European Medicines Agency
Press office

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Press release

EMEA Management Board considers the Agency's road map to 2010 and approves transparency proposal for orphan drugs

The EMEA Management Board held its forty-third meeting on 10 June 2004, under the chairman Prof. Hannes Wahlroos.

The Board considered the 'EMEA Road Map to 2010', a document outlining the Agency's strategy to further develop as one of the leading regulatory authorities that is public health oriented, science driven and transparent in the way it operates. Focusing on how to improve transparency, communication and information to patients in its discussion the Board welcomed the Agency's initiative for a European communications strategy that focuses on the information needs of patients, healthcare professionals and the public in general. A public consultation exercise on the Road Map was launched in April 2004 and comments are welcomed by 30 June 2004.

The Agency put forward 23 recommendations in October 2003 to promote transparency and communication, including the provision of information on applications for new medicines for the treatment of rare diseases ('orphan drugs'). Following consultation with interested parties, the Management Board approved a proposal to publish the name of the active substance (INN) together with the orphan condition and the name of the sponsor for all designated orphan drugs submitted for marketing authorisation.

As part of its corporate governance role, the Management Board adopted a new financial regulation and implementing rules for the EMEA. These bring the EMEA rules in line with those of other EU bodies. One important change in the rules will help the long-term financial stability of the EMEA, which will now for the first time be entitled to establish a financial reserve in years when there is a surplus of fee revenue.

The Board also revised the fee implementing rules. The new rules, which come into force on 11 June 2004, now include fees for certification of plasma master files and also changes that reduce the fee burden for companies involved in parallel distribution of centrally authorised medicines.

The next meeting of the Management Board is on 30 September 2004.

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NOTES:

1. The discussion paper "The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future" was published on 15 April 2004 (press release available here http://www.emea.eu.int/pdfs/general/direct/pr/936204en.pdf). Comments should be sent to emearoadmap@emea.eu.int by the 30 June 2004 deadline.
2. 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

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