



BOARD OF MEMBER STATES ON ERNS

20 JUNE 2017, 10:00-15:30

VENUE: CCAB 1D

Centre Albert Borschette, rue Froissart 36, 1040 Brussels, room AB-1D

FINAL MINUTES

Chairs: Andrzej Rys (AR) & Till Voigtländer (TV)

1. Welcome, approval of the agenda and of past meeting minutes *(Chair AR)*

DG SANTE.B Director Andrzej Rys (AR) welcomed all participants. All EU Member States (except Croatia and Luxembourg, excused) and Norway were represented.

The minutes of the past Board meeting were considered approved. The agenda of the day was also approved.

2. Affiliated Partners *(Greek Board representative, chair of the Working Group)* *(Chair AR)*

The next version of the “Strategic document of the Board of Member States on the definition and minimum recommended criteria for Associated National Centres and Coordination Hubs designated by Member States and their link to European Reference Networks” was circulated to the Board on 20 June 2017.

The aim of the presentation at the Board meeting was to come to a consensus on the advanced and almost agreed final version of the document and start an initial discussion on the Termination of Affiliation, to be included later as a section at the end of the document.

The discussion of the Board firstly focussed on the decision process for the designation of affiliated partners and the respective roles of the Board and ERN Coordinators. One MS expressed particular concerns about the potentially enormous number of Affiliated Partners to join the existing ERNs in the near future, which could seriously affect the work and structure of the Networks.

Following a thorough discussion it was agreed by all MS that the operational ability of the Networks is the highest priority; in line with this a significant majority also agreed that affiliation is in fact an exceptional tool to help patients access the Networks when there is no ERN member in their country. The Board will work in close collaboration with the ERN Coordinators to understand the needs and criteria of the respective ERNs

but will remain the point of reference and make the final decision in case of disagreement or conflict with an ERN Coordinator related with the designation of an Affiliated Partner in a given ERN.

The discussion then focused on the Termination of Affiliation, a very important element so far missing from the paper and not yet agreed in the Board. The Austrian representative of the Working Group presented the reasons for termination of an affiliated membership, the rules and procedures and reporting requirements. Whereas there was an agreement on most of the points, there were two conflicting proposals with regard to the automatic termination of affiliation of an associated partner as soon as a full member of the same Member State enters the ERN:

- 1) The Full Member becomes the new point of entry, and affiliation is terminated.
- 2) In the occasion that the Affiliated Partner and the new Full Member take care for different groups of rare diseases within the thematic area of a given ERN, both should remain in the ERN representing different disease group-specific entry points into the ERN.

The EC, asked by the co-Chair to provide a legal opinion, argued that in line with Recital 14 of the Commission delegated decision of 10 March 2014, the Affiliated Partner is meant to address a specific situation of need: the lack of Member (the text reads as follows: "*Member States with no Member of a given Network may decide to designate a healthcare provider with a special link to a given Network*"). Evidently, from the moment there is a new healthcare provider from that Member State joining the ERN as full member the situation of need ceases to exist. The EC noted that even if the Recital doesn't explicitly say what shall happen to a designated partner in case a healthcare provider from the same Member States becomes Member of the Network, according to their understanding of the legal provisions, at the moment in which the situation of need which justified the presence of a designated partner ceases to exist, the affiliated partner shall leave the Network.

Several Board members agreed with this reading, highlighting the need to maintain an integrated approach to the Network area of expertise through the approved members. An effective national organization of the referrals and national patient pathways should ensure that all needs and patients related with a given area of expertise of a Network should be channeled through the approved members.

The Austrian member, supported by some others, pointed instead to the interest of keeping affiliated partners in the Networks even after a full Member is approved when this is justified by different types of expertise, since – depending on the structure of the national healthcare system – this strategy would make it at least far easier for patients affected by rare diseases from different disease groups, all covered within the scope of the same ERN, to benefit from the combined expertise of the Network in a similar way.

The Board of Member States shall take a decision on the procedural rules related with the Affiliated Partners which reflects the intentions of the legislator. It was mentioned that the text included in the statement should be in line with the legal provision and in

particular regarding the use of the term "centres of expertise". Following an EC proposal, it was agreed to substitute "centers of expertise" by "healthcare providers".

