European Medicines Agency
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PRESS RELEASE
EMEA reports strong performance in regulatory and public-health activities in 2007; the outlook for 2008 is even higher application numbers and a focus on advanced-therapy medicines

Application numbers for initial marketing authorisations, post-authorisation variations and requests for scientific advice relating to medicines for human use were all higher in 2007 than in any previous year, according to the EMEA annual report 2007 adopted by the Agency's Management Board on 6 March 2008. A greater number of positive opinions were adopted too, contributing to the increased availability of new and innovative medicines for patients in Europe. Despite the high volume of applications, all were evaluated within the regulatory timelines.

A major public-health initiative highlighted in the annual report was the launch of the EMEA's Paediatric Committee, in July 2007. The Agency, in conjunction with national competent authorities, created this, its fifth scientific committee, as part of its implementation of the new European Union legislation on paediatric medicines, which entered into force in January 2007. With its new responsibilities for assessing and approving development plans for medicines intended for use in children, the EMEA now plays a central role in EU-wide efforts to deliver better medicines for children.

Considerable efforts were made in 2007 to strengthen the proactive approach to safety of medicines. Major progress on establishing an intensive drug-monitoring system was achieved through the delivery of the EudraVigilance Datawarehouse and Analysis System, which supports signal-detection and the assessment of adverse drug reaction reports, and the identification of centres across the EU as the first phase in the launch of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

EMEA activities in 2007 in the areas of supporting innovation and improving availability of medicines also yielded positive results, notably through the Agency's dedicated support to small and medium-sized enterprises, its high output in relation to medicines for rare diseases, the continuing work of its Innovation Task Force and Think-tank on Innovative Drug Development, and its engagement in wider EU and international initiatives in these areas.

The EMEA made good progress on developing its interaction with patients' and consumers' organisations and on increasing their involvement at different levels of the Agency's work, such as the review of summaries of European public assessment reports (EPAR) and package leaflets.

Summarising the Agency's activities in 2007, Executive Director Thomas Lönngren said, "the EMEA delivered a strong performance in its core activity areas relating to the evaluation and supervision of medicines, while also pursuing with good results its broader mandate to stimulate innovation within the EU and contribute to European and global cooperation on scientific and regulatory development in the field of medicines."

Highlights of the annual report 2007

- 90 applications for marketing authorisations for medicines for human use were received – 12 more than in 2006 – including 11 applications for orphan medicines, 10 for generics and 10 for similar biological medicines. In addition, 1 application was made for a scientific opinion on a medicinal

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product intended for use outside the European Union, as part of EU efforts to support developing countries.

- 65 opinions on initial marketing authorisations for medicines for human use were adopted – 14 more than in 2006. Cancer medicines were the most-represented therapeutic category, followed by anti-infectives and alimentary-tract medicines.
- 281 scientific-advice requests relating to the development of medicines for human use were received – 22 more than in 2006.
- 125 orphan-designation applications were received – 21 more than in 2006, and the fourth year in a row that applications for medicines for rare diseases numbered over a hundred.
- 10 opinions were adopted by the Paediatric Committee: 2 on paediatric investigation plans and 8 on full waivers in all subsets of the paediatric population.
- 15 applications for marketing authorisations for medicines for veterinary use were received.
- 9 positive opinions on initial marketing authorisations for medicines for veterinary use were adopted.
- 2 positive opinions on initial marketing authorisations for vaccines against avian influenza in poultry were adopted, following an accelerated evaluation procedure.

Further intensification of activity and focus on advanced therapies expected

The volume of activity in 2008 is expected to surpass the reported figures for 2007, according to the EMEA work programme for this year. The Agency forecasts a 12% increase in the number of initial applications for marketing authorisations for human medicines – up to 102 applications. Strong growth is also forecast in the number of requests for scientific advice for human medicines, with more than 360 requests expected. Initial marketing-authorisation applications for veterinary medicines are expected to remain at the same level.

Changes in the scientific and regulatory environment stemming from the further implementation of the new pharmaceutical legislation will shape the EMEA's priorities for 2008. The Agency will focus its efforts on implementing the new regulation on advanced-therapy medicines, which will apply in the EU from 30 December 2008. The legislation requires the creation of a sixth scientific committee within the Agency – the Committee for Advanced Therapies – and the operation of new procedures for the assessment of advanced-therapy medicines. In addition, the globalisation of the regulatory environment will lead the Agency to intensify and extend its international role within the context of interaction with international organisations and cooperation with Canadian, Japanese and US authorities.

In the European framework, the EMEA will continue to support EU-wide efforts to facilitate research and innovation, mainly through participation in the work of the Innovative Medicines Initiative, for human medicines, and the European Technology Platform for Global Animal Health, for veterinary medicines.

Efforts to reinforce a proactive approach to the monitoring of the safety of medicines will remain high on the Agency's agenda, including initiatives to be undertaken in the context of the European Risk Management Strategy (notably the ENCePP project), the further development of EudraVigilance databases, and the improvement of the concept of risk-management plans for human medicines.

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Notes:

1. The full EMEA annual report 2007 will be available shortly on the EMEA website here. A public-friendly summary will be published at a later date.
2. The EMEA work programme 2008 is available on the EMEA website here.
3. More information about the Paediatric Committee is available in the 'Medicines for children' section of the EMEA website: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm

4. More information about advanced-therapy medicines is available in the 'Medicines and emerging science' section of the EMEA website: http://www.emea.europa.eu/htms/human/mes/advancedtherapies.htm
5. The next meeting of the Management Board will be on 12 June 2008.
6. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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