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 23 – 25 September 2003

The Committee adopted a positive opinion on the marketing authorisation application for **Zevalin** (ibritumomab tiuxetan), from Schering AG, which is intended for the treatment of non-Hodgkin's lymphoma. EMEA review began on 24 March 2003 and the opinion was adopted on 25 September 2003, with an active review time of 115 days.

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

The Committee also adopted an opinion on extending the indication for **Enbrel** (etanercept), from Wyeth Europe Ltd, to include the treatment of severe ankylosing spondylitis in adults. Enbrel is currently indicated for the treatment of rheumatoid arthritis and psoriatic arthritis in adults and for juvenile chronic arthritis. Enbrel was first authorised in the European Union in February 2000. Further information will be included in the public assessment report (EPAR) once the European Commission has taken its decision.

The Committee finalised three Community-wide reviews for

- **Zestril** and associated names (lisinopril). The product is already authorised in all the EU Member States and Norway. The CPMP recommended harmonisation of the authorised indications of these products as follows: treatment of hypertension, treatment of symptomatic heart failure, short-term (6 months) treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction, treatment of renal disease in hypertensive patients with type 2 diabetes mellitus and incipient nephropathy. The review was initiated by The Netherlands under Article 30 of the Community Code on human medicines in July 2002.

- **Laurina and associated names** (containing desogestrel and ethinyl estradiol). These combined oral contraceptives are currently licensed in a number of Member States. The arbitration referral related to proposed changes to the wording of the product information. The CPMP concluded that the data were not sufficient to support the requested product safety claims, but agreed to changes in the warnings and statements about venous and arterial thromboembolism to bring the product information in line with the September 2001 CPMP position on combined oral contraceptives. The referral was made by Germany under Article 7(5) of the Variations Regulation (Commission Regulation (EC) No 541/95) in November 2002.

- **Gatifloxacin**-containing medicinal products. These products are either already authorised or awaiting authorisation in a number of EU Member States and Iceland. The referral related to safety and efficacy concerns of the products. The CPMP concluded that there was a positive balance of benefits and risks for these products in the treatment of community-acquired pneumonia (mild to moderate) and in the treatment of complicated urinary tract infections (excluding prostatitis and epididymitis). The review was initiated by Belgium under Article 31 of the Community Code on human medicines in April 2002.

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