European Medicines Agency
Press office

London, 6 August 2007
Doc. Ref. EMEA/354317/2007

PRESS RELEASE
Meeting highlights from the Paediatric Committee,
1-2 August 2007

The European Medicines Agency's (EMEA) new Paediatric Committee (PDCO) held its second meeting on 1-2 August 2007 at the EMEA. Continuing the preparation of the framework for its activities, the PDCO adopted its rules of procedure, which are now being sent to the Agency's Management Board.

The PDCO's rules of procedure provide details of the Paediatric Committee's responsibilities and tasks as defined in the Paediatric Regulation [(EC) No 1901/2006 as amended].

The PDCO further discussed organisational matters in relation to the process for assessing Paediatric Investigation Plan (PIP) applications and/or request for waivers, as well as a number of scientific aspects related to its responsibilities, including:

- a list of waivers for conditions not affecting the paediatric population;
- a draft guideline on the investigation of medicines in neonates, prepared by the Paediatric Working Party (PEG), the EMEA's former temporary expert working party on paediatric medicines;
- the list of paediatric needs, particularly the newly published assessment of paediatric needs related to psychiatry, as well as a future list related to gastroenterology;
- the survey of existing uses of medicinal products in the paediatric population;
- the draft implementing strategy of the EU Paediatric network, which is published on the EMEA website for public consultation until 20 August 2007.

The PDCO members were informed about the 'Principles of Interaction between the EMEA and FDA Pediatric Therapeutics' in order to set up the rules for the future exchange of information.

The PDCO's second meeting also marked the start of the assessment of the first applications for PIPs and/or request for waiver. For each application, a rapporteur and peer reviewer(s) are appointed by the Paediatric Committee, taking into account areas of expertise and distribution of workload.
Adoption of the first scientific opinions on PIPs or requests for modification of the proposed PIP is expected for 26-28 September 2007.

The next meeting of the PDCO will be held on 29-31 August 2007.

-- ENDS --

Notes:
1. More information about the PDCO's role and composition is available here http://www.emea.europa.eu/htms/general/contacts/PDCO/PDCO.html
2. The EMEA's 'Medicines for children' website can be consulted here http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm
3. The rules of procedure of the PDCO will be published once the EMEA Management Board and the European Commission have given their opinion.
4. The list of paediatric needs can be found here: http://www.emea.europa.eu/htms/human/paediatrics/inventory.htm
5. The 'Principles of Interactions: Between EMEA and FDA Pediatric Therapeutics' can be found here: http://www.emea.europa.eu/pdfs/general/direct/pr/interactions.pdf

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: mail@emea.europa.eu http://www.emea.europa.eu

6. The ‘Network of Paediatric Networks at the EMEA Draft Implementing Strategy’ is available here: http://www.emea.europa.eu/pdfs/human/paediatrics/29559407en.pdf
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

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