Minutes - Enpr-EMA Coordinating Group

Date: 15 February 2023; 15:00-16:30 CEST; By Webex

Chairpersons: Pirkko Lepola / Gunter Egger

Invitees: Coordinating Group members and observers

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Adoption of agenda	The agenda was adopted without changes.
Introduction of new members and observers of the Coordinating Group (CG)	Hettie Janssens, new representative of ECFS-CTN (member), Bernhard Sandner, representing NETSTAP (member) and Collin Hovinga, representing C-Path (observer) introduced themselves, briefly presenting their organisations. The new members were warmly welcomed.
Topics for discussion: 1- Landscape and aims of Enpr-EMA 2- Composition of the Coordinating Group 3- Membership and self-assessment form	The objective of the meeting was to review the current situation of Enpr-EMA, its aims, objectives, structure and composition within the current landscape, and to evaluate if any changes are needed to make Enpr-EMA more efficient, less bureaucratic and to optimise the value to its members. The timelines for this review were defined as follows: firstly, brainstorming by the CG and network members at the current CG meeting and next network meeting in Q2/2023, with the aim to reach some conclusions during the Enpr-EMA Annual Meeting. <u>1- Landscape and aims of Enpr-EMA:</u> Since the adoption of Enpr-EMA´s mandate and implementing strategy in 2008, many new networks and initiatives have arisen, which warrants a review of Enpr-EMA's role in this

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	changed landscape. The members were invited to discuss if the initial goals of the network, comprising among others the development of quality standards and recognition criteria, the development of training, the organisation of scientific meetings, and the promotion of new networks and research on trial methodology, could still be applicable or if different or additional activities should be Enpr-EMA's focus in the future. The following opinions were expressed by the members: - The revision of the Paediatric Regulation might bring a new opportunity for Enpr-EMA to acquire a role in facilitating the implementation of the new legislation focusing on the topics of unmet medical needs, and prioritisation of medicinal products. - The close links of Enpr-EMA to EMA's Paediatric Committee (PDCO) are an asset of the network. - Training needs were identified on the following topics: • Clinical Trial Application (CTA) and Clinical Trial Information System (CTIS) functionality. The ERN representative informed participants about their initiative in collaboration with c4c to create webinars on the authorisation process, set-up, and conduct of paediatric clinical trials. The possibility of having Enpr-EMA collaboration in these webinars was welcomed. • Support for academics regarding the creation of clinical trial protocols. • Requirements and regulatory steps to set up and manage investigator sponsored trials, with specific input on the patient enrolment process. • Regulatory steps to register or repurpose a medicinal product for new indications. - Health Technology Assessments (HTA) and the differences of access to the medicines across the member states was identified as an important

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	issue. Follow-up on this topic through Enpr-EMA would be appreciated. During the discussion it was highlighted that currently there are other ongoing initiatives covering the topic of paediatric HTA, such as the multistakeholder conferences organised recently by the paediatric initiative of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT), the information about which Enpr-EMA regularly shares with its stakeholders. Potential synergies should be evaluated. - The challenges of conducting clinical studies in infants and younger children and the need to identify meaningful clinical endpoints for these populations was identified as another area where Enpr-EMA could provide support by organising meetings focused on specific diseases/conditions. - Additionally, the regulatory and ethical requirements for emergency clinical trials, and neonatal acute situation trials, when the patient enrolment and participation may be extremely difficult, may warrant training, information sharing via Enpr-EMA. <u>2- Composition of the Coordinating Group</u> The mandate of the CG establishes three different categories for the members depending on the fulfilment of specific criteria as indicated in the self-assessment form. Only category 1 members are part of the CG, which is involved in the strategic decisions of the network. Currently Enpr-EMA counts with national networks and some specialty networks. Almost half of the members are category 1 members being part of the CG. However, many category 2 members are expected to become category 1 soon, leading to a situation in which almost all the members would, therefore, be part of the CG. The following opinions were expressed by the members: - A clear definition and identification of the benefits of being a member of Enpr-EMA should be consolidated. Also, in view of the possibility of having double and triple membership for different

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	networks. Some examples for the benefits include the exchange of expertise and information among the networks and to count with input from the Regulators. - There is a need to raise awareness among the public about Enpr-EMA and the benefits it offers, including the possibility of providing targeted public information about the Enpr-EMA deliverables and activities for paediatric patient representatives and young people, by publishing these in a simplified and short format adapted to the paediatric population. <u>3- Membership and self-assessment form</u> The following opinions were expressed by the members: - The process for filling in the self-assessment form was identified as long and time consuming. Furthermore, the ultimate use of the data included in the assessment form and the differences and benefits from pertaining to the different categories were not clearly recognised by the members. Nevertheless, the assessment form is the basis for the information included in the publicly searchable Enpr-EMA member database. The contract research organisation (CRO) representative pointed out that the database is a powerful source of information and routinely used for planning paediatric clinical trials. Awareness of the existence of the database could be raised. Also, the database needs to be updated regularly to provide accurate information to the users. It was concluded that the information to be collected in the self-assessment form and ultimately in the database should be reviewed in order to collect meaningful information that could provide enough level of detail in order to enable the characterisation and distinction of the members. The chairs thanked the members for their valuable participation in the discussions and confirmed that the work on optimising the set-up of Enpr-EMA will continue throughout the year. It is expected that these improvements will also pave the way for the

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	potential future changes that may be necessary in light of the revision of the Paediatric Regulation.
Next meetings planned AOB End of meeting	Members were informed about the upcoming meetings: - The next coordinating group meeting will take place at the end of May or beginning of June. A survey regarding members' availabilities will be sent out in due course. - The Enpr-EMA Annual Meeting is planned to take place end September/beginning October at the EMA's premises in Amsterdam, being open to all interested participants. The date will be confirmed to Enpr-EMA's stakeholders in a few weeks' time.