European Medicines Agency
*Press office*

London, 25 October 2006
Doc. Ref. EMEA/416788/2006

**PRESS RELEASE**
**EMEA Workshop on Neonates: Development of medicines for neonates needs multi-disciplinary cooperation**

The development of safe and effective medicines for newborn babies requires stronger cooperation between researchers, developers and regulators. This was one of the main conclusions of a workshop, organised by the European Medicines Agency (EMEA) on 11 October 2006, which looked at scientific issues related to the investigation of medicinal products intended for the treatment of neonates.

Highlighting the Agency's commitment to stimulate multidisciplinary cooperation in the development of medicines for children, the workshop brought together some 70 experts from academia and learned societies, industry and regulatory authorities, and also healthcare professionals involved in looking after and treating newborn babies, including babies born prematurely.

The participants discussed the impact of organ immaturity and the rapid changes in the first days and weeks of life when investigating medicines for neonates. The outcome of the workshop - together with a series of concept papers on the impact of brain, liver, kidney, heart and lung immaturity prepared by the Agency's Paediatric Working Party (PEG)- will form the basis of a future EMEA guideline on this issue. Other aspects covered during the workshop included formulations appropriate for neonates, ethical aspects in relation to the conduct of clinical trials in newborn babies, novel study design methods and safety and pharmacovigilance aspects.

The EMEA neonates workshop was organised in the framework of the Agency's preparation for the entry into force of the new European legislation on medicines for children later in 2006. The new legislation will introduce incentives aimed at the stimulation of research, development and authorisation of medicines for children. It is expected that this will result in an increase of clinical trials in children, including neonates. The workshop provided a platform for a multidisciplinary scientific dialogue among European experts, to identify appropriate measures to encourage high-quality research into medicines for neonates, while also putting in place safeguards and precautions to protect this highly vulnerable patient population.

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Notes:

1. The proceedings of the conference will soon be made available on the EMEA website: www.emea.europa.eu
2. The Agency's Paediatric Working Party (PEG) has prepared four concept papers focusing on organ immaturity in neonates. The "Concept Paper on the Impact of Brain Immaturity when investigating medicinal products intended for Neonatal use" can be found here, the "Concept Paper on the Impact of Lung and heart Immaturity when investigating medicinal products intended for Neonatal use" can be found here and the "Concept Paper on the Impact of Liver Immaturity when investigating medicinal products intended for Neonatal use" can be found here. A "Discussion Paper on Renal Immaturity when Investigating Medicinal Products for Paediatric Use" has also been published and can be found here.
3. On 4 October 2006, the European Commission released a draft document on 'Ethical Considerations for Clinical Trials Performed in Children – Recommendations of the Ad Hoc Group for the

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development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use', which can be found here.

4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu.

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