



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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ANNOUNCEMENT

FIRST EMEA WORKSHOP ON EUROPEAN PAEDIATRIC NETWORK

**to be held at the EMEA
on Monday, 16 February 2009**

The EMEA will convene a one-day workshop on the European paediatric network. One of the objectives of the Paediatric Regulation (EC) No 1901/2006, as amended, is to foster high quality ethical research on medicinal products to be used in children. This should be achieved through efficient inter-network and stakeholder collaboration. To achieve this objective, the EMEA is tasked with developing a European paediatric network of existing national and European networks, investigators and centers with specific expertise in the performance of studies in the paediatric population.

This European paediatric network itself is not intended to perform trials, or to fund studies or research. One of the goals is to link together and co-ordinate existing networks and to establish a platform for communication and exchange of information between networks inside and outside the EU. (A detailed list of the short term and long term goals of the network can be found in and downloaded from “The Network of Paediatric Networks at the EMEA: Implementing Strategy” <http://www.emea.europa.eu/pdfs/human/paediatrics/54352307en.pdf>)

While there is no formal obligation for networks to participate in the European paediatric network, their active contribution is strongly encouraged for the benefit of the paediatric population. Advantages to joining the network include

- Be visible as a potential site for externally sponsored clinical trials
- Be consulted for expert opinion when paediatric investigation plans in their field of expertise are discussed and developed
- Share the skills and expertise of other national and European networks
- Shape and influence future development in paediatric research

The first step will be to establish a resource-saving structure for the operation of this network. It is proposed to create a ‘Coordinating Group’ which will contribute to the short and long-term strategy of the network, to discuss and solve operational and scientific issues for the network, and to report to the EMEA Paediatric Committee acting as the Scientific Committee of the network.

During the construction phase of the European paediatric network, participants invited by the EMEA will work together on an informal basis to define scientific and operational quality standards and recognition criteria for networks to be fulfilled. The EMEA secretariat will only act as facilitator but will not decide on recognition.

The draft agenda of the first workshop includes:

- Presentation of the EU Paediatric Regulation and the role of the Paediatric Committee
- Presentation of the objectives of the European paediatric network
- Discussion and definition of quality standards and recognition criteria
- Discussion of the proposed organisation and structure of the network

For detailed topics see draft agenda.

The workshop will be interactive. Participants in the workshop will be asked to express their expectations of the EMEA European paediatric network and to prepare suggestions for scientific and operational quality standards and recognition criteria as a basis for the discussion during the workshop.

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