



Brussels, 20 March 2018

## **BOARD OF MEMBER STATES ON ERNS**

**06 MARCH 2018, 10:00-16:15**

**VENUE: ALBERT BORSCHETTE CENTRE, ROOM 3A**

Rue Froissart 36, 1040 Etterbeek, Brussels

### **DRAFT MINUTES**

**CHAIRS: ANDRZEJ RYS & TILL VOIGTLAENDER (Co-Chairs)**

#### **1. Welcome and approval of the agenda (*Chair AR*)**

DG SANTE B Director Andrzej Rys welcomed all participants and opened the meeting. All EU Member States (except Germany, Italy and Bulgaria) and Norway were represented. The Chair reminded the Board that the minutes of last meeting had been approved in written procedure.

The Board considered the agenda prepared by the Secretariat and approved it as proposed.

#### **2. Feedback on the activities of the ERN Coordinators Group (*Chair AR*)**

The Chair of ERN Coordinators Group (ERN-CG), presented a summary of the discussions at the ERN-CG meeting held the day before the Board meeting. The Board was updated on activities being carried out by the different ERN-CG working groups (WGs). The ERN-CG Chair also presented the challenges and the 2018 outlook.

- The ERN-CG has finalised and approved its Rules of Procedure. At present the ERN-CG operates with six WGs: IT & data-sharing, research, ethics & legal issues, cross-border healthcare & business continuity, monitoring and clinical guidelines.
- Report from the WGs activities:
  - WG on Research - ERNs extremely well fit into the European Joint Programme Cofund on Rare Diseases. ERNs are "research machines" in many different areas (e.g. in diagnostics, genetics, new therapies, basic research) and this needs to be "exploited". For that matter a paper on research capacity of ERNs will be prepared.

- WG on Cross-Border healthcare and business continuity – The WG has organised a survey and collected data on cross-border healthcare services as provided by ERN healthcare providers (HCPs) in 2017. Related to this, the ERN-CG Chair voiced the concern to cope with the administrative burden on Coordinators and ERN HCPs and pleaded for support by Member States.
- WG on ethics and legal issues - The WG has prepared a document on “ERN Conflict of Interest Policy” together with a disclosure form. Following consultation with DG SANTE the scope of the Policy was reviewed. Patient care restricted to the use of the Clinical Patient Management System (CPMS) and research activities are now included in the scope of the Conflict of Interest Policy. The revised version of the document will be finalised and submitted to the Board in June.
- Challenges and 2018 outlook:

A survey to all members of the ERN-CG was performed in January 2018. 20 Networks responded to a set of questions on 1) challenges and expectations and 2) Affiliated Partners. Based on this survey one of the priorities for next year will be to find a solution for the “lack of financial resources”. On a wider scale, integration of ERNs into national health systems represents a major challenge. The ERN-CG Chair referred to the fact that, while a large majority of ERN HCPs participate very actively in their Network's activities, a small minority is rather inactive and he raised the need to address this challenge. Overrepresentation of some Member States in the Networks as well as underrepresentation notably of Eastern Member States was also mentioned. In view of the process of designation of Affiliated Partners, the ERN-CG Chair welcomed the October statement of the Board and presented the ERN-CG requests: 1) finalised guidelines for internal network monitoring; 2) a template for an agreement; 3) more administrative and financial support due to the expected significant amount of work; 4) clear rules for affiliated membership; and 5) clear termination rules.

On this aspect related with Affiliated Partners, two Member States reiterated the importance of having the Network specific criteria available for the next call. Transparency in this process is the key issue.

- Survey on Patient access to ERNs:

The ERN-CG Vice-Chair presented the outcomes of a survey carried out among ERN HCPs on patient access to ERNs. The survey revealed very interesting insights as regards patient pathways, notably on how patients are referred to ERNs, and what barriers might prevent patient cases from being taken up in the CPMS, which measures could maximise the utilization of ERN services and how awareness on ERNs could be increased.

