The European Agency for the Evaluation of Medicinal Products
Directorate

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PRESS RELEASE
EMEA brings in new openness measures and acts to encourage development of veterinary medicines

The EMEA Management Board met on 2 October 2003, under the vice-chairman Dr Philippe Duneton. The Board heard that Dr Keith Jones has decided to step down as chairman. Speaking on behalf of the Board, Dr Duneton thanked Dr Jones, "for his hard work and valuable contribution to the EMEA and the European medicines system as a whole". A new chairman will be elected at the Board's December meeting.

The Board approved new measures to increase the openness of the Agency. The 10 initiatives, which had been endorsed by a public consultation exercise, relate mainly to improvements to the EMEA web site and the Agency's communication activities and information tools. The EMEA working group with patient organisations will in particular be asked to look at ways of making the Agency's information more patient-friendly. The Board asked the Executive Director to report back in the second half of 2004 on progress made. As part of the Agency's commitment to the EU orphan drug policy, the Management Board supported a request from the Executive Director to consult with interested parties on publication of the name and indication of designated orphan drugs when they apply for marketing authorisation.

The Management Board approved a 12-month pilot project to offer free scientific advice for companies developing veterinary medicines for minor uses and minor species (MUMS). This is part of the Agency's Committee for Veterinary Medicinal Products strategy to encourage the availability of veterinary medicines for MUMS.

The Board adjusted the Agency's 2003 budget to a new total of € 84.2 million, in particular to take into account higher than expected fee revenue. The Board noted that fewer applications have been received for approval of orphan drugs than expected, while there were significantly more applications for type II variations. Half of the fee revenue is used to pay for the scientific evaluation and it was decided to use the other half to help fund development work on two European databases; the 'EuroPharm' database of authorised medicines and the 'EudraCT' database for clinical trials.

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NOTES:

1. Fees for scientific advice for veterinary medicines currently range from € 11 600 to € 34 800. The budgetary impact of 12-month pilot project is estimated at € 100 000.
2. The initial EMEA forecasts were 38 marketing authorisation applications in 2003 and 245 type II variations. The revised forecasts are for a total of 42 applications and 381 variations. The number of applications for approval of designated orphan drugs is expected to fall from 16 to 9, while applications from other medicines are expected to increase from initial forecasts of 22 to 33. The new estimates continue the trend seen in 2002 (31 applications) and remain below application levels in previous years (2000: 54, 2001: 58).
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int
4. The next meeting of the Management Board is on 18 December 2003.

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