The European Agency for the Evaluation of Medicinal Products
Directorate

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PRESS RELEASE
Twenty-ninth meeting of the Management Board

The EMEA Management Board met on 21-22 February 2001. Dr Keith Jones was elected as chairman of the Management Board. He succeeds Prof. André Broekmans who resigned in December 2000. His term of office runs until the end of 2002. Dr Jones has been a member of the Management Board since 1994 and is Director and Chief Executive of the UK Medicines Control Agency.

The Board adopted the EMEA work programme for 2001-2002, together with the preliminary draft budget for 2002 of € 70 332 000. The work programme forecasts increased numbers of new applications for human and veterinary medicines

- human medicines: increase from 54 in 2000 to 73 in 2001 and 74 in 2002 (mainly as a result in applications for orphan medicines designated in 2000 following the recent introduction of orphan medicines legislation)
- veterinary medicines: increase from 6 to 10 in 2001 and 2002 and for maximum residue limit applications to increase from 2 in 2000 to 5 in 2001 and 2002

A substantial increase in post-authorisation activities for human and veterinary medicines is expected.

Dependent on the forecast increase in applications, fee revenue is expected to rise to € 46 521 000 in 2002 (€42 610 000 in 2001). There will be a need for additional staff to manage the overall increase in activities and the number of authorised staff requested in the budget is 251 (220 in 2001). The budget request will be submitted to the EU institutions before final adoption by the Board at its December meeting.

Priorities presented by Thomas Lönngren, EMEA Executive Director, include:
- implement a European pharmacovigilance system ('EudraVigilance')
- improve the scientific advice service offered by the EMEA
- a new Pan-European Regulatory Forum (PERF II) programme to help EU associated countries prepare for future accession
- prepare the EMEA and scientific committees for future scientific challenges and new therapies

Following the transparency workshop of November 2000, the Board gave the mandate to the Executive Director to implement the recommendations made by the workshop with effect from 1 April 2001. These recommendations include the publication on the day of adoption of CPMP opinions for initial applications and certain post-authorisation evaluations. Opinions of the CVMP will now be published two weeks after their adoption, instead of the current 2-month delay.

The next meeting of the Management Board will be on 6 June 2001.

NOTES:
1. This press release, together with other information about the work of the EMEA, may be found on the new EMEA web site at the following location: *http://www.emea.eu.int*
2. The report of the 23 November 2000 transparency workshop, together with presentations made at the meeting, can be found at: *http://www.eudra.org/gendocs/general/MB_AR.htm*
3. The latest documents on the revision of the European marketing authorisation system are available on the Commission Pharmaceutical Unit web site: *http://pharmacos.eudra.org/review/index.htm*

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