London, 26 April 2002
Doc. Ref: EMEA/CPMP/1747/02/en

PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 23 to 25 April 2002

The Agency's scientific committee, the CPMP, adopted 8 opinions on initial marketing authorisation applications at this meeting:

- Positive opinions for **Actrapid, Actraphane, Insulatard, Mixtard, Monotard, Protophane, Ultratard and Velosulin** (recombinant human insulin) from Novo Nordisk indicated for the treatment of diabetes mellitus. EMEA review of these applications began on 22 May 2001, 16 June 2001 and 17 July 2001. The opinions were adopted on 25 April 2002 with active review times of 181 and 184 days.

Summaries of these opinions are available on the EMEA web site: http://www.emea.eu.int

A number of other procedures were initiatied at the meeting:

- The CPMP began a Community-level review on the risk-benefit of **gatifloxacin** containing medicinal products (Bonoq, Crispin, Urobonoq, Urocrispin and associated product names) following a referral by Belgium under Article 31 of the Community Code on human medicines (ex-Article 12 of Council Directive 75/319/EEC). The review was initiated because of safety and efficacy concerns.

- The CPMP began Community-level reviews of **loratadine** and **desloratadine** containing medicinal products (Clarityn, Azomyr and other associated product names) following referral by Sweden under Article 31 of the Community Code on human medicines (ex-Article 12 of Council Directive 75/319/EEC). Initiated because of a potential safety issue, the reviews will look at both the safety and efficacy of these medicinal products.

- The CPMP began a Community-level review on the risk-benefit of **nimesulide** containing medicinal products (Aulin, Mesulide, Nimed and associated product names), following a referral by Finland under Article 31 of the Community Code on human medicines (ex-Article 12 of Council Directive 75/319/EEC). The review was initiated because of safety concerns.

- The CPMP began an arbitration referral for medicinal products containing a fixed combination of **salmeterol and fluticasone** (Seretide Diskus, Viani Diskus and associated product names) following a referral by Ireland under Article 7(5) of Commission Regulation (EC) No 541/95. The referral relates to two applications under the mutual recognition procedure for a new indication ('type II variation') for chronic obstructive pulmonary disease.

Continues/…

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.eu.int http://www.emea.eu.int

A number of procedures were finalised at the meeting:

- The CPMP finalised a harmonisation review for **Captea**, **Ecazide** and associated product names (medicinal products containing a fixed combination of captopril and hydrochlorothiazide). The procedure was initiated 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). The referral was initiated because of divergences in the disease indications and dosage information for prescribers (summary of product characteristics) in the different Member States.

- The CPMP finalised an arbitration referral for **Dacarbazine Faulding** (dacarbazine). The procedure was initiated in November 2001 following a referral by France under Article 29(2) of the Community Code on human medicines (ex-Article 10(2) of Council Directive 75/319/EEC). The CPMP found that concerns raised by France relating to the quality of the product had been resolved and that harmonised national marketing authorisations could be issued.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 22 April 2002.

--ENDS--

For further information, please contact:
Martin Harvey, EMEA press officer
Tel. (+44-20) 74 18 84 27, E-mail: martin.harvey@emea.eu.int