European Medicines Agency
*Press office*

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# Press release
# European Medicines Agency annual report for 2006 shows record numbers of applications; assessment times in core processes significantly reduced

The European Medicines Agency reviewed more new medicines in 2006 than in any previous year, as detailed in the Agency's 2006 annual report, adopted by the Management Board on 8 March 2007.

In 2006, the Agency received record numbers of initial marketing-authorisation applications, post-authorisation-variation applications and requests for scientific advice. While the volume of applications increased, the Agency was able to achieve a substantial reduction in assessment times for initial evaluation, orphan designation and scientific advice, thereby helping to speed up the availability of new and innovative medicines for patients.

EMEA Executive Director Thomas Lönngren said: "I am very pleased by our performance in 2006, which was one of the busiest years ever, and the first full year in which we operated under the terms of the revised pharmaceutical legislation. The fact that we managed record numbers of applications while speeding up assessment times demonstrates that we have successfully adapted to the new legal framework."

## Some highlights of the annual report 2006

- 78[1] applications for marketing authorisation for medicines for human use were received – 37 more than in 2005. This includes: 18 applications for orphan medicines; 3 for biosimilar medicines; 9 for generics. In addition, 1 application was made for a scientific opinion on a medicinal product intended to be used outside the European Union.
- 51 positive opinions for initial marketing authorisation for medicines for human use were adopted – the highest number ever.
- 257 scientific-advice and protocol-assistance requests relating to the development of medicines for human use were received – 25% more than in 2005.
- 104 orphan designation applications were received – the third year in a row that over a hundred were received.
- 8 applications for marketing authorisation for medicines for veterinary use were received.
- 13 positive opinions for initial marketing authorisation for medicines for veterinary use were adopted.
- 14 scientific-advice requests relating to the development of veterinary medicines were received – 40% more than in 2005.

## Outlook to 2008

The Management Board also adopted the Agency's draft work programme for 2008. With a preliminary draft budget for 2008 of €164.5 million (2007: €154.5 million, 2006: €138.7 million), the Agency will focus on improving the safety and availability of medicines, stimulating research and development, strengthening the European medicines network, improving transparency and provision of information, and increasing the Agency's international role, in particular its cooperation with its non-EU partners.

[1] Number of applications has been corrected.

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NOTES:

1. The annual report for 2006 can be found on the EMEA website here.
2. The next meeting of the Management Board is on 7 June 2007.
3. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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