12 January 2016
EMA/421449/2011 Rev.1
Human Medicines Development and Evaluation

# Policy on transparency and the handling of potential conflicts of interests of members of the European network of paediatric research at the European Medicines Agency (Enpr-EMA) coordinating group and working groups

## 1. General considerations

One of the objectives of the Paediatric Regulation (EC) No 1901/2006, as amended, is to foster high quality ethical research on medicinal products for use in children by 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 has been established at the European Medicines Agency. The aim of the European network of paediatric research at the EMA (Enpr-EMA) is to coordinate studies relating to paediatric medicinal products, to build the necessary scientific and administrative competences at European level, to avoid duplication of studies and testing in children, to strengthen the foundations of the European Research Area and promote European Commission framework programme applications.

The benefits of Enpr-EMA include, but are not limited to strengthening complementary scientific, technical and/or administrative competences in the performance of paediatric clinical trials through effective collaboration. They also include the avoidance of duplication of work and effort, making the best use of existing research facilities, developing common methods of working with special attention to quality assurance and recruitment of patients.

The network itself is not intended to initiate and fund trials, or to decide on priority areas of paediatric research, which will remain the responsibilities of individual networks, Member States, and the Commission through its research and Community programmes.

## 2. Introduction and purpose

The activities of Enpr-EMA and all its members should be governed by principles of transparency as far as potential conflicts of interest are concerned. Whereas individuals directly involved in Agency's procedures relating to the development and evaluation of medicinal products are required to declare any conflicts of interest and withdraw from any discussions when such conflicts arise, the same

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requirements are not required for members of Enpr-EMA. However in the interests of transparency members' interests should be declared while securing the best (specialist) scientific expertise.

A conflict of interest could be seen to exist if Enpr-EMA members or their institutions have financial or personal relationships with individuals or organisations that could influence (bias) their actions. Financial relationships can be easily identified, whereas others including personal relationships, academic competition, or personal research interests can be less obvious. A conflict can be actual or potential, and full disclosure therefore is the safest course to ensure maximum transparency.

By applying the principles of transparency, robustness, and scientific independence, the policy aims to strengthen the confidence of the general public, researchers and regulators in the integrity and value of research into paediatric medicines in general and the working of Enpr-EMA in particular.

# 3. Scope and Definitions

The policy outlined here applies to the members of the Enpr-EMA coordinating group and working groups for activities defined in the mandate of the Enpr-EMA coordinating group and the Enpr-EMA working groups, respectively.

The policy complements the European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee members and experts. All activities relating to the development and evaluation of medicinal products relating to EMA procedures are covered by the general EMA policy.

# 4. Definitions

For direct and indirect interests, the definitions of the European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee members and experts shall apply.

# 5. Policy principles

## *5.1. Principles of the policy*

The coordinating group is tasked with the oversight of the network's activities in order to achieve the objectives of Enpr-EMA outlined in section 1.

The ad-hoc Enpr-EMA working groups are tasked with addressing the most important needs identified at the annual Enpr-EMA workshop by developing pragmatic responses that can be implemented within a reasonably short timeframe.

With Enpr-EMA as currently constituted and within its existing brief the declared interests of individual members would not be a bar to participation. The purpose of such declarations of interest is to maintain the credibility and reputation of Enpr-EMA and to ensure transparency.

It is comprised of two components; 1) the declaration of interests of the individual representing a network within the Enpr-EMA coordinating group or in a working group (mandatory); 2) the network's financial disclosure as to its funding source (voluntary).

### *5.2. Steps for the operation of the policy*

**Submission of a declaration of interests**

At the beginning of their mandate and once yearly, all members of the Coordinating Group and working groups shall submit their declaration of interests and curriculum vitae.

The names of the members of Enpr-EMA coordinating group will be published on the Agency's website; their declarations of interests will be kept in an EMA repository and made available on request.

Every network is encouraged to publish on the network's own individual webpages the completed and up-to-date network disclosure/funding source. They will not be published on the Enpr-EMA webpages. However, a list of networks that have disclosed the financial information will be made available to promote this good practice.

**Inclusion in the Agency's Expert Database**

Members of the Enpr-EMA coordinating group and/or working groups are not involved in activities at the level of the Agency as outlined in the European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts and are therefore not automatically included in the Agency's experts' database.

Only members of Enpr-EMA coordinating group and/or working groups who participate on other EMA activities such as scientific advisory bodies and ad-hoc expert groups shall be included in the Agency's experts' database

### *5.3. Revision of the policy*

The policy shall be reviewed after 3 years of operation or at an earlier stage if considered necessary.

## 6. Related documents

- Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended.
- Handling conflicts of interests.
- The Network of Paediatric Networks at the EMEA. Implementing Strategy.
- EMA Code of Conduct.
- Mandate of the Coordinating Group of the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA).
- Mandate for Enpr-EMA Working Groups.
- Enpr-EMA Networks funding source form.