The presentations triggered a lively discussion.

Several members of the Board requested the Coordinators to finalise, as soon as possible, the mapping exercise, assessing the geographical and scientific/diseases gaps for each Network and defining the network development needs both in terms of geographic and thematic coverage needs so as to pave the way for an efficient enlargement. It was agreed that the mapping will be finalized by May.

One member of the Board inquired about the proper mechanism to get more financial support for the ERNs. The Chair reminded that the Commission is supporting the work of the Networks as much as possible. The terms of reference for a contract on secretarial support to the Coordinators are under finalisation and the ERN team in DG SANTE has been reinforced. Moreover, the Commission will renew its efforts to support the ERNs in the future MFF. At the same time, the support of Member States to ERNs and Coordinators is crucial for the ERN good functioning. As an example, the representative of Portugal explained that based on an economic evaluation, his country raised the funding of patients treated in ERN HCPs by 50%.

The ERN-CG Vice-Chair noted that there was a need to accelerate the Affiliated Partners process as the current geographical coverage of the ERNs was less than 50%. Moreover, the largest needs in terms of lack of expertise for rare disease treatments are primarily in those countries which are underrepresented in the Networks.

### **3. Feedback on the activities of the ERN Working Group on Monitoring** (*Chair AR*)

Michelle Battye on behalf of the ERN-CG WG on Monitoring presented the document the WG has drafted and that was finalised the day before at the ERN-CG meeting.

The document focuses on:

- the development of a workable continuous monitoring system of the ERN activities which can be utilised across all ERNs;
- A periodical self-assessment by the ERNs and reporting of the activities of the ERNs and HCPs to the European Commission and the Board of Member States;

With this document the WG provides a framework to carry out continuous monitoring of ERNs by identifying common indicators to all the networks. These indicators (related to the structure, process and outcome) cover seven intervention areas that are aligned with the operational criteria at the time of the application.

The discussion focused on the necessity and urgency of the implementation of the ERNs monitoring system. Identifying underperforming HCPs as well as the thresholds to apply for the assessment of Affiliated Partners were two aspects that were specifically pointed out. The ERN-CG Chair confirmed the relevance of monitoring and asked the Board to consider how to finance this activity. He stated that it should be supported like the CPMS.

The Chair urged that both Coordinators and the Board Monitoring WG work closely at this issue. It is essential to start assessments and to ensure consistency across them. Also, accountability of ERNs is necessary. The Board Monitoring WG is composed of members of Norway, Spain, France, UK and Austria (chair). The WG committed to eventually agree on the next steps of the Monitoring system at the next Board meeting.

In addition, some members of the Board raised concerns about data protection and the use of the CPMS. The Chair noted that the Commission services were aware of the fact that there were different approaches by countries. In some Member States there was a national, centralised approach to clear the use of the CPMS by the HCPs while in other this was done at regional or local level. Apart from the different approaches it is essential to speed up the process. For this reason, the commitment of the Member States is needed. The Commission services will prepare a letter to remind Health Ministries of this issue.

#### **4. Affiliated Partners: Timeline for the designation process and rules for termination** (*Chair AR*)

The Chair recalled that at the meeting of the Board on 10 October 2017, the Member States adopted “*Statement on the definition and minimum recommended criteria for Associated National Centres and Coordination Hubs designated by Member States and their link to European Reference Networks*”. Further, it was decided that Commission services will prepare two separate standalone documents 1) a statement on the timeline for the designation of the Affiliated Partners and 2) on the rules for their termination.

The Deputy Head of DG SANTE Policy Unit, presented the rationale of the two drafts in details.

The discussion of the Board started with a proposal of HU to amend the statement on the Timeline. The objective of the amendment was to allow also Member States that expect to have full members in individual networks in the future, to designate these potential future full members as Affiliated Partners for these networks already in 2018. A few other members made additional suggestions for change with the aim to further clarify the text. In general, however, there was support for the draft statement on the Timeline with the proposed amendments. In this context the question of the timing of the invitation for HCP to join existing ERNs was raised. The Commission answered that this is expected by the end of 2018.

