The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

Committee for Proprietary Medicinal Products
Meeting of 11 to 13 December 2001

The CPMP adopted 4 opinions on initial marketing authorisation applications at this meeting:

- Positive opinions for the double application **Arixtra** (fondaparinux) from Sanofi-Synthelabo and **Quixidar** (fondaparinux) from NV Organon indicated for the prevention of venous thromboembolic events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as hip fracture, major knee or hip replacement surgery. Review by the EMEA began on 1 March 2001 and the opinion was adopted on 13 December 2001, with an active review time of 205 days.

- A positive opinion for **Dynepo** (epoetin delta) from Aventis Pharma SA France indicated for the treatment of anaemia in patients with chronic renal failure. Review by the EMEA began on 26 September 2000 and the opinion was adopted on 13 December 2001, with an active review time of 206 days.

- A positive opinion for **Vfend** (voriconazole) from Pfizer Limited indicated for the intended for the treatment of invasive aspergillosis and invasive infections due to *Candida, Scedosporium* and *Fusarium* species. Review by the EMEA began on 28 November 2000 and the opinion was adopted on 13 December 2001, with an active review time of 203 days.

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

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 10 December 2001.

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