European Medicines Agency

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The Network of Paediatric Networks at the EMEA Implementing Strategy

Table of Contents

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I Introduction

This document intends to fulfil the Agency's obligation to develop a European paediatric network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population. This obligation was created by Article 44 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended, hereafter the Paediatric Regulation.

II Background

1. Legal basis

The legal basis for the development of a European network is set out in the Paediatric Regulation in Recital 3 and Article 44.

Recital 3:
"Clinical trials in the paediatric population may require specific expertise, specific methodology and, in some cases, specific facilities and should be carried out by appropriately trained investigators. A network linking together existing national and European initiatives and study centres in order to build up the necessary competences at a European level, would help facilitating co-operation and avoiding duplication of studies. This network should contribute to the work of strengthening the foundations of the European Research Area in the context of Community Framework Programmes for Research, Technological Development and Demonstration Activities, benefit the paediatric population and provide a source of information and expertise for industry."

Article 44:
"1. The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.
2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid duplication of studies and testing in children.
3. Within one year of the entry into force of this Regulation, the Management Board of the Agency shall, on a proposal from the Executive Director and following consultation with the Commission, the Member States and interested parties, adopt an implementing strategy for the launching and operation of the European network. This network must, where appropriate, be compatible with the work of strengthening the foundations of the European Research Area in the context of the Community Framework Programmes for Research, Technological Development and Demonstration Activities."

Additionally, Article 6 includes a task for the Paediatric Committee:
The tasks of the Paediatric Committee shall include the following:
(f) to support and advise the Agency on establishing the European network referred to in Article 44.

2. Definition of a network

A network is a virtual structure defined by a formal agreement between individuals, organisations or structures sharing and collaborating towards the same objectives, goals and quality standards.

3. Basis for the current proposal

Following an initiative from a group of academics aware of the future Regulation, the Agency hosted in 2005 and 2006 a number of meetings with representatives of existing or developing paediatric networks with an interest in the development of medicinal products. The Agency strived to invite representatives of all existing networks to attend these meetings. Members participated on a voluntary basis and did not receive any compensation from the Agency. The discussions resulted in the identification of additional networks, and a proposal for a mandate and more detailed objectives for the future European Network. The proposed implementing strategy is largely based on the outcome of these discussions.

4. Existing paediatric networks

In parallel to the meetings held at the EMEA in 2005 and 2006, an informal inventory has identified that many different paediatric networks, investigators and centres with specific expertise*[1] exist in the Community, or are under construction. The relevant networks are those with an interest in the development of medicinal products. They can be identified as:

- national networks, generally benefiting from public funding (at present 7 national networks have been identified),
- European networks publicly funded, such as TEDDY (Task Force in Europe for Drug Development of the Young) which is funded through the 6th Framework Programme,
- paediatric 'sub-speciality' networks at European level and beyond, which group centres working in the same therapeutic area (e.g. HIV infection, rheumatology),
- age-related networks (e.g. neonatal networks),
- activity or structure-related networks (e.g. community-practitioners networks, hospital-based dedicated clinical-research centres linked by a common structure, pharmacovigilance networks)
- networks including paediatric centres but not dedicated solely to paediatric research.

The inventory will be expanded and developed.

5. Stakeholders of the future network

In addition to the members of the European network, the stakeholders or interested parties include:

- Patients, parents and families, organisations representing children, patients' organisations
- Paediatric and other relevant learned societies
- Academia (EU and international), including cooperative research groups, methodologists and other relevant groups
- Government-funded research institutions (including outside EU)
- Research funding bodies (e.g. European Commission DG Research, Technology and Development)
- National Competent Authorities (for authorisation of trials or medicines authorisation, GCP and GMP compliance evaluation)
- Paediatric health care providers
- Government-funded health services and National Health Systems
- Ethics Committees (and Investigational Review Boards)
- Pharmaceutical industry
- Medical devices industry
- Clinical Research Organisations
- Hospital pharmacists
- Laboratories and imaging centres

6. Consultation process

The legislation provides for consultation on the implementing strategy with the Commission, the Member States and interested parties. In order to meet the requirements and timelines of the Paediatric Regulation, the following consultation process was undertaken:

1. Consultation of existing networks (since 2005)
2. Consultation of Member States and the public, in particular patients via patients' organisations, and industry via trade organisations, and the European Parliament (1st July – 20th August 2007)
3. Consultation of the Paediatric Committee at the EMEA (1st – 2nd meeting)
4. Consultation of the Commission (September 2007)
5. Submission to the Pharmaceutical Committee (September 2007)
6. Submission to the Management Board (4th October 2007)

* For the purpose of this document and to avoid repetition, 'paediatric networks' means existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population as stated in Article 44(1) of Regulation (EC) No 1901/2006, as amended.

