European Medicines Agency
Press office

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PRESS RELEASE
New Paediatric Committee holds its first meeting

The European Medicines Agency's (EMEA) new Paediatric Committee (PDCO) held its first meeting on 4 and 5 July 2007 at the EMEA in London. The establishment of the fifth scientific committee within the EMEA is part of the implementation of the new Paediatric Regulation, which came into force in January 2007. The PDCO's main responsibility will be to provide opinions on the development of medicines for use in children.

The PDCO brings to the Agency the best scientific expertise available in the European Union in areas relating to paediatric medicinal products, such as pharmaceutical development, paediatric medicine, general practice, paediatric pharmacy, paediatric pharmacology, paediatric research, pharmacovigilance, ethics and public health. In its full composition the PDCO will include:

- five members of the Committee for Medicinal Products for Human Use (CHMP) with their alternates, appointed by the CHMP itself;
- one member and one alternate appointed by each Member State (except Member States already represented through the members appointed by the CHMP);
- three members and alternates representing healthcare professionals' associations;
- three members and alternates representing patients' associations.

The members representing healthcare professionals' and patients' associations have not yet joined the PDCO but will be appointed by the European Commission, after consultation with the European Parliament. A public call for expressions of interest is currently ongoing.

The members of the PDCO are appointed for a renewable period of three years. Daniel Brasseur, former chair of the Paediatric Working Party, was made acting chair, pending the election of a chair by the PDCO at its September 2007 meeting.

The first meeting of the PDCO was devoted to preparing the groundwork for the Committee's future activities, and included discussion of the following topics:

- scientific and procedural aspects for the assessment of paediatric investigation plans (PIPs);
- the EMEA implementation strategy for an EU-wide paediatric-research network;
- a recommendation to the European Commission on the selection of a symbol for medicines with a paediatric indication;
- criteria for a survey of existing uses of medicinal products in the paediatric population in the EU;
- funding of studies into off-patent medicines provided by the EU's Seventh Framework Programme (FP7).

The next meeting of the PDCO will be held at the EMEA on 1-3 August 2007.

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Notes:

1. Regulation (EC) No 1901/2006 on medicinal products for paediatric use can be found here.
2. More information about paediatric medicines and all relevant documents can be found in the 'Medicines for children' sections of the EMEA website: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm and the European Commission website: http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/index.htm.
3. Overview information about the Paediatric Committee, including its membership, is available here.
4. More information about the European Commission's call for expressions of interest for healthcare professionals' and patients' associations is available here.
5. The 2007 meeting dates of the Paediatric Committee are available here.
6. The Paediatric Committee is not responsible for marketing-authorisation applications for medicinal products for paediatric use. This remains the responsibility of the EMEA's Committee for Medicinal Products for Human Use (CHMP). However, the CHMP may request the PDCO to prepare an opinion on the quality, safety and efficacy of a medicinal product for use in the paediatric population if the relevant data have been generated in accordance with an agreed paediatric investigation plan.
7. 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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