



BOARD OF MEMBER STATES ON ERNS

20 NOVEMBER 2018, 13:30-16:30

VENUE: BORSCHETTE, CCAB 3A

Rue Froissart 36, 1040, Etterbeek, Brussels

DRAFT MINUTES

CHAIRS: ANDRZEJ RYS (CHAIR) & TILL VOIGTLAENDER (CO-CHAIR)

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

The Head of Unit of DG SANTE Policy Unit welcomed all participants and opened the meeting. All EU Member States (except Bulgaria and Luxembourg) and Norway were represented.

The Board was reminded that the minutes of the last meeting were approved in written procedure and are publically available on SANTE's website¹.

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

2. Amendment of the Implementing Decision 2014/287/EU and call for new members to join existing Networks (*chair AR*)

The Deputy Head of DG SANTE Policy Unit reported briefly on the process of adoption of the amendment of the 2014 ERN Implementing Decision and on the call for new members to join existing Networks.

The main contents of the current draft aim to clarify the role of Board of Member States in steering the ERNs, to modify the procedure concerning the application for membership of existing ERNs and to add provisions concerning the establishment of the Clinical Patient Management System (CPMS) and rules on co-controllership of personal data in compliance with the General Data Protection Regulation (GDPR). The new text will be discussed at the Cross-border Health Committee (CBHC) on the 18th of December 2018. The amendment is expected to be adopted in the 1st quarter of 2019 and after entry into force, the Commission intends to launch the call for application for membership of exiting ERNs. This should ideally happen mid-2019.

After a brief summary, the Member States asked to receive the new draft before it is discussed in the CBHC. The Commission promised to do so and to share the list of participants to the CBHC, and emphasized that this meeting is organized for discussion of the current proposal and no vote is foreseen.

¹ https://ec.europa.eu/health/sites/health/files/ern/docs/ev_20180626_mi_en.pdf

One member asked if their proposal regarding some changes in the role of the Board in a potential future amendment of the Assessment Manual and in the development of the Evaluation manual, namely a voting role on the final drafts instead of a consultation role only, was taken on board. In its answer the Commission underlined that this idea was only raised at the previous Board meeting, but no formal proposal was made afterwards at the CBHC meeting. Therefore, this matter does not appear in the draft.

As for the network specific criteria, one Member of the Board inquired about the state of play of the comprehensive summary table the Commission circulated in October 2018. The Commission explained that two comments were made by the Network Coordinators: one by ERN Transplant-Child asking for the addition of details which would give further technical explanation, the other by ERN ReCONNET with the aim to reduce the threshold in relation to a very specific illness based on the advice of their Steering Committee. That adjustment would allow more health care providers to join ERN ReCONNET, however at the same time would preserve the level of expertise required to join this ERN. It was decided that the first change was to be implemented while the other would require the agreement of the Board following further explanations from the Network.

3. Affiliated Partners (*chair AR*)

Chair AR, DG SANTE B Director B explained that all elements needed for the identification and designation of Affiliated Partners are at the disposal of the Member States. These include:

- 2016 Statement on Affiliated Partners²;
- 2017 Statement on the definition and minimum recommended criteria for Affiliated Partners³;
- 2018 Statement on the timeline for designation of Affiliated Partners⁴;
- 2018 Rules for termination of Affiliated Partners⁵;
- a comprehensive table on the Network specific criteria.

The Deputy Head of DG SANTE Policy Unit presented the template for the designation of Affiliated Partners that the Commission is proposing, at Member States' request, in agreement with the Working Group on Affiliated Partners, hoping that such model could help and ease the designation process for the Member States and the Networks.

The Member States, of course, remain free to use or not such template. The Member States also remain free to add any national specific content to the templates, if needed.

It was agreed that it is important to provide to the Coordinators a minimum level of information to ease the process of integration. Based on a Member State's proposal the annexes will be slightly amended so as to clarify that the Networks can request further information from the designated Affiliated Partner. As for the timeline is concerned, it was agreed that the deadline for the designation, initially set for December 2018, will be extended till the next Call for new Members.