The Working Group will finalise the strategic document based on the comments of the Board and the information with regards to the legislation and circulate the new version in the following two weeks to then have an approval via written procedure as originally foreseen.

Actions: a) Work on the text to adapt the terminology of "centres of expertise" to "Healthcare provider" as established in the ERN legal acts. b) WG to circulate new version of the strategic document in the next two weeks

3. Monitoring and assessment of ERNs (DG SANTE B3, Austrian Board representative, chair of the Working Group) (Chair AR)

The EC presented the draft proposal on the continuous monitoring and assessment of ERNs and provided feedback from the RD-Action workshop of 1 and 2 June in Newcastle.

In order to achieve a solid and valid ERN monitoring and assessment system, three complementary dimensions need to be taken into account:

1. continuous monitoring, through Key Performance Indicators
2. periodical self-assessment and reporting of the ERNs and Healthcare providers (HCPs),
3. strong involvement of Member States in the assessment.

While the Board of Member States is welcome to provide useful inputs on all these dimensions, it is certainly expected to deliver on the third dimension: "strong involvement of Member States in the assessment", for example by verifying that the different thresholds clearly defined in the Assessment Manual are met by the HCPs nationally or by performing on-site visits to their respective HCPs.

The ERN Coordinators have already set up a working group on the Continuous Monitoring process, led by the ERN eUROGEN's Coordinator, currently discussing indicators. The EC proposed that the Working Group of the Board starts working closely with the Coordinators' Working Group and advised that the group should not only focus on the strategic thinking regarding the size of Networks but should develop concrete thinking on how to actively participate in the monitoring process.

This was followed by a presentation of the views of the Working Group of the Board, closely reflecting the EC's proposal. The Board Working Group will support the Coordinators' Working Group in the development of meaningful indicators and develop a common strategic understanding of the role of full members.

With regards to the further re-assessment by the IAB of the approved HCP not assessed in the initial process (Sampling process), the Chair (AR) proposed to see the results of

the second assessment and to reflect whether the sampling process still makes sense. The Chair suggested shifting focus on new-comers, and on the resources to assess them.

A short discussion took place on the consequences for an HCP of not meeting the criteria and on what should occur if the result of the assessment of an HCP is negative. It was proposed that, in case of negative report, the Board should be responsible for taking a decision on that HCP. The Board agreed with this approach.

A joint meeting involving both Working Groups is scheduled for October 2017 and communication will be maintained through electronic means and web conferences.

Action: Exchange of information, web conferences and Joint meeting of the two groups to take place in October 2017.

4. Working Group on Industry (*Finnish Board representative, chair of the Working Group*) (*Chair TV*)

In November 2016, under lead from the Finnish Board representative, the Working Group (IE, ES, IT, UK, FR) elaborated a statement on the relationship of ERNs with the Industry, which is publically available on the Commission's website. The chair of the Working Group reminded the Board of that statement and opened a discussion on the possible next steps, following the approval of the ERNs and the new questions emerging from the ERN activities. Furthermore, it was confirmed that the statement will also apply to Affiliated Partners.

The Board was also informed that the ERN Coordinators are setting up a Working Group on ethics which will address the "conflict of interest" policy of the ERNs, led by ERN GENTURIS's Coordinator. The Working Group will produce a draft proposal of conflict of interest policy to be discussed in October in the next meeting of the ERN-CG and the ERN Board. Further to this, the RD-Action is organising a workshop on this specific topic. Dates and programme will be agreed with the RD-Action coordinators.

Following a short discussion, the Board confirmed the intention to help and guide the ERNs in developing their strategy and agreed to participate to the workshop as well as to future discussions on the topic.

Finally, the chair of the Working Group welcomed the participation from new countries to the Working Group. A special request was made to central European Board members that are not represented at the moment. All experts interested to participate should contact the Working Group chair.

Actions: a) Agreement and coordination with the RD-Action on the dates and content of the Workshop; b) Board members interested to join the WG on Industry to contact the Working Group chair.

