European Medicines Agency
Press office

London, 8 October 2008
Doc. Ref. EMEA/MB/521956/2008

PRESS RELEASE
EMEA half-year report for 2008 shows activities to be on target, with a marked increase in the provision of scientific advice

At its 60th meeting, held in London on 2 October 2008, the Management Board of the European Medicines Agency (EMEA) welcomed the half-year report for 2008 presented to them by EMEA Executive Director Thomas Lönngren. The report shows good performance by the Agency in the first six months of the year, with the provision of scientific advice and protocol assistance being one area where activity was particularly high.

One hundred and seventy-nine requests for scientific advice and protocol assistance were received in the first half of 2008 – a 28% increase on the number received during the same period in 2007 – with a further 186 applications expected to be received by the end of the year. The provision of this advice in support of pharmaceutical companies' research and development of medicines is a key activity area for the EMEA – one which fosters research and innovation in the pharmaceuticals sector and therefore promotes the earlier availability of medicines for the treatment of patients.

Numbers of applications for the initial evaluation of medicinal products remained at a similar level to what was recorded during the first half of 2007, with six being received for orphan medicines (medicines for rare diseases) and 26 for non-orphan medicines.

The report to the Management Board indicated that the performance of the Agency in other areas of activity, relating to both human and veterinary medicines, was, on the whole, on target. The Board noted the important contribution made by the Agency – working closely with the European Commission, the Member States of the European Union (EU) and other EU bodies – to the successful operation of regulatory procedures for paediatric medicines and the implementation of the new legislation on advanced-therapy medicines. In the paediatrics area, the Agency's workload continued to be high, following the first year of activity of its Paediatric Committee, with a total of 227 applications for review of paediatric investigation plans (PIPs) and waiver requests being received in the first half of 2008.

The EMEA's role in protecting and promoting animal health was also reflected in the half-year report. Notably, the Agency's Committee for Medicinal Products for Veterinary Use (CVMP) received five applications for 'authorisation under exceptional circumstances'. These applications concerned inactivated vaccines against Bluetongue – a midge-borne viral disease that affects ruminant animals such as sheep and cattle –, and were processed in accordance with the EMEA's accelerated procedure in order to help combat the dramatic increase in new cases of the disease seen in farms across the EU since summer/autumn 2006.

EU telematics master plan
The Management Board also endorsed an updated EU telematics master plan, covering the period 2008-2013. The plan sets the vision and schedule for implementation of a set of pan-European IT systems and databases used to support the post-authorisation monitoring of the risk-benefit balance of medicines in the EU, increased efficiency across the European medicines regulatory network, and increased transparency and availability of high-quality information on medicines for the public.

-- ENDS --

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: info@emea.europa.eu http://www.emea.europa.eu

Notes:

1. EMEA half-year reports are internal documents presented by the Executive Director to the Management Board. A public report on EMEA activities for the whole year is published each year in spring.
2. The EU telematics master plan was adopted by the Management Board in October 2007.
3. EU telematics websites (some of which have restricted access) can be accessed via the homepage of the EMEA website: www.emea.europa.eu
4. The next meeting of the Management Board will be on 11 December 2008.
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu