



BOARD OF MEMBER STATES ON ERNS

25 NOVEMBER 2020, 9:00-14:00

VIDEO-CONFERENCING VIA WEBEX

MINUTES

CO-CHAIRS: IOANA GLIGOR (COMMISSION CO-CHAIR) & LENNART CHRISTIANSSON (MEMBER STATES CO-CHAIR)

1. Welcome, approval of the agenda and minutes of past meeting

The Commission Co-Chair welcomed all participants and opened the meeting. The minutes of last meeting were then approved. The Board considered the agenda prepared by the Secretariat and approved it as proposed.

2. Update on EU4Health Programme proposal

An update on the latest development regarding the EU4Health Programme proposal was provided by the Commission. The Commission emphasised that negotiations in the European Parliament and Council are still ongoing and therefore the overall budget for the EU4Health Programme for the period 2021-2027 is still uncertain. The European Reference Networks are among the priorities of the the EU4Health Programme in the Commission proposal and neither the European Parliament nor the Council seem to propose any changes in this respect so far.

3. Update from the ERN Coordinators Group

The Chair of the ERN Coordinators Group presented to the Board recent activities of the networks and outcomes of the internal meeting of the ERN Coordinators Group. ERN coordinators identified 5 areas that they consider to be the main priorities that should be supported in the near future:

- (1) ERN central management: need to increase financial support for the, including change of the 40% co-funding requirement;
- (2) ERN registries: need to ensure sustainable funding for the staff and maintenance of the registries;
- (3) CPMS: need to optimize and simplify the IT tool for virtual consultations;
- (4) Educational and training activities of ERNs: further support should be provided in this area;
- (5) Support for ERN research activities.

With regard to these areas identified by the ERN coordinators the Commission explained that some of these issues are already being addressed (e.g. CPMS improvements), whilst

others will depend on the final outcome of the EU4H negotiations (e.g. change of the co-funding requirement).

4. Enlargement of the Networks – state of play and next steps for the on-going call

The Commission presented the current state of play of the procedure for the enlargement of the existing networks by new members. The assessment of applications by the networks that was suspended due to the Covid-19 crisis was resumed in September 2020 and the boards of the networks have already issued their opinions on most of the applications. At the time of the meeting the boards of the networks issued 637 favourable and 134 unfavourable opinions but assessment of some of the applications was still ongoing.

The Commission also explained that in case of the final negative opinion issued by the board of the network there is a possibility for applicants to contact their competent national authorities to request reassessment of the opinion by the Board of the Member States under Article 8(6) of Implementing Decision 2014/287/EC as amended by Implementing Decision 2019/1269/EC. The Commission summarised the practical procedural steps of the procedure in a document that was sent to the Board on 4 November 2020. The document was presented by the Commission and agreed by the Board.

Once the assessment of the networks, including potential reassessment by the Board of the Member States, is finalised all the successful applications will be submitted for in-depth assessment by the Independent Assessment Body (IAB). The Commission is to sign the contract with the IAB in the coming weeks. Once the IAB concludes the assessment the Board of the Member States will approve the final list of successful applicants. The aim is to finalise the whole exercise of this enlargement in 2021.

5. Managing disease areas within existing Networks

The Commission presented a draft protocol for the management of the coverage of diseases and conditions within the current networks and members. The aim of the protocol is to ensure a dynamic system to address the possible gaps in the existing diseases coverage of the current Networks, to complete these gaps and to assess and validate the expertise of the current members to cover diseases for which they were not initially approved.

The Board was generally positive towards the draft document. After a thorough discussion on the draft protocol the Board agreed that the document will be circulated after the meeting for further comments in writing and should be validated in a written procedure.

6. Potential new European Reference Networks

The Commission presented the current considerations regarding potential future creation of new ERNs in rare and complex disease areas not sufficiently covered by existing ERNs. The presentation included a summary of the gap analysis and state of play for the three disease groups to be potentially considered: rare infectious diseases, rare gynaecological/obstetric/pregnancy related diseases, rare mental diseases or conditions.

The Board members were generally supportive regarding further exploration of the potential extension of the ERN system in these disease areas but requested further

reflection and more information on some of the issues. It was agreed that the Commission would consult the Board members in writing on four specific questions with the deadline of March 2020.

The Commission will also circulate to the Board the previously conducted study on the rare infectious diseases. With regard to the rare mental diseases, the current Joint Action on mental health should be contacted and their expert opinion requested. Based on this input, the issue will be further discussed at the next Board's meeting with the aim to prepare a Board's statement for adoption in autumn 2021. On that basis the Commission will consider potential launch of the new call and its scope.

With regard to the suggestion raised in recent discussions in the EP in the context of EU4Health Programme to create a new "paediatric ERN" most of the Board members disagreed with the idea as the childhood diseases are covered under the current ERNs (structured along diseases). Where specific aspects had to be taken into account, specific ERNs were created (eg on paediatric cancer) or adult and paediatric aspects of the same disease are coordinated separately within the same network.

7. Termination of ERN membership – criteria and procedure

A document on the procedure and criteria for the termination of ERN membership for healthcare providers that are not complying with their obligations is being prepared by the Commission and the ERN Coordinators Group. The Commission presented the state of play and informed the Board that the discussions with the ERN Coordinators Group are still ongoing. Some of the open issues may be clarified during the meeting of coordinators on 27 November 2020 and the Board will be kept informed of the progress and will receive the document once finalised.

