European Medicines Agency
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Press release

European Medicines Agency Management Board holds its 50th meeting: Annual report 2005 shows a reduction in applications for new medicines but suggests increases in the years to come

The European Medicines Agency Management Board adopted the Agency's annual report for 2005 at its 50th meeting, on 9 March 2006. The report shows that fewer initial marketing authorisation applications for new medicines for human use were received in 2005 than expected. Whereas 52 were forecast, 43 were actually received (2004: 51, 2003: 39). The number of applications for authorisation of designated orphan medicines, however, remained strong, with 15 applications received.

Forecast figures indicate an upward trend for 2006 and 2007, with 62 and 79 initial marketing authorisation applications expected respectively, including applications for similar biological and generic medicinal products.

The 2005 annual report also shows that there was an increase in the number of applications for orphan designation, at 118 (2004: 108, 2003: 87), and that requests for scientific advice and protocol assistance for new human medicines were up by almost 60% compared to levels in 2004 (2005: 194, 2004: 122).

A similar increase in scientific advice requests was seen for veterinary medicines, with twice as many received in 2005 as in 2004 (2005: 10, 2004: 5). The number of marketing authorisation applications for veterinary medicines was in line with the forecast (2005: 11; 2004: 8). A positive trend is forecast in the coming years for veterinary medicines, with 14 and 16 applications expected for 2006 and 2007 respectively.

Draft work programme and budget for 2007

The Management Board also adopted the draft work programme for 2007, as well as a preliminary draft budget for 2007 that, once approved by the European Parliament and Council later in 2006, would see the Agency's total budget rise to € 144.1 million (2006: € 123.6 million, 2005: € 111.8 million). This increase reflects the forecast increase in number of applications and new workload in 2007, with total fee revenue expected to reach € 91.8 million (2006: € 83.6 million, 2005: € 77.5 million). The Board approved requests for 17 new staff members in 2007, which would take the maximum staff complement to 441.

EMEA priorities for 2007, as outlined in the draft work programme, follow the Agency's long-term strategy and build on priorities set in previous years. Priorities for 2007 include:

- Improving the safety of medicines for human and veterinary use.
- Establishing the new Paediatric Committee, which will provide opinions on Paediatric Investigation Plans, plus coordinating a paediatric research network and providing information on paediatric clinical trials, as part of the Agency's implementation of the upcoming legislation on medicines for children.
- Contributing towards the stimulation of research and development in Europe to allow for better access to new and innovative medicines.
- Increasing openness and transparency of the Agency's operations, and providing high-quality and timely information on medicines to patients and healthcare professionals.
- Increasing international cooperation and interaction with non-EU countries.

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NOTES:

1. The annual report for 2005 will be published shortly on the EMEA website.
2. The next meeting of the Management Board is on 8 June 2006.
3. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: www.emea.eu.int

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