European Medicines Agency
Press office

London, 17 February 2005
Doc. Ref. EMEA/59424/2005

PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
14-17 February 2005

The Committee adopted one positive opinion on an initial marketing authorisation application for **Duloxetin Lilly** (duloxetine), Eli Lilly Nederland B.V., for the treatment of diabetic peripheral neuropathic pain. EMEA review began on 17 May 2004, with an active review time of 210 days. A summary of this opinion, including the full indication for the product, is available on the EMEA web site: http://www.emea.eu.int

The Committee also gave positive opinions on the extension of indication for medicinal products that are already authorised in the EU:

- **Paxene** (paclitaxel), Norton HealthCare Ltd, to extend its use in combination with cisplatin to the treatment of advanced ovarian cancer and to the treatment of non-small cell lung cancer. Paxene was first authorised in the European Union on 19 July 1999.
- **InductOs** (dibotermin alfa), Wyeth Europa Ltd, to extend its use to include single-level (L4 - S1) anterior lumbar spine fusion as a substitute for autogenous bone graft in adults with degenerative disc disease who have had at least 6 months of non-operative treatment for this condition. InductOs was first authorised in the European Union on 9 September 2002.
- **Levemir** (insulin detemir), Novo Nordisk, to extend its use for treatment of children and adolescents of 6-17 years of age. Levemir was first authorised in the European Union on 1 June 2004.
- **NovoRapid** (insulin aspart), Novo Nordisk, to extend its use for treatment of children of 2-6 years of age. Novorapid was authorised in the European Union on 7 September 1999.
- **Xeloda** (capecitabine), Roche Registration Ltd, to extend its use to the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Xeloda was first authorised in the European Union on 2 February 2001.

Summaries of opinion for Paxene, InductOs and Xeloda are available on the EMEA web site: http://www.emea.eu.int.

The Committee agreed on a number of urgent regulatory actions as part of its ongoing review of **COX-2 inhibitors**. A separate statement is available on the EMEA web site that details the contraindications and warnings introduced by the Committee.

The CHMP began a formal review procedure under Article 18 of Council Regulation (EEC) No 2309/93 for Hexavac, from Aventis Pasteur MSD. The review was initiated following a request from Germany to the European Commission (EC). The EC has requested the CHMP to review the safety of the centrally authorised vaccine and to give an opinion whether regulatory action is warranted at this time. The Committee already completed a review in December 2003 on hexavalent vaccines and had previously concluded that there was no need to introduce changes to the conditions of use.

--ENDS--

Media enquiries only to:
Martin Harvey Allchurch
Tel. (44-20) 74 18 84 27, E-mail: press@emea.eu.int