As for the proposal on the Rules for Termination, various comments were raised. The termination of Affiliated Partners in case of approval of a new member from the same Member State raised opposition from one Member State while another raised the question of the timing of the termination upon approval of a full member. The Commission services, notably supported by some Member States, argued that the termination of the Affiliated Partner in case of approval of a full member was in line with the Commission interpretation of the will of the legislator.

It was underlined that a prompt adoption of both proposals would pave the way for a smooth integration of Affiliated Partners thus expanding the geographic coverage of existing Networks and facilitating patients access to ERNs.

In conclusion the Chair summarised that:

- the mapping document assessing the ERNs development needs due by end of May will feed into this discussion;
- the Secretariat will amend both proposals and will circulate them for approval in written procedure;
- the aim was to trigger the Affiliated Partners process after summer.

## **5. Progress on clinical patient work, CPMS functioning, ITAG meeting debrief** (Chair TV)

The Head of DG SANTE IT Unit provided an overview of the latest developments of the CPMS and the on-going updates. By the end of February, 75 consultation panels were opened in CPMS, 8 panels were closed. This included 185 active users. Work is also ongoing with regard to some customisation requests by the Networks. Flexibility was added to existing workflow and customised datasets were created for two Networks.

One member informed the Board that they need to carry out a risk evaluation of the system at national level. Commission services responded that the system was in accordance with the specifications and the ISO standards but then will follow-up on a bilateral basis.

The Head of DG SANTE Policy Unit, provided clarification on the use of the CPMS and on data protection. In summary the message was that the European Data Protection Supervisor (EDPS) has concluded after careful analysis that the CPMS complies with the EU data protection rules and considered the standardised consent form that the Commission provided to be in line with the EU data protection rules. The Commission services emphasised that national obligations may contain specificities not covered by the EU consent form. Therefore, if further checking is needed with the data protection authority at national level, the hospital legal service is best positioned to handle this. Each hospital remains responsible for their data protection practice. National obligations may require specificities not covered by the EU consent form. The Commission referred to the toolkit and guidelines that have been made available to Board members as well. The consent form was translated into all EU languages plus Norwegian. These language versions will also be made available to Board members.

The Commission services invited the members of the Board to indicate where there are centralised clearance procedures. As discussed under point 3, the Commission services will prepare a letter on this issue.

The member of the ERN team in DG SANTE Policy Unit in charge of CPMS debriefed the Board on the last meeting of the IT Advisory Group (23 January 2018). Furthermore, it was explained that for the evaluation of the CPMS Pilot phase (20 November 2017 – 28 February 2018) a questionnaire is being carried out with a scope to review and analyse process needs for the ERNs.

## **6. Amendment of the Implementing Decision 2014/287/EU** (Chair TV)

The members of the Board received an informal text with the amendments that Commission services are proposing. The Deputy Head of DG SANTE Policy Unit, presented the rationale of proposed amendments: they aim to modify the procedure concerning the application for membership in existing European Reference Networks (ERN) and to clarify the role of the Board of Member States in steering the ERN initiative. The objective is to ensure an objective, transparent and effective enlargement process, which could bring into the ERNs clinical and technological excellence.

As for the membership application procedure, it is proposed that each membership application shall be accompanied, not only by the endorsement from the Member State of establishment, but also by a favourable pre-assessment from the Network that the healthcare provider wishes to join. If a membership application fails to receive this favourable pre-assessment while having received the endorsement from the HCP's Member State of establishment, either the Member State of establishment or the HCP may ask the Board to decide if the application can nevertheless be submitted to the Commission. The Commission services highlighted that this proposed amendment aims at ensuring a peer-to-peer recognition which is key for building trusts among current and future Network members. At the same time, it does not change the equilibrium between Member States and Networks compared to the 2016 procedure. Safeguards have also been put in place to protect the Member States and the HCPs and the final decision remains in any event with the Board. The Commission services also reminded that the Coordinators had expressed the wish to be involved in the enlargement process.