8. Integration of ERNs into the health systems of the Member States

The Commission recalled that following the 2019 Board's Statement on the integration of ERNs in national health systems a series of brainstorming meetings took place over the summer with the participation of the Board, the ERN Coordinators Group and the Commission to consider ways forward to support implementation of the recommendations included in that Statement. Organising of a Joint Action was identified as potentially useful instrument.

The state of play was presented by the chair of the ERN Working Group on Integration. The Working Group continues preparatory discussions on potential work areas and deliverables that the future Joint Action may possibly cover. The Commission welcomed the preparatory work but emphasised that any formal process can be launched only once the EU4Health proposal is adopted and there is an approved work programme including the Joint Action within its scope.

The Board was generally supportive for continuation of the preparatory discussions to be taken forward by the Working Group. It was agreed that the next meetings of the Working Group will be open for extended participation by all interested Board and the ERN Coordinators Group in order to ensure broad input on the work areas and deliverables.

9. Monitoring – outcome of the latest data collection exercise

The core set of 18 key performance, structure and outcomes indicators for ERNs have been already identified and agreed. The data collection exercise in the ERNs was carried out in the first semester of 2020 and the main preliminary outcomes were presented.

ERNs are showing an exponential grow in most of the key monitored indicators. The coverage of ERN population is growing with an estimated 1.6 million patients managed or consulted by the ERNs members. There is also an increasing engagement of the ERNs in the research, educational activities and knowledge generation activities. Once the analysis is finalised, it will be shared with the Board.

10. CPMS activity report

The Commission provided update on the state of play of the clinical activity per country that is using the CPMS (ERN IT tool for virtual consultations). The Commission recalled the panels with UK participation should be closed or transferred in view of the Brexit. The Commission informed the Board that it will be possible to provide them an annual report per country or to give them access to a standing report that can be downloaded whenever they want.

11. ERNs IT Advisory Group (ITAG) meeting debrief

The Commission informed the Board about the latest meeting of the ITAG group.

With regard to ERN IT tools in general the Commission explained that Indicators, HCPA (tool for the applications for ERN membership) and Service Directory are stable applications. CPMS is also a stable application but it is undergoing considerable improvements:

- the workflow is being simplified,
- a simple way to invite experts is being analysed
- a mobile app for simplifying some CPMS tasks is under discussion with the ERN community

EC also presented two new tools that are expected for 2021/2022:

- ERN Virtual Academy – a centralized e-learning platform based on Moodle, provisionally planned for 2021.
- ERN Mobile App – a mobile application for Android and iOS, still under discussion with the ERN community, provisionally planned for 2022, to be developed following Open Source principles.

12. Communication – presentation of the Interactive Map

The Commission presented the recently published ERN interactive map with details of all the ERN members and affiliated partners and made a short demo of its features. The interactive map is available at: https://webgate.ec.europa.eu/ernsd/cgi-bin/ern_public.cgi?npage=ern_portal.html#!/

13. European Health Data Space and ERN registries

The Commission presented the state of play of the work on the creation of the European Health Data Space (EHDS). The objective of the European Health Data Space is to provide easier and secure access to health data across borders in order to facilitate better healthcare delivery, better health research and evidence-based decisions of health authorities. The Commission plans to adopt a legislative proposal on the EHDS in 2021 and also to launch in 2021 a pilot project on interoperable infrastructure for the EHDS.

The Commission emphasized the importance of the ERN registries to become an integral part of the EHDS. An issue still to be addressed is what should be the entry point of the ERN registries to the EHDS, in view of their pan-European nature. There was a general interest of the Board Members for the registries to be included in the discussions on the EHDS but specific and targeted discussions still need to be held on particular points, including the governance, data quality and interoperability in the future.

14. ERN Knowledge Generation

a. ERN Strategy on professional training and education

Draft strategy document was prepared by the members of the ERN working group on knowledge generation and presented to the Board during the meeting. The focus of the draft strategy is on two main priorities: (i) develop a model postgraduate rare and complex disease-training curriculum; (ii) develop, in collaboration with patient representatives, and across-ERNs educational program for patient representatives.

The discussion of the Board on the draft strategy was positive and supportive but also recognised the challenges that are related to the implementation of the draft strategy, in particular to the development of training programs, curricula and certification system at the EU level. The draft document will be further improved and submitted again for further review to the Board in writing after the meeting.

b. ERN Virtual Academy project

The Commission informed the Board about this future project for a centralized e-learning platform based on Moodle that is provisionally planned for 2021.

c. Clinical Practice Guidelines Programme

Short update on the ongoing programme for support of development of ERN Clinical Practice Guidelines was presented by the Commission.

15. Any other business

a. Rare 2030 Project

The objectives, state of play and the planned events of the project Rare 2030 supported by the European Parliament were presented to the Board. Many members of the Board or representatives of the ERNs actively participate in the project. The final report with policy recommendations and the final conference are planned for February 2021.

b. Board meetings in 2021

The Board was informed on the tentative meeting dates for 2021:

- 29 April 2021,
- 11 November 2021
- Another Board's meeting during 2021 will be dedicated primarily to the final Board's approval of the new ERN members. The date of this meeting will be announced later.

END OF THE MEETING