The European Agency for the Evaluation of Medicinal Products
Directorate

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PRESS RELEASE
Thirty-first meeting of the Management Board

The EMEA Management Board met on 4 October 2001, chaired by Dr Keith Jones.

The Management Board endorsed a report on the EMEA experience with the current fees system. This will be transmitted to the European Commission as part of the planned report to the European Parliament and Council of Ministers on the implementation of the fee system. It will be published by the EMEA. In the report, the Agency considers that it is premature to make definitive recommendations at this stage, particularly in the light of the impact of future EU enlargement and the proposed revision of EMEA tasks and responsibilities. Changes will however need to be made before 2003-2004 and recommendations will be made during 2002.

The Board made progress in its consideration of the future mandate and functioning of the Herbal Medicinal Products Working Party in light of the Commission proposals currently under preparation for a future new regulatory framework for herbal and traditional medicines.

The Board welcomed a report from the Executive Director on progress being made by the Agency towards implementation of the EudraVigilance pharmacovigilance database.

A third supplementary and amending budget for 2001 was adopted, increasing the total budget from € 62.338 million to € 65.866 million. The increase in revenue is mainly due to a higher number of applications for variations and extensions to marketing authorisations for both human and veterinary medicines. About half of the increased revenue will be paid to rapporteurs and co-rapporteurs for evaluation services. The Board also approved expenditure in preparation for the Agency's role within the future Community-wide strategic IT plan for pharmaceuticals.

The Board noted preparations for the next phase in the implementation of the EMEA transparency initiative. The Management Board welcomed the agreement by the European Federation for Animal Health (FEDESA) to the publication of CVMP opinions at the time of adoption, so-called 'day 0' publication, for veterinary medicines and recommendations for maximum residue limits. The preparation of proposals for publication of CPMP opinions on post-authorisation applications from 2002 onwards was also noted.

As part of its general oversight responsibilities for the Agency, the Board heard presentations on the internal quality management systems and financial control mechanisms in place at the EMEA.

The next meeting of the Management Board is on 18 December 2001.

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NOTES:

1. 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*
2. The report on the implementation of the fee system is foreseen by December 2001 in Article 12 of the revised Fee Regulation (EC) No 297/95.
3. Details of the transparency initiatives are in *Report to the Management Board on the workshop "A clear step forward: transparency at the EMEA"* (EMEA/MB/053/00) available on the web site.

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