5. Information on the preparations for the call for new ERN members to join existing Networks (DG SANTE B3) (Chair TV)

The EC briefly presented to the Board the plans for the call for new ERN members to join existing Networks. The call will be announced in December 2017, launched in March 2018 and remain open until June 2018. The general rules and procedures of the call will be similar to the first call for ERNs. The forms and application process will be improved and clarified taken in account the lesson learned from the previous call for ERNs.

Two Board members expressed concerns about the burden of this procedure both for the Member States and ERN Coordinators and suggested to reduce the burden by providing useful information to the interested HCPs on the features of each Network, namely: the areas and sub-areas they are covering, the thresholds, the minimum criteria to join and their annual commitments. This would also be useful for Affiliated Partners.

The EC specified that the ERN Coordinators will keep a key role in this process.

*Actions: a) Preparation and update of the forms and procedures of the Call
b) Publication of the main criteria and thresholds established by the ERNs in cooperation with the ERNs Coordinators*

6. Information on EU funding (Chair AR)

The EC provided feedback on

- the grants for Coordinators of approved ERNs (SGAs) and for patient registries (CHAFEA excused)

On 20 June 2017, the state of play was:

- FPAs: all 23 are signed.
- SGAs: 20 are signed, 2 are with ERN Coordinators, 1 is with CHAFEA for a check on technical and financial specifications. These grants will be retroactive as of 1 March 2017.
- other activities under the EU Health Programme for 2017-2018

The overall budget that Member States have attributed to the ERN project is more than 6 million euros. This will notably finance the assessment of a sample of HCPs already approved and the assessment of new members. There is also budget for the 4th ERN Conference scheduled for October 2018. Funds will also be available through calls for tenders on:

- ERN training programmes and seminars,
- knowledge transfer to patients and
- technical support for the functioning of the ERNs.

- Research activities

DG RTD and DG SANTE gave a joint presentation on the European Joint Programme Co-fund on Rare Diseases (EJP-RD), to be included as a topic in the H2020 Work Programme 2018-2020. Preparations for launching the EJP-RD are underway, with several meetings with Member States representatives taking place since October 2016.

EJP-RD explicitly recognises the ERN role to provide the link between research and clinical practice and to identify research needs from an end-user perspective, to take up of research in clinical settings and to provide a feedback loop "from bedside to patient". The French Ministry of Research, leading the EJP-RD initiative, hosted a workshop in Paris on 15 June including representatives from 12 ERNs and 3 Board representatives (CZ, LT, UK) to refine the scope and develop details of the three proposed pillars of the EJP- RD: 1) research funding, 2) data & information and 3) capacity building (and strategy & coordination).

The ERNs have demonstrated a high interest in this topic that will be discussed in the newly established ERN Coordinator Working Group on Research. Through this Working Group, DG SANTE has strongly encouraged ERNs to develop a collaborative approach to their participation in the EJP.

Board members suggested to start a discussion with ERN Coordinators on the legal entity of the Networks as this may influence the ability of the ERNs to receive funding for research projects in the future as opposed to specific ERN member healthcare providers.

- INEA Call

The CEF call was launched on 6 May 2017 including 3 million EUR, so approx. 125000 EUR funding for provision of IT technical support per ERN (i.e. helpdesk) to support ERN IT operations (collaborative and clinical patient management platforms) for a duration of 12 months. The EC will support ERNs in their application by providing a generic application template, to be completed and adapted by each ERN.

7. ERN IT Platform and related activities: update on the developments (DG SANTE A4) (Chair AR)

The Chair introduced the session by informing the Board that, at that same moment, the ERN Coordinators were having a training session on the Clinical Patient Management Platform (CPMS).

The presentation by SANTE A4 covered both IT tools delivered to ERNs:

- the ERN collaborative platform (ECP)
- the CPMS, for which a short demo was shown,

and provided some feedback on the IT Advisory Board meeting of 7 June.

The ECP, already in use, aims to support ERN collaboration activities: online communication, document management, event organisation – but is not foreseen for the exchange of clinical patient data. Since its launch, there is a steady increase of users registered and posts uploaded.

A new feature is now being provided: a videoconferencing tool (WebEx) to allow ERNs to schedule online meetings. ERN Coordinators have also requested a more specific document management tool, to be implemented within the ECP.

