



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

**26 MARCH 2019, 10:00-17:15**

**VENUE: BORSCHETTE**

Rue Froissart 36, 1040, Etterbeek, Brussels

### **DRAFT MINUTES**

**CHAIRS: ANDRZEJ RYS (CHAIR) & LENNART CHRISTIANSSON (CO-CHAIR)**

#### **1. Welcome and election of the Member State representative co-chair of the BoMS**

The Chair, DG SANTE B Director welcomed all participants and opened the meeting. All EU Member States (except Denmark)<sup>1</sup> and Norway were represented.

The Chair recalled that the mandate of the current Co-chair has come to an end, therefore, the Board needs to elect a new co-chair. A mail calling for expression of interest was sent ahead of the meeting to all Board members. The Commission has received three expressions of interest, notably from the representatives of Italy, Sweden and Austria. The Chair asked the three candidates to briefly present their ideas and priorities they see for the two years ahead.

Following the presentations, the Swedish representative was elected in a two-turn vote.

The Chair thanked the Austrian representative, outgoing Co-chair, for his valuable inputs and his commitment with the ERN initiative.

#### **2. Approval of the agenda and minutes of last meeting**

The Chair welcomed the new representatives from Spain, Luxembourg and Cyprus.

Board members were asked if they had any comments to the minutes of the last meeting. This was not the case, therefore, the minutes were approved and have been made publically available on SANTE's website<sup>2</sup>.

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

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<sup>1</sup> One Member State has not yet arrived at the time the Chair proceeded to vote.

<sup>2</sup> [https://ec.europa.eu/health/sites/health/files/ern/docs/ev\\_20181120\\_mi\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ern/docs/ev_20181120_mi_en.pdf)

### **3. Feedback on the activities of the ERN Coordinators Group**

The presentation of the Chair of the ERN-CG focused on the on-going affiliation procedure. The procedure consists of three steps:

- 1) identification and designation of Affiliated Partners by the Member States;
- 2) development of an integration strategy by the ERNs;
- 3) implementation of the integration strategy.

Templates for an integration strategy and for a bilateral agreement (setting policy objectives) between the Affiliated Partner and the respective ERN are being developed.

When presenting the table summarising the number of Affiliate Partners reported to the Coordinators, it turned out that there was a difference compared to the numbers reported to the Commission. Also, some Member States noticed inaccuracies related to their own country data. These inaccuracies were noted and flagged as well.

The Chair of the ERN-CG stressed that 2/3 of the Member States have not (yet) designated Affiliated Partners and there is a persistently slow expansion of ERN services to underrepresented regions. On the other hand, some Member States designated up to 5 Affiliated Partner per ERN. In such cases, Member States are requested to provide written information on how smooth coordination of referral process among multiple Affiliated Partners will be ensured at national level. The workload on Coordinators and the costs strain on budgets were also underlined. National authorities were asked to contribute to the operational costs (travel to ERN meetings, documentation efforts etc.) of Affiliated Partners. Overall, there is a huge financial challenge on the ERN budgets and the expected ERN expansion by 30-50% (new full members and Affiliated Partners) is unfinanced. There is growing disappointment and demotivation of sites and Member States are largely reluctant to support ERN activities at site level. On the other hand, there are numerous European PPP models, it is not clear, why it is not possible to adopt such a model to make private money available for ERNs.

The Chair stressed that DG SANTE is doing its best to find new funding possibilities and there is also a role to play for the Member States. We have some countries as good examples and we need to be careful about how much we ask from Coordinators.

The Chair of the Integration Working Group underpinned the importance to know what are the functionalities at central and local level that are not financed.

Some Member States presented their national situation and explained the logic behind their enlargement approach. One country argued in favour of postponing integration of Affiliated Partners for after the new call is over.

The timeline for the designation of Affiliated Partners was also discussed. Some members argued in favour of leaving it open at all times. The Chair however stressed that leaving the process open was not possible and as agreed at the November 2018 Board meeting, the deadline for Affiliated Partner designation (initially set for December 2018) was extended until the launch of the next Call for new Members joining existing Networks.

### **4. Board Statement on relations with Industry**

The Chair recalled that at the Board meeting of June 2018, the ERN representatives requested an amendment to the Board statement on relations with Industry with the aims

of: update elements that have changed since 2016 and clarifying which activities are allowed (or not) for industry (or other private) support and possibly allowing for the exploration of "joint" funding mechanisms where several private partners could jointly support one (or even several) ERN(s).