² https://ec.europa.eu/health/sites/health/files/ern/docs/boms_strategicview_affiliatedpartners_en.pdf

³ https://ec.europa.eu/health/sites/health/files/ern/docs/boms_affiliated_partners_en.pdf

⁴ https://ec.europa.eu/health/sites/health/files/ern/docs/2018_statementtimeline_ap_en.pdf

⁵ https://ec.europa.eu/health/sites/health/files/ern/docs/2018_rulestermination_ap_en.pdf

4. Preparedness actions to UK withdrawal from the EU (*chair AR*)

Chair AR provided the information on preparedness actions for the withdrawal of the United Kingdom from the European Union.

He reminded that the UK withdrawal, announced for 29 March 2019, will essentially mean that the British hospitals which are currently ERN members will stop being members of these Networks and that in particular the 6 ERN with British Coordinating Members, in ERN EpiCARE, ERN eUROGEN, ERN ITHACA, ERN EURO-NMD, ERN RARE-LIVER, ERN RITA, will stop being Coordinating Members, thus not being eligible for EU funding. Therefore, in case of a ‘no deal scenario’, on 29 March 2019, if no precaution measures are taken, the 6 ERNs would risk ending up without a Coordinating Member and without EU funding.

At this stage, the Commission has no certainty that a withdrawal agreement, which will define a transition period during which the UK hospitals will continue being members of the ENRs, will be reached before 29 March, signed and ratified by the EU and the UK. For this reason, to guarantee business continuity and financial stability of the Networks, in their interest and in the patients’ interest, the Commission has been investigating together with the UK Coordinators appropriate solutions that could minimise the disruptions that a ‘no-deal scenario’ would create. Following these exchanges, the 6 British Coordinators took the decision to step down as the Network Coordinators. All Networks have already identified their successors and have sent a designation letter to the Commission nominating the new Coordinating Members and new Coordinators. Out of the 6 new Coordinating Members, 3 are French, 2 are Dutch, and 1 is German.

The new Coordinating Members are:

- **ERN EpiCARE** - Centre Hospitalier Universitaire de Lyon, CHU Lyon, FR;
- **ERN eUROGEN** - Radboud University Medical Center Nijmegen, NL;
- **ERN ITHACA** - Assistance Publique - Hôpitaux de Paris - Hôpital Robert-Debré, Paris, FR;
- **ERN EURO-NMD** - Assistance Publique - Hôpitaux de Paris - Hôpital La Pitié-Salpêtrière, Paris, **FR**;
- **ERN RARE-LIVER** - Universitätsklinikum Hamburg-Eppendorf, DE;
- **ERN RITA** - University Medical Center Utrecht, NL.

The Commission underlined its appreciation to the UK Coordinators for the sense of responsibility and dedication that they have shown towards the Networks.

It was agreed the Board will send a thanking letter to the former UK Coordinators. Several Member States expressed their regret for the loss of expertise that the UK withdrawal from the EU will trigger in the ENRs. One Member State complained that the Health Program 2017 Grants, which will terminate in February 2019, will not be immediately transferred to the new Coordinators. Some Member States expressed their regret that the current reshuffling will not lead to a more equal distribution of Coordinating Members across the Member States.

5. Working Group activities (*chair TV*)

a. Working Group on Integration

The Chair of the WG on Integration, briefed the Board on the latest developments in the WG.

It was underlined that additional members from both the Board and the ERN-CG are needed to have a better representation in terms of diversity of the health systems. At present small, Nordic and underrepresented (in terms of ERNs) countries are missing from the Working Group. A call for new members to join the WG was launched.

Further, it was recalled that based on the position paper from last June, the WG made a prioritisation among the 6 areas of intervention. Referral procedures and patient pathways are now the first priority for the WG to have an enhanced picture of how patient's cases arrive to ERNs. Collection of best practices to share and learn from each other is ongoing. A call for providing best practice examples was made.