7. Proposal for adoption by the Management Board in December 2007 meeting (i.e. the last meeting before the legal deadline).

III Proposed Implementing Strategy

The implementing strategy presented here determines objectives (including long-term), organisation and structure, action programme, priorities, resource allocation, and monitoring of the outcomes and performance of the network. Its strategic goals are the milestones the network aims to achieve, according to the strategy, and are translated into specific performance targets.

1. Objectives

1.1 High level objectives

One of the high level objectives of the Regulation is to foster high quality ethical research on medicinal products to be used in children. Research is aimed at demonstrating the quality, safety and efficacy of medicinal products and their formulations. This should be achieved through efficient inter-network and stakeholder collaboration. The network's objectives are to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, in order to avoid duplication of studies and testing in children. The benefits of a European network of paediatric research include, but are not limited to building up and strengthening complementary scientific, technical and/or administrative competences in the performance of paediatric clinical trials through effective collaboration. They also include avoiding duplication of work and efforts, making the use of facilities more efficient and profitable, developing common methods of working with special attention to quality assurance.
Additional benefits are the facilitation of recruitment of patients, and avoiding unnecessary studies in children.
Finally the EU network aims at strengthening the foundations of the European Research Area by promoting European Commission framework programme applications.

The network itself is not intended to perform trials, or to decide on areas of paediatric research, which is under the responsibilities of the Member States, of the Commission through the Community programmes, or of each individual network. The network will not fund studies or research. The EMEA will ensure collaboration through a secretariat.

1.2 Detailed goals of the network

The short term and long term goals of the network encompass:
Collaboration:
- identify, co-ordinate and link together existing networks
- ensure efficient, timely communication and exchange of information between networks inside and outside the EU, including with WHO
- be a source of information and expertise for health professionals
- provide a forum for scientific discussion related to paediatric clinical trials with all stakeholders, where necessary

Building competences:
- define scientific and operational quality standards, and recognition criteria by networks themselves for the purpose of the operation of the network in particular not yet covered by existing quality standards (e.g. GCP)
- develop and agree training and education curricula and provide training to network partners
- stimulate the development of new networks, centres and investigators
- organise and hold scientific meetings to discuss specific topics as identified by the Coordinating Group
- stimulate research on trial methodology and educate

Avoiding unnecessary studies:
- avoid duplication of clinical trials in children by sharing information with European as well as international partners, in particular through the use of EudraCT
- develop multidisciplinary research partnership

Stimulating high quality research
- raise awareness on the need for clinical trials for children and increasing understanding of the purpose of research
- contribute to GCP compliance
- advocate for ethical clinical research, especially when trials include patients outside the EU.

Strengthening the foundation of the European Research Area:
- Support development and research into off-patent medicines for children, including contribution to priority list of off-patent medicines
- stimulate research in areas of relevance such as trial methodology or non-invasive assays

Facilitation of implementation and recruitment of clinical trials:
- enable rapid attainment of sample sizes large enough to allow valid conclusions through effective network collaboration and facilitation of performance of trials across Member States; this is especially relevant and crucial for paediatric trials.

2. Proposed organisation and structure

2.1 Network level

A resource-saving structure for the operation of the network needs to be established at the EMEA. It is proposed to create a 'Coordinating Group' which will contribute to the short and long-term strategy of the network, discuss and solve operational and scientific issues for the network, report to the Paediatric Committee and act as a forum for communication. The Coordinating Group should primarily be a group of active network participants.

The Coordinating Group should consist of the following members and should not exceed 20 members in total:

- 1 representative per recognised[2] network or group of centres (networks or centres may have to group themselves to be represented once the maximum number has been reached)
- 2 members of the Paediatric Committee
- 1 representative of the European Commission (namely DG Research)

The Coordinating Group is co-chaired by the EMEA and a chair elected from among the members.

