European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency sees strong level of applications in 2007

The number of applications for marketing authorisations submitted to the European Medicines Agency (EMEA) remains strong according to the half-year report presented to the Agency's Management Board by Thomas Lönngren, EMEA Executive Director, at its 4 October 2007 meeting.

The Agency has received a total of 42 applications by mid-2007, with a further 52 forecast by the end of the year. This follows the record number of applications made to the Agency in 2006. One area of growth is applications for biosimilar medicines, with 8 applications made in the first half of 2007 and a further 8 expected by the end of the year.

Reviewing the Agency's implementation of the 2007 work programme, the Board highlighted two major achievements from the first half year. One is the Agency's progress on implementing the new Paediatric Regulation, including the successful establishment of the Paediatric Committee (PDCO). The other is the roll-out of a new data analysis system for EudraVigilance, the European pharmacovigilance data-processing network management system, to all competent authorities in the EU Member States, which has significantly improved the systems capabilities to monitor the safety of medicines.

The Management Board also adopted the EU telematics master plan that aims to provide a coherent development strategy for 2007-2013 for EU telematics – the set of pan-European IT systems and databases used for the collection and dissemination of information on medicines in the European Union.

The second status report on the implementation of the EMEA road map to 2010 was presented to the Management Board and will be published on the EMEA website. The report highlights progress made in 2006 and the first half of 2007 in areas that include improving safety of medicines; stimulating research and innovation in partnership with European institutions; improving availability to medicines; strengthening the provision of information and interaction with Agency stakeholders; reinforcing international collaboration; and strengthening the European Union regulatory system for medicines. Stepping up the implementation, a new action plan is currently under preparation, which will set out the initiatives to be undertaken in 2008 and 2009.

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Notes:

1. The 'Paediatric Regulation', Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, is available here.
2. The second status report on implementation of the EMEA Road Map will be published on the EMEA website soon. The first status report, covering implementation up to the end of 2005, is available here.
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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