The 4th ERN Conference and an informal meeting with health attachés are the two forthcoming dissemination activities of the WG. Lastly, the Opinion on the Application of the ERN model outside the rare diseases⁶ by the Expert Panel on Effective ways of Investing in Health was mentioned as the integration of ERNs into the national systems was identified in the Opinion as a prerequisite for the ERN system's effectiveness.

In the discussion following the presentation one member underlined the need to reflect on the criteria to be met for a patient's case to be eligible for referral to each Network.

b. Working Group on Ethical & Legal issues, relations with Stakeholders

The co-chair of the WG Ethical & Legal issues, relations with Stakeholders, FI representative of the Board briefed the Board on the latest developments in the WG.

It was recalled that at the last Board meeting it had been decided to merge the "old" BoMS WG on Industry (in which FI, ES, FR, IE, IT, UK were represented) with the ERN CG WG dealing with Ethical, Legal & relations with Stakeholders. This happened over summer 2018. The merged WG is co-chaired by the FI representative of the Board and since 1 October 2018 by the Coordinator of MetabERN.

The first priority of the merged WG, based on a request from the ERN-CG, is to update the Board statement on ERNs & Industry adopted in November 2016 prior to the approval of the first 24 Networks. The aim of the update is to clarify which activities are allowed (or not) for industry (or private) support and possibly to allow for the exploration of "joint" funding mechanisms where several private partners could jointly support one (or even several) ERN(s). The WG has prepared a draft proposal and agreed on each of the proposed changes except to the paragraph related to funding. The draft was shared with all Board members on 26 October 2018 with the request to provide written feedback

⁶ https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/021_erns_en.pdf

until the present Board meeting of 20 November. Only one Member State (SE) provided comments, thus the request to provide comments was expanded until 10 December 2018.

Further priorities of the WG are:

- Policy document on “Managing conflict of Interest”. This is under finalisation and will be sent for approval to the Board and ERN-CG given its importance.
- “Disclosure form” for conflicts of interest. Also under finalisation. The ERN-CG requested a digital system to disclose interests. For DG SANTE to organise internally or using EMA system. The form will be sent for approval to the Board and ECG-CG.
- Code of Conduct. The list of models is available. To be developed once the other priorities are finalised.

In the discussion followed by the presentation some Member States noted that the proposed amendment of the Statement was still not clear. The expression “initiatives”, as well as, the role of umbrella-type of industry partners need further clarification. It was mentioned that stating what cannot be funded by the industry could be a solution. One member also proposed to share alternative models that allow industry funding with full independence.

Lastly, Board members were reminded to provide written feedback on the Board Statement on ERNs & Industry by 10 December 2018.

c. Working Group on Research

The LT representative of the Board in the WG on Research, gave a short overview of the recent developments.

A call to reinforce the Board representation in the WG to help steering the process and formulating a common ERN research strategy was made. So far only two representatives of the Board (FR and LT) are involved in that WG.

The Commission is financing a contractor who is preparing a survey on ERN research capabilities. A Workshop will be organised at DG SANTE on 24 January 2019, where the results of the survey will be presented and discussed and first elements of a common research strategy will be proposed. Also, the WG is about to establish “sub-groups” to target specific objectives, on specific topics of interests (for example on clinical trials, registries, etc.). The organization of a meeting with the ERICs in the life science field is ongoing to define collaboration with ERNs. Lastly, the European Joint Program on Rare Diseases (EJP RD) was mentioned where 2 Coordinators represent ERNs in the EJP RD Operational Group. The official start of EJP RD is on the 1st of January 2019 and the kick-off-meeting is on 6th and 7th of December 2018 during the IRDiRC Consortium Assembly meeting.

d. Working Group on ERN Monitoring

The co-chair of the Board briefly informed the Board of the last developments of the work done by the WG.

