European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 26-28 September 2007

The European Medicines Agency's (EMEA) Paediatric Committee (PDCO) held its fourth meeting on 26-28 September at the EMEA. Following the election of its first chair, Dr Daniel Brasseur, from Belgium, and vice-chair, Prof. Gérard Pons, from France, the PDCO continued the discussion of the ongoing assessment of paediatric investigation plans (PIPs) and waivers. In addition, the PDCO continued to refine the procedural aspects for the operation of the Committee.

Assessment procedure for PIPs and waivers
Following the receipt of a letter of intent for the submission of a PIP or a request for waiver, the PDCO appoints a rapporteur and a peer reviewer for each dossier to carry out the assessment. Once the application has been validated, a first scientific discussion is held at day 30 of the procedure. A second scientific discussion takes place at day 60. At this stage, according to the regulation on paediatric medicines[1], the PDCO can either adopt an opinion on the PIP or request for waiver, or it can request the applicant to modify the proposal. In this case, the clock is stopped to give the applicant time to prepare the response and the modified PIP and/or waiver request. Once the responses have been received, the clock starts again and the PDCO gives its final opinion after another 60 days.

So far the PDCO has received applications corresponding to 105 requests for PIPs or waivers for medicinal products in various indications. The PIPs or waivers currently under assessment by the PDCO relate to indications in the areas of oncology, ophthalmology, infectious diseases, endocrinology, immunology, neurology, cardiovascular diseases and pneumology.

The next meeting of the PDCO will be held on 24-26 October 2007.

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Notes:
1. A separate press release with the information on the election of the first chair and vice-chair of the PDCO can be found here.
2. The EMEA's 'Medicines for children' web pages can be consulted 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

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

[1] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.