21 December 2010
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Human Medicines Development and Evaluation

Third Workshop on European Network of Paediatric Research at the EMA (Enpr-EMA)

To be held at the European Medicines Agency on Thursday and Friday 10-11 March 2011

The European Medicines Agency (EMA) will convene a two-day workshop to introduce Enpr-EMA to a wider audience. One of the objectives of the Paediatric Regulation (EC) No 1901/2006, 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 meet this objective, a European paediatric network of existing networks, investigators and centres with specific expertise in performing medicines trials in the paediatric population is to be formed.

Following the publication of research quality requirements, a set of recognition criteria, which have to be fulfilled to become a member of Enpr-EMA were agreed. So far, 32 networks and centres submitted self-assessment reports indicating whether or not they fulfil the agreed minimum criteria.

Sixteen networks fulfilled all minimum criteria and became therefore members of Enpr-EMA. The other networks, which are not yet fulfilling all criteria, as well as networks interested in becoming members of Enpr-EMA are also invited to participate in this event.

The first day of the workshop will be dedicated to discussions between networks to establish the coordinating group of Enpr-EMA, and to discuss and to define priority tasks of the coordinating group.

The second day is being organised with the assistance of TOPRA (The Organisation for Professionals in Regulatory Affairs) where Enpr-EMA will be introduced to all stakeholders, particularly patient organisations and clinical researchers and pharmaceutical industry staff responsible for paediatric studies. The aim is to define the expectations of the various stakeholders and to offer the possibility for industry engaged in paediatric clinical trials and networks to interact. On this second day there will be an opportunity for Enpr-EMA, EMA staff, PDCO, and other stakeholders to work together in small workshops on proposals for the effective use of this Enpr-EMA network.

The meeting is intended for an audience of patients organisations and industry participants directly involved in paediatric trials.

The agenda and details for registration will be published soon. See http://www.topra.org/european-network-of-paediatric-research-workshop for details of the second day on 11 March 2011.

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