It was noted that the proposal of a Core Set of ERN indicators was approved in written procedure in September 2018. The WG met twice in September and October 2018 to discuss the approach and the next steps for the implementation for the data collection exercise. DG SANTE IT unit has worked in the development of a web based IT system

for the collection of data that has been tested with the data provided by the ERN Eurogen in October 2018.

e. Working Group on Knowledge Generation

The co-chair of the Board briefly informed the Board of the last developments of the work done by the WG.

The WG on Knowledge generation, following the agreement on 26 June 2018, was relaunched integrating the previous members of the ERN-CG and new members appointed by the Board.

The integrated WG is currently composed by 3 Member States representatives and 12 ERNs. The Coordinator of MetabERN and the Hungarian representative of the Board have been appointed as co-Speakers of the WG.

The WG met virtually three times since the last meeting of the Board and developed an intensive work by mail including two surveys on the priorities for the EU support (through the Health Program) to the Clinical Practice Guidelines (CPGs) development and on the priorities for the newly created subgroup on eTraining / eEducation. The outcome of the survey on the priorities and objectives on CPGs to be supported by the Health Programme have been taken in account in the recently published Terms of Reference for the Health Programme Call for Tender⁷.

Further, the WG has been actively involved in the first steps of the “Taxonomy” project financed by the Health Programme. The taxonomy contract was awarded in August 2018 to the contractor Optimity.

6. Communication (chair TV)

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

The Commission is proposing two waves of dissemination.

Wave 1 (for the first semester of 2019) is planned to address healthcare providers and patients. To support this, the 2017 communication toolkit, composed of the general ERN video clip, 5 video reportages, the general flyer and a brochure is already available. A new toolkit specifically addressing patients and their health professionals will be made available after the ERN Conference. It will be composed of a new video clip, a flyer, a poster and a dedicated webpage on Europa (English version available by end 2018, all other languages in early 2019).

In Wave 2 (second semester 2019) new video reportages and an updated brochure are foreseen, and will complement the dissemination of wave 1.

⁷https://ted.europa.eu/TED/notice/udl?uri=TED:NOTICE:509273-2018:HTML:EN:HTML&tabId=1&tabLang=en&ticket=ST-17031096-rxK7x230W8G3RyXprD32Z5M9mPY9bK3JBxNJZN5eGJRig0843Pdp9Z0in9xJw6xMMblywTIZTv_dWGS2j6GQsW-Jj71zxYb8yr9zi19ofa9jzm-XgpXsizix1U9yfLFFM0hdq6KIN5aN3Hf6kfvQoeR6Zg

In the following weeks the new toolkit will be finalised and shared with the whole ERN community.

At the same time, national dissemination plans need to be elaborated. DG SANTE will involve the informal advisory group on communication as a first step to see how best to involve all the actors of the ERN community, and will then go back to the ERNs, BoMS, patients' organisations to help set up such dissemination plans. Dissemination activities in Member States are expected to be launched from February 2019.

7. Feedback on the activities of the ERN Coordinators Group (*chair TV*)

The Chair of the ERN-CG presented a mapping of the geographic and substance gaps of the Networks, as seen by the coordinators, in view of the Call for new membership that would be launched in 2019 and could help addressing the current disparities across the Networks.

This mapping exercise was done in advance to the new Call with the aim to mitigate current inequalities and also to prevent “over-flooding” of existing Networks, and thus jeopardise ERNs operability.

The mapping identifies the approximate number of additional centres needed per ERNs. Information will be sent to each Member State which, however, remain free to decide. The methodology with all disclaimers was presented.

In the discussion some Member States underlined that the methodology does not take into account all details, it also does not distinguish between paediatric and adult care. One Member State underlined the importance to have the same criteria as for the previous call.

Finally, answering to a request of increasing the Commission financing, DG SANTE B Director reminded the joint responsibility between the Commission and all the other stakeholders towards the Networks and called for a greater commitment of the Member States in the integration of the Networks in the national healthcare systems.

8. AOB (*chair TV*)

The Chair informed the members that the next Board meeting date is 26 March 2019 (Brussels).

END OF THE MEETING