The European Agency for the Evaluation of Medicinal Products
Directorate

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PRESS RELEASE

Twenty-sixth meeting of the Management Board

The EMEA Management Board met on 7 June 2000, chaired by Prof. André Broekmans.

1. The Board considered the outcome of the public consultation on new transparency initiatives. It was agreed that summaries of CPMP opinions on applications for marketing authorisations for medicinal products for human use (both negative and positive) will be published 15 days after the adoption of the opinion, once the right of appeal has expired and the opinion has become final. Applicant companies will be requested not to communicate before day 15. Companies' compliance will be monitored in liaison with EFPIA for a period of 6 months. The current 'day 60' publication policy will continue for CVMP opinions on veterinary medicines, pending discussions with FEDESA. A workshop will be convened during autumn 2000 with all interested parties to consider a strategy for post-marketing communications. The Board will finalise its position on all these aspects at its 20 December meeting.

2. Progress made by the Herbal Medicinal Products Working Party was noted and the Management Board endorsed the continuation of its work. Noting certain difficulties posed by current EU legislation to the assessment of the efficacy of herbal medicines, it was proposed to bring together the European Commission, the chairmen of the Management Board, CPMP and Herbal Medicinal Products Working Party and the Executive Director to identify options on how to proceed.

3. Following a favourable opinion of the EU Court of Auditors, the Board granted discharge to the Executive Director and EMEA accounting officer for the execution of the 1999 budget.

4. Following a meeting of the Working Group on Fees and Costing on 6 June 2000, the Board endorsed the continuation of the costing exercise. Rapporteurs, co-rapporteurs and inspection services will continue to provide details of the costs of centralised procedures. The Working Group meets again on 19 December 2000. Based on available data, the Group will look at the aggregate costs of centralised procedures, including rapporteur, co-rapporteur, inspection and EMEA costs.

5. Together with heads of agencies from EU and central and eastern European countries, the Board considered the impact of enlargement on the EMEA and in particular the composition and operation of the Management Board and the scientific committees, and the conduct of pharmacovigilance. These points will be considered as part of the 2001 review process currently being undertaken by the European Commission.

6. The meeting was followed on 8 June 2000 by the final meeting of the PERF priority action area 'Mandate and responsibilities of competent authorities'. Documents from the meeting will be made available on the PERF web site *http://perf.eudra.org*

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NOTES:
1. This press release, together with other information about the work of the EMEA, may be found on the Internet at the following location: *http://www.eudra.org/emea.html*

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