



## BOARD OF MEMBER STATES ON ERNS

26 NOVEMBER 2021, 14:00-17:00

VIDEO-CONFERENCING VIA WEBEX

### DRAFT MINUTES

CO-CHAIRS: EUROPEAN COMMISSION AND AUSTRIA		
1	14:00 – 14:10	<b>Opening of the meeting</b> - <i>Welcome</i>
2	14:10 – 14:40	<b>Independent Assessment Body Presentation of results of assessment of applications of new ERN members</b> Presentation + Discussion
3	14:40 – 15:10	<b>Board of Member States Discussion on the results of assessment of applications of new ERN members</b>
4	15:10 – 15:30	<b>Approval by the BoMS of new ERN members</b>
<b>15:30 – 15:45 Coffee Break</b>		
5	15:45 – 16:15	<b>Presentation of the outcomes of the approval process and the next steps</b> Presentation
6	16:15 – 16:30	<b>Presentation of the Belgium consortium within ERN EpiCARE</b> Presentation + Discussion
7	16:30 – 17:00	<b>Any Other Business</b>
<b>17:00 End of the meeting</b>		

#### 1. Opening of the meeting

The Commission Co-chair welcomed all participants and opened the meeting. He explained that the aim of the meeting was to discuss the results of the assessment by the Independent Assessment Body (IAB) of applications of new ERN members and approve the new members of ERNs.

## **2. Independent Assessment Body Presentation of results of assessment of applications of new ERN members**

The Independent Assessment Body (IAB) presented the assessment process for applications of new ERNs and the results of the assessment, showing that only 10 healthcare providers (HCPs) had been assessed negatively by the IAB, most of them due to missing documentation or failure to meet the requirements related to HCP staff. The IAB also mentioned some of the recommendations made by the audit assessors to the applicants, which included, for example, the need to provide easy access to the information on cross-border healthcare in different languages; increase patient involvement in the decision-making process; better communication with patients on possible complications and follow-up treatments; need to implement electronic medical records; and recommendation to use a coding system specific for rare diseases.

## **3. Board of Member States Discussion on the results of assessment of applications of new ERN members**

The discussion started with the IAB presenting their experience in carrying out the online audits. IAB was very positive and highlighted the flexibility that these online audits provide. IAB explained that the satisfaction survey showed that 85% of participants considered online audits a good option and 84% considered them to be comparable to face-to-face audits. Some Member States confirmed the positive feedback they had received regarding online audits and that they may be considered of similar quality and rigorousness as the face-to-face ones. The hybrid system of online and face-to-face audits was considered to be an adequate way to perform audits in an efficient way while keeping the costs low, and particularly ideal to manage the restrictions imposed to fight the COVID pandemic.

## **4. Approval by the BoMS of new ERN members**

A total of 24 Member States were present in the meeting and approved by consensus the list of the 620 HCPs as new full members of the ERNs starting on 1 January 2022. The Commission will circulate after the meeting the formal BoMS decision with a complete list of the ERN new members that were approved by BoMS in the Annex.

## **5. Presentation of the outcomes of the approval process and the next steps**

The Co-chair of the Member States explained that the next step for the new ERN members will be to connect to the ERNs, formally starting on 1<sup>st</sup> January. The process of “onboarding” of the new ERN members will be a joint effort carried out by EC, the ERN Coordinators and the new ERN members. EC explained that the Coordinators had asked for some flexibility in finalising the work that is required to incorporate the new members. This will mean that the new members will be gradually incorporated during the first three months of 2022 depending on the readiness of the different ERNs.

The EC explained that the practical steps that will follow are:

- 1- The new members will be informed by EC about the approval by the BoMS;
- 2- EC will send to the ERNs the list of new members for the ERNs to verify and correct any information that may be outdated;
- 3- Upon confirmation of the correctness of the data, EC will upload the new members to the Service Directory, which will give them access to ERN tools like CPMS;
- 4- EC will provide a logo to the new members, who will have to sign an agreement with the ERN.

EC alerted the BoMS that they may be contacted by the ERNs to, for instance, confirm the correctness of the names of the new members.

