European Medicines Agency
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Press release
Management Board prepares groundwork in anticipation of a busy 2006

Meeting for the final time this year, on 15 December, the Management Board of the European Medicines Agency (EMEA) focused on administrative and operational measures to support the Agency in what promises to be a challenging year ahead:

- **Adoption of the work programme for 2006**

Two-thousand-and-six will be the first full year of implementation of major new provisions in the EU pharmaceutical legislation, which entered into force on 20 November 2005. The Agency has tailored its priorities and objectives for the coming year accordingly, as detailed in its work programme 2006.

The work programme forecasts the receipt of 47 marketing-authorisation applications for new medicines next year — a marked increased over the 40 received in 2005. A number of applications are likely to result from new legal provisions giving the EMEA responsibility for evaluating generic and biosimilar medicines (8 applications expected), 'compassionate use' medicines, medicines for use outside the EU (in cooperation with the World Health Organization) and 'core dossier' applications for pandemic-influenza vaccines. The expected increase in applications also accounts for the fact that, in addition to biotechnology products, all new medicines for HIV/Aids, cancer, diabetes, neurodegenerative disorders and 'orphan' (rare) diseases must now be submitted through the centralised authorisation procedure.

Similarly, changes in the legislation should make using the centralised procedure more attractive to developers of veterinary medicines, especially for medicines for which there is a public or animal health interest in the Community, and those intended for limited markets or regional diseases. As a result, the Agency is expecting to receive 14 applications for new veterinary medicines and 12 applications for extension or modification of maximum residue limits of veterinary medicines.

- **Adoption of the budget for 2006**

The Management Board also adopted the 2006 budget, totalling €123,551,000 (2005: €111,835,000). The rise in expected applications is reflected in the increased forecast fee revenue of €83,580,000 (2005: €77,455,000). The EU general contribution will also rise, to €22 million (2005: €17,900,000), taking into account, in particular, the added costs for implementation of the new pharmaceutical legislation.

The special EU contribution for orphan drugs has been reduced from €5 million to €4 million for 2006, whereas the special EU contribution for telematics will increase from €7.5 million to €8 million.

The maximum permitted number of Agency staff will increase from 379 to 424. The Board approved this increase primarily to allow for new staff to work in areas relating to the implementation of obligations under the new legislation, to pharmacovigilance and to the safety of medicines.

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- **Adoption of strengthened rules on handling of conflicts of interests**

Following discussions at its May and September 2005 meetings, the Management Board adopted further changes to the way the Agency handles conflicts of interests of committee members and experts. While no such conflicts of interests have arisen, it has been decided to strengthen the Agency's policy on this issue by extending from 3 years to 5 years the declarable timeframe for an expert or committee member's involvement as an employee in the pharmaceutical industry or as a consultant or investigator, or other involvement, in the development of a medicinal product (or of a competitor product) under review by the EMEA.

In accordance with the Agency's founding legislation, the EMEA rules continue to exclude experts who have direct interests in the pharmaceutical industry.

- **Endorsement of framework on interaction with stakeholders**

The Management Board endorsed a framework for developing relations with the Agency's various stakeholders, focusing in particular on patients', consumers' and healthcare professionals' organisations and on the provision of information about medicines to the public. This framework complements the post-G10 initiatives being put in place by the European Commission, and focuses specifically on the Agency's implementation of new obligations under the pharmaceutical legislation.

Specific actions for the first phase of the framework include developing the interaction of the Agency's scientific committees, rapporteurs and working parties with patients' and consumers' organisations, with the active participation of the EMEA Working Group with Patients' and Consumers' Organisations and other stakeholders in developing this action.

- **Introduction of revised implementing rules on fees**

Following the adoption by the Council of the European Union of a new regulation on fees payable to the EMEA, the Management Board has introduced revised implementing rules providing, in particular, for graduations in the fee levels payable for generic and biosimilar medicines, and for other new types of applications, including for compassionate use and for medicines intended for use only outside of the EU. The revised rules on fees have been published on the EMEA website and entered into force on 15 December 2005.

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NOTES:

1. The next meeting of the Management Board is on 9 March 2006.
2. The document 'Rules for the implementation of Regulation (EC) No 297/95 as amended on fees payable to the European Medicines Agency and other measures' (EMEA/MB/356866/2005) is available here.
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the EMEA website: http://www.emea.eu.int

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