



London, 3 October 1997

PRESS RELEASE

Fifteenth Meeting of the Management Board

The Management Board of the EMEA met on 1 October 1997 under the Chairmanship of Mr Strachan Heppell. The Board welcomed a new member from Finland, Mr Kimmo Leppo.

The Management Board discussed recent questions raised concerning paediatric testing of medicinal products in Europe and US. The Board noted a report from the Committee for Proprietary Medicinal Products on its handling of opinions for a certain number of products and their paediatric use (CPMP/786/97). The report confirmed these opinions are in line with provisions currently in force. The Board welcomed the CPMP initiative in producing the updated *Note for guidance on clinical investigation of medicinal products in children* (CPMP/EWP/462/95), which came into operation in September 1997. The European Commission indicated that it would shortly initiate a debate to determine whether there is any need to reinforce the current regulatory framework to take into account the new guideline.

The Board welcomed clarifications from the European Commission on the creation of the new Scientific Committee for Medicinal Products and Medical Devices (see Commission Decision 97/579/EC) and underlined the need to prevent any operational conflict with the work of the EMEA scientific committees.

At the request of the European Parliament, the Commission will in 1998 assume the financial control responsibilities of all the recently created decentralised EU bodies - including the EMEA. The Board welcomed the pragmatic approach adopted by the Commission to future arrangements for the exercise of this function, including the possibility of EMEA creating a financial reserve in the future.

Continuing its long-term reflection on various subjects (see press release of 14th meeting of 4 June 1997), the Management Board looked at the role of the EMEA in supporting the international links of the EU. This includes EMEA technical support to ICH and VICH, future participation of Iceland and Norway in the work of the EMEA, on-going discussions with central and eastern European countries and Russia, and the management of mutual recognition agreements with US, Canada and other countries.

The Board also looked at the identification and management of regulatory costs at the pre-application, evaluation and post-authorisation phases. In particular it was recognised that the current fee reform debate forms part of a much wider debate on the resources and costs of the overall European authorisation system.

The Board noted the preparations for the Workshop on Transparency and Access to Documents of the EMEA to be held on 30 October 1997.

The next meeting of the Management Board will be held on 3 December 1997.

-- ENDS --

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>