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 28 to 30 May 2002

The Agency's scientific committee, the CPMP, adopted 5 opinions on initial marketing authorisation applications at this meeting:

- A positive opinion for **Ambirix** (inactivated hepatitis A virus and recombinant hepatitis B surface antigen) from GlaxoSmithKline. Ambirix is a vaccine for use in children and adolescents for protection against hepatitis A and hepatitis B infection. EMEA review began on 19 June 2001 and the opinion was adopted on 30 May 2002, with an active review time of 179 days.
- A positive opinion for **InductOs** (dibotermin alfa) from Genetics Institute of Europe. It is indicated for the treatment of long-bone fractures that require open surgical management. EMEA review began on 27 March 2001 and the opinion was adopted on 30 May 2002, with an active review time of 200 days.
- Positive opinions for the double application **Neulasta** and **Neupopeg** (pegfilgrastim) from Amgen Europe. It is indicated for use in reducing the duration of neutropenia (low white blood cell count) and the occurance of febrile neutropenia (low white blood cell count with fever) in patients treated with cytotoxic chemotherapy. EMEA review began on 22 May 2001 and the opinion was adopted on 30 May 2002, with an active review time of 179 days.
- A positive opinion for **Xigris** (recombinant human activated protein C) from Eli Lilly indicated for the treatment of severe sepsis. EMEA review began on 30 January 2001 and the opinion was adopted on 30 May 2002, with an active review time of 180 days.

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

The CPMP also revised its opinion of 21 February 2002 for **EVRA** to further address its potential environmental impact. EVRA is a transdermal patch for female contraception containing norelgestromin and ethinyl estradiol, from Janssen-Cilag International NV. The concern relates to the fact that residual amounts of the hormones are present on the patch after use, which may reach the aquatic environment if not properly disposed of. After consultation with the European Commission, the CPMP strengthened the instructions for the safe disposal of the patch after use. In addition, the company will include in the pack a disposal container for used patches.

The CPMP also began a Community-wide review for generic products containing **isotretinoin** from Schering Health Care (Isotretinoin, Scheritonin, Rexidal and Lurantal). The referral by France relates to public health concerns over the different pregnancy prevention measures proposed for the generic products in the Member States. In order to avoid disharmony between the pregnancy prevention measures already in place for the brand leader and those proposed for the generic products, the Committee also began a review at the request of France to harmonise product information in all Member States for **Roaccutane** (isotretinoin) from Roche.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 27 May 2002.

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