The rules of termination provide that the inclusion of new full members of ERNs may imply the removal of status of Affiliated Partner from the same Member State. The EC showed an overview of the MS that will be affected by the terminations and explained that most of the terminations were due to affiliated partners becoming full members. The termination process should finish within four months after the HCP becomes the full ERN member.

EC explained that the new members will participate in the periodic monitoring exercise. However, since the next collection of data will start on March 2022, it is not expected that all new members participate, but they should participate in the following monitoring exercise.

ES informed EC that there are some mismatches between the real name of an HCP and the name included in the assessment documents. EC invited MSs to inform new members that they can only use the names that they had provided in the application.

## **6. Presentation of the Belgian consortium within ERN EpiCARE**

EC presented a preliminary proposal for the procedure through which consortiums that already have a full member in the ERNs can be created. The procedure could be analogous to the protocol for managing diseases areas within current ERN members, and it could involve the following procedural steps: application to the ERN; endorsement by the MS; assessment or peer-review by the ERN; approval by the BoMS; update of the Service Directory.

EC announced that a proposal for the protocol will be circulated for comments in written procedure.

BE presented the case of an HCP who applied to become full member of an ERN EpiCARE in which another Belgian HCP was already full member. The ERN recommended the applicant to form a consortium with the already existing member. EC explained that as soon as the general protocol is approved by BoMS the application of this consortium within EpiCARE can be submitted for assessment

Some MS expressed preliminary comments on the proposed process. LT raised the concern that this practice may disperse expertise. ES expressed concerns that the formation of a consortium could be perceived as the easy entry point for an HCP that had received a negative opinion from the IAB. EC clarified that the formation of consortiums should be encouraged as this favours the cooperation between HCPs and reinforces the networking within the MS. In the endorsement process MSs play a key role and should take into account whether the HCPs already have regular interactions and fulfil all the requirements.

AT mentioned that there might be a similar case in Austria in which the members of the consortium will be complementing each other. FR commented that the creation of consortiums is a good way forward as it will strengthen the national networks and will prevent the overgrowth of ERN members.

NL asked what the status of the consortium within the ERN would be. BE clarified they have an agreement at the regional level, but that there is no legal framework for a consortium in the ERN environment yet.

## **7. Any Other Business**

The Co-chair informed the BoMS that ERN-CG welcomed the idea of having regular meetings with the BoMS, and that the next meeting between the chairs of the ERN-CG and BoMS will take place in February-March 2022 to discuss the results of the AMEQUIS project. The Co-chair urged MS to be more active in the working groups, and proposed to contact the representatives that are already participating in WG to discuss about any support they may need.

The Co-chair also explained that some Coordinators had raised concerns about the timing of the new 2022 ERN grants. The Co-chair and EC encouraged MS authorities to provide assurances to the ERN coordinators and CEOs of hospitals hosting ERN coordinating centres regarding financial issues and help to ensure continuity of the projects.

LT presented the upcoming Rare Disease Partnership, which intends to join funding and efforts from several parties including MS, EC, and industry. LT commented that for the public-private partnership to surge, it would be necessary that MS rethink the strategy of ERNs with industry, which currently blocks any possibility of financing ERNs by industry. AT proposed to discuss this issue in one of the virtual meetings of the BoMS.

EC explained that it is expected that the EU4Health Work Program 2022 be approved in January and that the first draft has already been sent to the MS Steering Committee.

ES asked how BoMS can contribute to the upcoming evaluation of ERNs that will start in 2022. EC clarified that the evaluation stems from the legal obligation included in the ERN Implementing Decision that mandates the evaluation of the ERN members at least every 5 years. This means that the new members will not be evaluated in this process. The evaluation will be based on the manual that AMEQUIS is preparing. In 2022 a new Independent Evaluation Body will be appointed, who will contact the ERNs informing them of the documents that will be needed for the evaluation. The formal evaluation will start in the second half of 2022 and the final reports are expected to be ready in 2023. EC clarified that the BoMS is only involved at the end of the process, when the results of the evaluation will be presented including either positive assessments or proposals for improvement of ERNs and/or HCPs. The BoMS will have the final word in accepting or rejecting the evaluation reports.

### **Meeting participants:**

**Members:** Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

**European Commission:** DG SANTE

**External companies:** ACSA