- A maximum of 4 additional members following a decision of the Coordinating Group to bring additional expertise needed for its operation (e.g. patients' representatives, Ethics Committee representative)

Industry is not represented in the Coordinating Group through membership, but is expected to be a major stakeholder in the discussions.

Finally the Coordinating Group should establish strong links with the ad-hoc Group for the development of implementing guidelines for Directive 2001/20/EC relating to the good clinical practice in the conduct of clinical trials on medicinal products for human use, the Clinical Trial Facilitation Group (CTFG) and the GCP Inspection Services group to develop a common understanding and improvement of processes.

Collaboration should also be established with ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) to avoid duplication of tasks and ensure effective collaboration where appropriate.

Membership of the Coordinating Group is for 3 years only, to ensure sufficient renewal and involvement of various members.

Representatives of networks under construction or still in the recognition process may attend as observers. Other participants may be invited to discuss specific issues on an ad-hoc basis, including representatives of stakeholders.

The Coordinating Group is set up in 2 steps. During the construction phase of the Network, members invited by the EMEA, work together on an informal basis. After agreement of quality standards and recognition according to these criteria set up, agreed and recognised by the participating networks, the Coordinating Group is formally established with members from these recognised networks. The EMEA and the Coordinating Group will also work towards the adoption of a conflict of interest policy. Agreeing quality standards and recognition should take about a year from the establishment of

[2] See set up of Coordinating Group below.

the Coordinating Group. The EMEA only plays a role of facilitator and does not decide on recognition of networks.

Meetings of the Coordinating Group take place usually 3 times a year. In addition, it is planned that a workshop should be held on a yearly basis, open to all network participants.

2.2 EMEA level

Secretarial support to the activities of the network and the organisation of the meetings of the Coordinating Group are provided by the EMEA as requested by the legislation. Support is focussed on the coordination of exchange of information between the network partners, providing information to external partners and stakeholders, and facilitating the work of the Coordinating Group to ensure the objectives are met.
Members of the Paediatric Committee are involved in the Coordinating Group to advise on scientific issues and on the future strategy of the network. The Coordinating Group reports to the Paediatric Committee on a regular basis. The Paediatric Committee will act as the Scientific Committee of the network.

3. Proposed Action Programme

3.1 Timelines for launching and implementing

The network will be launched in 2008 once the strategy has been adopted by the Management Board and the resources are available. For 2008, the definition of quality standards and recognition processes, and the conflict of interest policy for the Coordinating Group are the first priority. Once the standards are agreed, the Management Board will be consulted on the 'recognition' process. The Coordinating Group will agree the other priorities for further implementation.

3.2 Deliverables according to the defined objectives

Collaboration:
Necessary communication facilities such as meetings, and workshops with stakeholders (patients, industry, CRO's),
Network website
Information source (e.g. newsletter)

Building competences
Definition of quality standards by the participating networks for expertise, infrastructure, transparency and quality assurance systems
Self assessment of 'recognition'
Training for network partners
Harmonisation of standards, procedures and processes
Training and education curriculum development

Avoiding unnecessary studies
Inter-network communication tools
EudraCT search capabilities
Joint research projects

Stimulating high quality research
Provision of information
Use of inter-network communication tools

Strengthening the foundation of the European Research Area
Identification of research priorities from networks
Provision of information on applications for EU framework programmes

Facilitating recruitment and clinical trial implementation.
Information to patients' organisations on open recruitments into clinical trials

4. Resources

The main concern is to avoid creating a resource-intensive structure replicating existing bodies and generating potential overlap of activities and responsibilities. The network's human and financial resources will be allocated to match the needs and the network's efficiency will be monitored and kept under regular scrutiny by EMEA. .

The EMEA will act as a facilitator and a service provider in particular to ensure communication between networks and external partners. The EMEA will organise and host meetings. The EMEA will cover travel and accommodation expenses for the Coordinating Group meetings (3 per year) and provide financial support for the open meetings with stakeholders (e.g. to patients' organisations).

5. Performance Monitoring / Progress Indicators

The successful implementation of the network strategy will be monitored using measurable outcomes. These should follow the timelines for the implementation of the agreed objectives.

Progress indicators may include:

- Number of 'recognised' networks and new networks developed
- Total number of trials performed through network collaboration per year (including trails into off-patent medicinal products)
- Number of meetings of the Coordinating Group
- Number of workshops and training meetings with stakeholders
- Reaching agreement on quality and recognition criteria

Further indicators may be developed with experience.