European Medicines Agency
Press office

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PRESS RELEASE
EMEA Management Board adopts work programme for a busy year ahead and agrees to move towards greater transparency of its meetings

Preparing for a busy year ahead, the European Medicines Agency's Management Board adopted the Agency's work programme and draft budget for 2009 at its meeting on 11 December 2008.

One of the highlights in 2009 will be the implementation of the Agency's new responsibilities in relation to advanced-therapy medicines, including the inauguration of the new Committee for Advanced Therapies (CAT) on 15 January 2009. Provisions are being made in the 2009 budget so that the activities in this area will be supported by adequate resources.

Other priority areas for the Agency in 2009 include: the provision of scientific advice in the area of innovative development methods; further strengthening of the Agency's pharmacovigilance activities in relation to the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), risk management plans and signal detection; transparency and provision of information.

The draft budget for 2009 totals €188,689,000, an increase of 3.11% over the 2008 budget. Most core activity areas are expected to grow, most notably scientific advice, work with medicines for paediatric use, information and transparency, and cooperation with the Agency's international partners. The level of initial marketing authorisation applications for medicines for both human and veterinary use made to the Agency is expected to remain stable (112 applications for initial marketing authorisation for medicines for human use and 17 applications for initial marketing authorisation for medicines for veterinary use are expected).

EMEA Management Board meeting documents to be made public

The EMEA Management Board decided unanimously to publish its meeting documents, including agendas and minutes. From March 2009 onwards, all non-confidential Management Board documents will be accessible to the public in a dedicated area on the EMEA website. This step towards greater transparency underlines the Board's continuous commitment to improving the Agency's transparency.

The new Management Board initiative marks the first of a number of initiatives planned over the next two years to further open up the Agency to the public. A proposal to grant public access to EudraVigilance, the EU database on adverse drug reactions, will be presented for public consultation before the end of 2008. Another initiative currently under way is related to access of the public to information about paediatric clinical trials held in EudraCT, the EU database on clinical trials. To bring all of these initiatives together, the Agency has launched a major review of its current transparency provisions, which is expected to result in the development of an EMEA transparency policy for discussion with stakeholders.

In addition to these initiatives, the Agency has started to look at the way it provides information about medicines. A project has now been started to re-design the EMEA website. The results of this are expected to be visible by the end of 2009.

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NOTES:
1. The work programme 2009 will be published shortly on the EMEA website.
2. 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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