European Medicines Agency
Press office

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PRESS RELEASE
EMEA prepares for entry into force of new legislation on paediatric medicines

A new European regulation on paediatric medicines will be entering into force on 26 January 2007, the implementation of which is a main priority for the European Medicines Agency (EMEA) in its work programme for 2007. The Paediatric Regulation aims to improve the health of Europe's children by:

- stimulating research and development of medicines for use in children;
- ensuring that medicines used to treat children are appropriately tested and authorised;
- improving the availability of information on the use of medicines in children.

At the core of this new piece of legislation is the establishment of a new committee of scientific experts within the EMEA – the Paediatric Committee – which will be operational within six months of the date of entry into force of the legislation. The Paediatric Committee's primary responsibilities will be the assessment and agreement of:

- paediatric investigation plans (which set out measures for studying the medicinal product concerned in the paediatric population);
- waivers (granted in certain circumstances where paediatric studies are not required or desirable);
- deferrals (granted in certain circumstances where the initiation or completion of paediatric studies should be deferred until appropriate studies in adults have been performed).

The Paediatric Committee will also work with the EU Member States – building on work already performed by the EMEA's Paediatric Working Party (PEG) – to establish an inventory of the therapeutic needs of children, so that focus can be placed on the research, development and authorisation of medicines in areas where there are unmet medical needs. Paediatric Committee experts will also be advising the EMEA on its development of a European network for clinical trials in children, to be based on existing networks.

An internal action plan for implementing the Paediatric Regulation is currently underway within the EMEA. As part of this, the EMEA and European Commission published (in September 2006) a joint document on their priorities for the implementation. The Agency has also published an FAQ (frequently asked questions) document intended to help companies during the run-up to the entry into force of the new legislation.

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Notes:

1. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use was published in the Official Journal on 27 December 2006. The Regulation will enter into force on 26 January 2007 and can be found here.
2. Amending Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 can be found here.
3. The 'Joint European Commission/EMEA Document: Priorities for Implementation of the Regulation on Medicinal Products for Paediatric Use' can be found here.

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4. The document ‘Frequently asked questions on regulatory aspects of Regulation (EC) No 1901/2006 (Paediatric Regulation) amended by Regulation (EC) No 1902/2006’ is available here.
5. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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