European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency 2009 mid-year report shows it is still on target, despite influenza pandemic activities

The European Medicines Agency is performing on target despite the increase of activities relating to the influenza pandemic. This was the message given by the Agency's Executive Director, Thomas Lönngren, when he presented the mid-year report to the Management Board at its meeting on 1 October 2009.

The mid-year report includes a number of highlights, such as a higher than expected number of generic applications (31 in the first half of year, compared to a forecast of 20 for the year as a whole) and the successful establishment of the new Committee on Advanced Therapies, which was able to adopt its first opinions within a few months of its creation. The Agency has also implemented a set of measures enabling it to grant incentives for veterinary medicinal products indicated for minor use minor species (MUMS) limited markets.

The Board also noted some deviations from the 2009 work programme, including the increase in the number of applications for designation of orphan medicinal products (80 applications received compared to 54 in the same period in 2008), the number and complexity of referrals in the veterinary field and the current output of the Committee on Herbal Medicinal Products, apparently due to the difficulties experienced by the Member States in allocating scientific resources to work in the field of traditional medicinal products.

The Board took the opportunity to recognise the Agency's staff, committee members and the many European experts for their efforts and cooperation in responding to the influenza pandemic and the review of vaccines.

Other issues addressed by the Board included the adoption of revised implementing rules for fees payable to the Agency, including fees for consultation on line extensions for ancillary substances, including blood derivates, incorporated in medical devices, and the implementation of the new regulation on maximum residue limits. A further revision is expected in December 2009 as part of the implementation of new legislation on variations.

Given the increasing importance of telematics systems in the European medicines systems, for example EudraVigilance, and the role of the Agency in coordinating the systems, the Board agreed to take over responsibility for the Telematics Steering Committee. Previously chaired by the European Commission, the committee's chair will be appointed by the Management Board and be composed of representatives of the Board (including patient representatives), the Heads of Medicines Agencies, the European Commission and of the Agency.

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Notes:

1. The Agency's mid-year report for 2009, together with other meeting documents, is available on the Management Board website here.
2. The next meeting of the Management Board is on 10 December 2009.
3. 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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