The Chair of the Ethical and Legal issues Working Group gave a general update on the main developments within the Working Group. She explained the nature and purpose of the proposed amendments, in particular, the necessity to clarify Member States' "red lines" for which a direct funding of ERN activities would not be accepted. In this context, the chair highlighted that in the new draft document presented to the Board today the Working Group itself could not reach an unanimous agreement on a few aspects regarding private funding, therefore providing a document reflecting the position of the majority of the Group members with footnotes pointing out the alternative view of one other Working Group member. In relation to the Workshop with the Industry, a proposal to develop two "pilots" (firstly a concept, then implementing them as "proof of concept" that cooperation between ERNs & industry could work under certain conditions) was presented. The two proposals were to work on clinical trials and data/registries and moving forward with them in two steps: 1) developing the concept for the pilots and 2) implementing them.

The Chair then opened the floor for a tour de table by stressing that the objective of today's meeting is to achieve a consensual position and finalise the amended version of the Board statement.

Members of the Board were divided on the issue of private funding. Some argued against opening the door to private funding as each country has its own regulatory framework. The concept of "multiple funding" and its indirect nature was questioned. Other Member States expressed support towards the amended version of the Statement, arguing that transparency was the most important principle. Further, the need for alternative funding of ERNs was added to the discussion.

On the proposal to develop pilots, one member underlined that it would be dangerous to let the industry accessing registries. Others expressed doubts about the whole concept of piloting. Starting with pilots assumes that the Board already decided on how the cooperation with the industry should be.

The Chair concluded that the text proposed by the Working Group was not sufficiently mature and requested further reflection. Members have two weeks to send written comments. The text will then be finalised, with the aim to make the Statement shorter and simpler. Soft reference to pilots should be included.

## **5. Amendment of the Implementing decision**

The Chair informed the Board that in the meeting of the Cross border Healthcare Committee (CBHC) on 18 March the debate on the chapters concerning the role of the Board and the procedure for new membership were closed. The CPMS chapter was also finalised after some comments received. However, doubts were raised regarding data processing in CPMS and also about how to safeguard a coherent legal approach between

the amendment of the ERN Implementing Decision and the Implementing Decision on the eHealth Network.

The Commission services stressed that this is still under discussion mainly because of reasons of different legal purposes of the two initiatives and not least, the different data protection aspects. The dangers related to further delaying the adoption were underlined. Without the Implementing decision, the launch of the call for new membership will be delayed. The ERN initiative could also lose the money foreseen in the 2019 budget for the evaluation of the applications by the Independent Assessment Body. More importantly, without the Implementing decision, the Commission would need to sign more than 300 individual agreements with all the hospitals working in the ERNs to define the allocation of responsibilities among joint-controllers of personal data, which would be extremely cumbersome.

Board members inquired about the next steps. The Commission explained that the plan was to proceed with a written procedure. In case the CBHC issues a positive opinion, the Commission's decision making process will be launched. Adoption is likely to happen end of May, early June.

In reply to a comment from a member of the Board emphasising that applicants do not know for what they have to prepare, the Commission stated that the assessment manual cannot be published now, as it has to be adapted to modified procedure concerning the application for membership of existing ERNs.

## **6. Enlargement process of the Networks (designation of Affiliated Partners, new call)**

The Commission services, updated the Board on the current numbers of Affiliated Partners (APs) that have been designated by the Member States. Questions raised by individual Member States prior to the meeting about the designation process of APs were presented and answered.

Commission services made reference to the debate on enlargement that took place in the Coordinators Group the day before where Coordinators stressed the fact that APs cannot be a replacement for a full membership in the long term. They pointed out that there is a will to extend the geographic coverage of the ERNs while maintaining the numbers to a manageable level. Therefore, designating too many APs would not be a good strategy in terms of the long term sustainability of ERNs.

Member States were also encouraged to fill all the boxes possibly with the designation of Coordination Hubs so as to put an end to accessibility problems for patients.

In order to provide a good overview, the Commission services will publish the designation letters received on the ECP, the ERN Collaborative Platform.

In response to a question from one member, the Commission repeated that leaving the process open forever was not possible and as agreed at the November 2018 Board meeting, the deadline for Affiliated Partner designation (initially set for December 2018) was already extended until the launch of the next Call for new Members joining existing Networks.

## **7. Preparedness actions to UK withdrawal from the EU**

The Chairs expressed their gratitude to the UK Coordinators.

It was announced that the European Council has agreed on an extension of the UK withdrawal date until May 22 2019. The extension still has to be voted by the UK Parliament and if it is rejected, the new Brexit date will be April 12, 2019. Until any decision is taken, the UK remains part of the European Union and the UK hospitals remain part of the ERNs.

In case of a hard Brexit, the UK hospitals will immediately stop being ERNs members. As a consequence, they will stop having access to the ERN IT tools and notably to the CPMS. However, in the interest of the patients, the Commission services intend to permit the continuation of virtual panels concerning patients enrolled by UK healthcare providers. If the UK healthcare provider is a panel lead, it will have to be replaced. An analysis is being performed on the Commission's side.

