinion 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 **Enbrel** (etanercept) from Wyeth Europe to include second-line treatment of active and progressive psoriatic arthritis in adults. Enbrel was first authorised in the European Union in February 2000.
- Two extension of indications for **Glivec** (imatinib mesylate) from Novartis. These relate to an extension to include first-line treatment of chronic myeloid leukaemia (CML) for adults and also an extension to include first-line treatment of children with CML. Glivec is a designated orphan drug in the European Union and was first authorised in November 2001.
- Two extension of indications for **Taxotere** (docetaxel) from Aventis. These relate to an extension to include the first-line treatment of non-small cell lung cancer and also an extension to include a second-line therapy in combination with capecitabine in patients with locally advanced or metastatic breast cancer. Taxotere was first authorised in the European Union in November 1995.

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:

- Five generic **felodipine**-containing medicinal products authorised in a number of Member States through the mutual recognition procedure. The referral relates to concerns raised following a GCP inspection on the studies submitted in support of the marketing authorisations. The referral, made by Germany under Article 36 of the Community Code on human medicines (ex-Article 15a of Council Directive 75/319/EEC), does not relate to the reference product.

The Committee concluded its Community-wide reviews for:

- **Prozac** and associated product names (fluoxetine) from Eli Lilly. The purpose of the referral was to harmonise the product information for these products in all EU Member States. The harmonised indications recommended by the Committee are for the product's use in major depressive episodes, obsessive-compulsive disorder and as a complement of psychotherapy in the treatment of bulimia nervosa. The procedure began in March 2001, following a referral by France under Article 30 of the Community Code on human medicines (ex-Article 11 of Council Directive 75/319/EEC).

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- **Renitec** and associated product names (enalapril) from Merck Sharp & Dohme. The main purpose of the referral was to harmonise the product information for these products in all EU Member States. The harmonised indications recommended by the Committee are for the product's use in treatment of hypertension, symptomatic heart failure and the prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction. The procedure began in May 2001, following a referral by France under Article 30 of the Community Code on human medicines (ex-Article 11 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 16 September 2002.

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