The CPMS is built according to the clinical needs of ERNs and is the official tool for diagnosis and treatment of patients through a virtual consultation system. It also provides a Glossary of Terms and a Patient Workflow. The rollout steps are as follow:

- contractual acceptance testing in July 2017,
- piloting with ERNs to assess the fit-for-purpose tool until Data Protection Notification has been approved by the DPO,
- feedback integration,
- final decision on deployment date.

8. Member States and ERNs: State of play at National level (*members of the Board, summary DG SANTE B3*) (*Chair TV*)

Since the Board meeting of September 2016, Board members were asked to report on these three questions, which are fundamental to provide support to the ERNs once approved and running:

1.	How MS are addressing the link of the national networks or highly specialised centres to the ERNs?
2.	How MS are envisaging the connection/case management of patient cases to be presented to the ERNs?
3.	How MS are addressing the support to the Network Coordinators or members?

To this day, 20 contributions have been received (CY, CZ, DE, DK, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, NO, PT, SK, SE, UK).

There are two lines to be taken into account in this discussion. First, the direct support of Member States to ERN Coordinators and members (through, for example, coordination activities of the Ministries of Health or in kind contributions) and second, the national coordination and referral process to the ERN members.

With ERNs now being a reality, and more questions being raised by the patients and citizens, the EC made a proposal to the Board to reflect on the two lines above and update their fiches on the public website: (http://ec.europa.eu/health/ern/board_member_states_en) as the current information needs to be completed by a number of Member States (AT, IT, LV, LUX, CZ, EE, RO and FR) and updated by most of them. Board members should contact the ERN team in the EC with the text to be uploaded.

This was followed by national presentations from HU, NL and NO.

One Board representative raised the issue that some Member States with many ERN coordinating centres currently face. Although it is fine to have many ERN Coordinators within the country, these Member States are spending a lot of resources to support the activities of these ERNs. Since this is a European operation that benefits all European patients, it is only fair that all countries should participate to the costs of these operations that do not only fall under the responsibility of the coordinating country. This is a complicated matter that requires further attention.

Action: Board members to send their national procedures or updated fiches to the ERN team

09. Presentation on the reimbursement mechanisms under the CBHC Directive

This point was not addressed during the meeting due to time constraints but the presentation will be shared with the Board.

10. Update on communication strategies and tools regarding ERNs (DG SANTE 02) (Chair TV)

The representative of the Communication Unit in DG SANTE (DG SANTE 02) presented the newest tools developed and the communication strategies foreseen for ERNs. He reminded the Board that although the EC will provide all the necessary support and tools, the ERN communication is a joint effort involving all the players.

At present, the idea is to move towards a tailor-made, national focused communication campaign. New tools have recently been added to the communication toolkit (http://ec.europa.eu/health/ern/toolkit_en) for this purpose: guidelines for online communication as well as translated versions of the ERN brochure and factsheet in all languages.

The latest communication product developed is a series of 5 videos, featuring the real-life stories of the ERNs. These videos, set in four different European Countries (IT, NL, ES, FR) follow four different patients through their journey and focus on four different angles of the ERN activities (http://ec.europa.eu/health/ern/videos_en).

The representative of DG SANTE 02 thanked all Board members for the contributions in designing the next steps of the communications strategy. The main information gap, as identified by members of the Boards, is about how patients can access the Networks. With the help of ERN Coordinators and Board members, DG SANTE 02 is currently in the process of mapping useful and relevant multipliers (professional associations, national health authorities, expert centres) and upcoming outreach events in the Member States, to spread the stories of ERN at national level. Board members are invited to send additional suggestions for multipliers or events in their countries in the coming months.

The Lithuanian Board representative suggested establishing a Working Group on communication strategy, which was welcomed by the EC. Members interested to participate should communicate their interest with the rest of the Board in the next 2 weeks.

Actions: a) Board members interested to create a WG on Communication strategy to share their interest with the rest of the Board in the next two weeks. b) Board members to send additional suggestions for multipliers or planned outreach events/communication opportunities in their country.

11. Any Other Business (Chair AR)

- Next Board meeting is foreseen for 10 October 2017 in Brussels, back-to-back with a meeting of the ERN Coordinators' Group (ECG).

END OF THE MEETING