## **8. Working Group on Integration**

The Chair of the WG on Integration updated the Board on the developments in the WG.

The Working Group on Integration was mandated by the Board to support the Member States in the integration process of ERNs into the national healthcare systems. Besides the 10 Member States (FR, DE, ES, NL, LT, HU, NO, SI, MT, EL) 3 ERN Coordinators (ERKNet, ERN RND, and MetabERN) are members of the Working Group.

The Working Group has prepared a Position Paper for this meeting of the Board with the aim to list the most important strategic issues that need to be addressed and challenges to be overcome to ensure a proper integration of ERNs and with the aim to ask for a mandate from the Board to prepare a proposal for a Statement on Integration. Further a collection of good practice examples, arranged into 6 WHO axes for healthcare systems' comparison was prepared and compiled in a Conceptual framework.

Reference to the 4<sup>th</sup> ERN Conference where a roundtable discussion was dedicated to integration was made. Further the special report of the European Court of Auditors on Cross-border healthcare expected to be adopted at the beginning of June was also mentioned, which will probably insist on the fact that Member States will need to address challenges, like integration of ERNs.

Following the brief debate, the Working Group has been mandated to continue its work and prepare a draft Statement on Integration with possible recommendations to the Member States.

## **9. The French approach on Integration**

In the context of exchanging good practices on how to link, integrate ERNs into the national health system, the French representative of the Board made a presentation on the French approach.

The first French national plan for rare diseases in 2004 encouraged patient associations, healthcare players, researchers and policy makers to liaise more closely. The first two plans contributed to some major achievements. They defined the implementation of

centres of expertise and the establishment of the 23 rare disease clinical networks (Filières de santé maladies rares). The third plan, launched the 4 July 2018, is the result of the concerted efforts of all the stakeholders committed to promoting an ambitious health and research policy designed to help patients with rare diseases and their families. It facilitates and encourages synergies with the research area and is also in line with the current National Health Strategy and all health-related national plans. Orphanet, EJP are also closely linked. Labelling was pointed as a key element. In France, only labelled reference centres can be endorsed as ERN members. It is a way to prevent the entrance of too many French HCPs and to have a proportionate representation to the French population. The endorsement procedures are defined at national level. The national organisation perfectly fits with the ERN infrastructure.

Actions for integrating ERNs into the French health system were presented. The eight French Coordinators receive administrative, organisational, communication and financial (60.000 EUR/year/Coordinator) support from the French government. The Ministry of Health is running a working group which provides a platform for involving, informing Coordinators in the decision making process related to ERNs. Main issues the working group is dealing with recently: manageability of ERNs as well as Affiliated Partners and their integration into the Networks.

Commission services thanked the French presentation and encouraged Member States to volunteer to provide such an overview on their respective national approaches in one of the forthcoming meetings of the Board.

## **10. The Structural Reform Support Service**

The Chair informed the Board that the Structural Reform Support Service (SRSS) is a Service of the European Commission and is meant to help Member States in designing and carrying out structural reforms. The support is provided at the request of a Member State and healthcare do fall under the areas of support.

After the brief introduction, the representative of the SRSS presented how the support works and what benefits it can bring. It is a tailor-made support on the ground that can be mobilised for any specific reform. Work starts on demand of the country in an annual cycle. The SRSS has the ability to mobilise all sorts of expertise (private-public), no co-financing is required and there is low administrative burden. Some concrete examples were presented. The deadline for submitting requests is the end of October 2019, selection will run until the end of the year and projects will be launched in spring 2020, the earliest.

## **11. Health Programme – Work Programme for 2019**

Commission services informed the Board that the 2019 Work Programme has received a positive opinion of the Programme Committee at its meeting on 14 March 2019 and briefly summarised the ERNs related parts of it:

- Grant for registries (19 grants foreseen in 2019);
- Contract for assessment of new healthcare providers in the next call by IAB;
- Development of an integrated assessment, monitoring, evaluation and quality improvement system (AMEQIS) for the Networks;

- Capacity building and technical support to the working groups and governance bodies of the ERNs ( workshops and studies);
- Support to the ERN capacity and knowledge sharing activities through short term mobility and exchanges of healthcare professionals;
- Implementation of training to ERN members in the use of the ERN IT Platform (CPMS, ECP and other relevant tools).

**12. AOB** (*chair*)

The Chair informed the members that the next Board meeting date is 25 June 2019 (Brussels). The third meeting in 2019 is booked for 15 November, also to take place in Brussels.

END OF THE MEETING