



The European Agency for the Evaluation of Medicinal Products
Directorate

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PRESS RELEASE

Thirty-fifth meeting of the Management Board

The EMEA Management Board met on 3 October 2002, chaired by Dr Keith Jones. Matters discussed included:

- The Management Board adopted a decision amending the 2002 budget. The reduction in the annual budget from € 70 547 000 to € 65 423 000 reflects a decrease in the number of applications received so far in 2002. Only 25 applications have been received by the end of September 2002 (2001=58), which appears to confirm a trend observed by other international regulators. The Board noted that the number of applications for authorisation of orphan medicines and also the number of post-authorisation applications for existing medicines were largely on target.
- As part of the Agency's ongoing process of improvements to transparency, the Management Board endorsed a number of proposals that seek to increase the provision of information by the EMEA. The Board noted that the revision of EU pharmaceutical legislation currently being looked at by the European Parliament and Council of Ministers contain a number of transparency-related proposals. It was agreed that EMEA initiatives at this time should focus on refining existing tools and on a number of new tools that do not require legislative change. Proposals include publication of information on safety and efficacy referrals made to the EMEA, publication of information on decisions taken after a medicine has been authorised, in particular where new indications are granted or where there are safety issues, and improvements to the European public assessment report (EPAR) to include, for example, details of divergent opinions within the scientific committees.

It is intended to issue a more detailed public consultation document towards the end of October, with the results of the consultation presented to the Management Board at its December 2002. The Board will consider the proposals in the context of the Agency's work programme for 2003 and the available resources.

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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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