As for the role of the Board of Member States, it is proposed to expand the Board's tasks which are currently limited to the approval of proposals for Networks, their membership and their termination, and establish the Board as the forum for the exchange of information and expertise in line with Article 12(4)(c) of the Cross-border Healthcare Directive.

The Chair underlined that the vote by the Member States on the proposal should take place in the Cross-border Healthcare Committee.

While no objections have been raised on the proposed added competence of the Board, Member States were divided on the proposed membership application procedure.

Some members of the Board expressed a clear support as they a) considered it is legitimate to recognise the Networks as new actors and rely on their experience; b) were satisfied with the role of the Board to act as a final judge; c) recognised that the context has changed and that there was a need to ensure the sustainability of the ERNs; d) acknowledged that the new rules were useful for coping with the success of the ERNs.

On the other hand, some members of the Board expressed particular concern about the proposal. They were of the opinion that a) there was no need to change the legislation and the rules of the game while the process is not finalised; b) too much power would be given to the Coordinators; c) ERNs were meant to be inclusive; d) politically, it would be difficult for the Board to overrule a negative decision of the Coordinators; e) new rules would treat differently the applicant HCPs and would increase the waiting time of the HCPs ready to apply; f) new applicants would receive an assessment by the Coordinators while there are current members of the Network that have not been assessed so far; g) there is a substantial difference from the previous call and that is that at first, criteria to join the Networks was not available.

A proposal to cancel the possibility for the HCPs to appeal the BoMS against the opinion of the ERN has been made.

Furthermore, the question whether the favourable pre-assessment should come after or before the endorsement was raised and a preference was expressed for the endorsement to be done first.

The Commission services concluded that there was a clear need to further deepen the discussion. Regarding the timing, the Commission services explained that the amendment of the Implementing Decision is expected to be finalised in autumn 2018. Therefore, the invitation for HCPs to join existing ERNs will not be launched before Q4 2018.

## **7. Integration of ERNs into the national health system of the Member States** (*Chair TV*)

Paul Boom, Chair of the WG on Integration informed the Board on the outcome of a survey addressed to Member States and covering all the aspects of Integration. As there were only a limited number of Member States who replied (13) and Integration is such an important area, which goes directly to the essence of the ERNs, it was agreed to leave the questionnaire open till the end of March.

Few members qualified some of the questions, especially the one on reimbursement and the distinction between Regulation 883/2004 and the Directive on patients' rights in cross-border healthcare, as too difficult, or being out of the competence, scope of the WG.

## **8. Communication activities** (*Chair TV*)

The member of DG SANTE ERN team in charge of Communication provided a brief state of play related to communication activities.

A quick overview of ERN websites and last guidelines to meet EU requirements was provided. The Board was informed that the ERN videos and clip will soon be subtitled in all EU languages and Norwegian. Communication activities on real patients' cases were mentioned as well as the articles already published on the occasion of Rare Diseases Day. Lastly, Board members were informed on the ERN Conference of 21-22 November in Brussels. In response to a question, the European Collaborative Platform was mentioned as a possible platform for internal communication.

## **Any Other Business** (*Chair TV*)

- A member of DG SANTE ERN team informed the Board on the upcoming second wave of technical assessment and audit of HCPs by an Independent Assessment Body. 79 HCPs will undergo a thorough documentation assessment and 23 of them will also receive an on-site audit.
- The UK representative shared information on a draft declaration on "Towards access to at least 1 Million Genomes in the EU by 2022".
- The Chair proposed to hold occasionally WebEx meetings in between the physical meetings to make the work of the Board more interactive.
- The EURORDIS letter on "ERNs collaboration and interaction with industry", dated 26 February 2018, was distributed to all participants.
- Next Board meetings scheduled for: 26 June 2018 and 20 November 2018.

END OF THE MEETING