



BOARD OF MEMBER STATES ON ERNS

29 JANUARY 2021, 10:00-17:00

VIDEO-CONFERENCING VIA WEBEX

MINUTES

CO-CHAIRS: ANDRZEJ RYS (EUROPEAN COMMISSION) & LENNART CHRISTIANSSON (MEMBER STATES)

Part 1 of the meeting (open also to representatives of ERN Coordinators Group)

1. Welcome, approval of the agenda

The Co-Chairs welcomed all participants and opened the meeting. The Board approved the agenda as proposed.

2. State of play of the assessment process of the applications for ERN membership

The Commission in its general introduction explained that the meeting is taking place in the context of the procedure set out in Article 8(6) of Implementing Decision 2014/287/EC as amended by Implementing Decision 2019/1269/EC. The purpose of the meeting was for the Board of Member States (BoMS) to decide on the reassessment of applications that received negative opinion by the respective board of ERNs and for which reassessment was requested by the competent national authority.

9 competent national competent authorities submitted 27 applications for re-assessment by the Board of Member States. These 27 applications include: 4 (CRANIO), 7 (EpiCARE), 4 (ERNICA), 3 (GENTURIS) 2 (GUARD-HEART), 2 (ReCONNET), 3 (RITA), 1 (ERN-RND), 1 (VASCERN). The Commission informed that the decision shall be taken in accordance with the rules of procedure of the ERN BoMS, either by consensus or by voting. If the BoMS does not decide to issue a favourable opinion the procedure for the application concerned ends with a negative outcome. All the applications for which the BoMS decides to issue a positive opinion will undergo detailed technical assessment by the Independent Assessment Body in accordance with Article 9 of Implementing Decision 2014/287/EC, including on-site audits.

The Implementing Decision 2014/287/EC as amended by Implementing Decision 2019/1269/EC sets out the different steps and actors involved in the assessment procedure. An assessment manual was published in 2019 including a detailed description of the process, formats and forms to be used. Further to this, the Commission launched an IT application for the call and the subsequent steps of the assessment. The respective boards of the networks performed a robust and thorough peer review by the most relevant experts in the thematic field of each ERNs. The review has been done according to the legislation, the instructions contained in the Assessment Manual and the specific criteria for each ERN.

The BoMS was informed on the timeline and state of play. The call was closed on 30 November 2019 and an eligibility check was performed between 15 December 2019 and 31 January 2020. In total 843 applications were received, 623 of which were eligible, 51 applications were withdrawn during the process of assessment. Afterwards the applications were sent to the concerned ERNs for review by the boards of the networks. Due to the COVID-19 crisis, the review process was suspended in April 2020 and resumed on 1 September 2020. The boards of the networks re-started their assessment and provided 627 positive opinions and 136 negative opinions to the applicants. Details were given on the role of the Board of Member States in the assessment process.

3. Assessment of applications by ERNs (boards of networks): General overview and main conclusions

The representatives of the ERN Coordinators Group presented the overview of the assessment of applications by the respective boards of the networks. The ERN Coordinators emphasised the thoroughness of the assessment conducted by the ERN boards and requested that except for cases of purely procedural issues the decisions of the ERN boards should be respected.

Part 2 of the meeting (restricted only to the BoMS members)

4. Requests for BoMS reassessment of applications that received negative opinion by the boards of the networks and BoMS decision

The list of the 27 applications for which BoMS reassessment was requested is provided in Annex 1. Each competent national authority requesting the re-assessment was given the opportunity to present their case. Discussion among the BoMS members followed for each application concerned.

The decision of the BoMS on each application was made in accordance with Article 7 of the BoMS rules of procedure through a vote, using an online voting tool.

During the meeting, Portugal made an additional request for re-assessment of an application. It was decided that the decision on this specific case will be taken in a written procedure after the meeting within the next ten days, provided that Portugal will submit all the required documentation immediately after the meeting. [**Post meeting note:** the result of BoMS decision-making on this additional case is already taken into account in the final list in Annex 2 to these minutes].

The BoMS agreed on the overall outcome of the reassessment. The list of all the applications for which the BoMS decided to issue a positive opinion in accordance with Article 8(6) of Implementing Decision 2014/287/EC as amended by Commission Implementing Decision (EU) 2019/1269 is provided in Annex 2

The next step in the procedure is the assessment by the Independent Assessment Body of all applications that received positive opinion from the respective boards of the networks and also the applications listed in Annex 2 that received positive opinion after the reassessment by the BoMS. The assessment by the Independent Assessment Body will involve also in-depth documentation review and on-site (or remote) audits. The assessment process should be concluded and the new members announced in the second half of 2021, after the final approval by the BoMS.

5. AOB

The BoMS was informed about recent changes in the Commission team dealing with ERNs, including the departure of Enrique Terol who was involved in the process of the creation of the ERNs since the very beginning.

END OF THE MEETING

ANNEXES:

Annex 1 – List of applications for which BoMS reassessment was requested by the competent national authorities

Annex 2 – List of applications for which BoMS issued a positive opinion according to Article 8(6) of Implementing Decision 2014/287/EC as amended by Commission Implementing Decision (EU) 2019/1269