



EUROPEAN MEDICINES AGENCY
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Press Office

Press release

European paediatric research network ready to start

European Medicines Agency asks interested networks to start self-assessment process; operational structure agreed with networks

The European Medicines Agency today announced further progress in building a high-quality network of existing research networks, investigators and centres with recognised expertise in performing clinical studies in children.

Membership in the European Paediatric Research Network at the European Medicines Agency (EnprEMA) is open to networks that fulfil the requirements laid down in a set of recognition criteria, which have now been published following a public consultation process.

Networks interested in becoming a partner of EnprEMA have until the 31 of July 2010 to perform a self-assessment against the 6 recognition criteria. They will have to provide evidence of their research experience and their scientific competencies, their organisational structure and quality management processes, their training and education programme and the involvement of patients, parents and their organisations in their work. The results of these self-assessments will be made publicly available by the networks and the Agency.

Following a workshop, participants from 38 national research networks or clinical trials centres and the European Medicines Agency agreed an organisational structure for the European Network. The operational centre of EnprEMA is a 'Coordinating Group' responsible for the long- and short-term strategy of the network. The Group will be composed of a maximum of 20 members, representing as many types of networks as possible to take account of different therapeutic areas, age groups or specific activities such as pharmacovigilance.

The Coordinating Group has an ambitious catalogue of tasks to fulfil, including: to facilitate access of pharmaceutical industry to paediatric clinical study centres and experts; to identify new networks not presently included in EnprEMA; or to develop common educational tools for children and parents to increase their willingness to participate in clinical trials.

Agnès Saint-Raymond, responsible for medicines for children at the European Medicines Agency, said: "The agreement on the recognition criteria and the operational structure represents a milestone in getting this network off the ground. We have a clear idea now what expertise and experience we are



looking for in this network and how it is going to be run. What we have seen from working with the existing networks, investigators and clinical trials centres so far, has given us a lot of reasons to be confident that EnprEMA with its emphasis on inter-network and stakeholder collaboration will help fostering high-quality, ethical research of medicines in children."

The first meeting of the EnprEMA Coordinating Group is expected to take place in the second half of the year. Further updates and information on new developments will be provided by the European Medicines Agency.

Notes

1. A report on the outcomes of the second workshop of the European Paediatric Research Network, held on 16 March 2010 is available [here](#).
2. The recognition criteria for self assessment of the European Network of Paediatric Research at the European Medicines Agency are available [here](#).
3. More information about the European Medicines Agency's activities in relation to medicines for children can be found here: <http://www.ema.europa.eu/htms/human/paediatrics/introduction.htm>
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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