



Brussels, 2 June 2017

## **BOARD OF MEMBER STATES ON ERNS**

**8 MARCH 2017, 14:00-17:00**

**VENUE: Santariskiu str. 2, Vilnius**

**(Vilnius University Santariskiu Clinics, auditorium)**

### **DRAFT MINUTES**

**Chairs: Andrzej Rys (AR) & co-chair (MS) to be elected**

#### **1. Welcome and election of the co-chair (*Chair AR*)**

SANTE Director B. Andrzej Rys (AR) welcomed all participants. All Member States (except Cyprus, Estonia and Romania, excused) and Norway were represented.

Since the mandate of the co-chair of the Board representing Member States expired in December 2016, after two years, the Board had decided at the previous Board meeting in December to proceed with elections at the next physical meeting of the Board in March 2017. The previous co-chair, Till Voigtländer (Austrian representative), expressed his interest in continuing as co-chair, no other Board member expressed his interest. Till Voigtländer (TV) was unanimously re-elected as co-chair of the Board.

#### **2. Approval of the agenda and of past meeting minutes (*Chairs*)**

Minutes of the past Board meeting were considered approved<sup>1</sup>.

The agenda of the day was also approved, with the following points to be addressed under AOB (if time allows): a) Update on Research at EU level, b) "Structured cooperation in highly specialised healthcare" (Maltese presentation), c) Supporting to the financing of ERN activities, d) Establishment of a group of ERN Coordinators, e) Update on the PWC study funded under the EU Health Programme for ERNs, f) Network agreement, g) ERN Logo, h) JRC Workshop on registries (Luxembourg, 30 Nov.), i) update on activities on the field of Rare diseases at EU level.

#### **3. Information on the outcomes of the assessment process on the first call for ERNs (*DG SANTE B3*) (*Chair TV*)**

DG SANTE briefly updated the Board on the outcomes of the assessment process of the first call for ERNs in 2016:

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<sup>1</sup> [https://ec.europa.eu/health/ern/events\\_en#anchor0](https://ec.europa.eu/health/ern/events_en#anchor0)

1) first wave with 23 ERNs positively assessed by the Independent Assessment Body (IAB) in Sept.-Nov. 2016 and approved by the Board on 15 December 2016;

2) second wave with 24<sup>th</sup> ERN (ERN eUROGEN) positively assessed until January 2017 by the IAB and approved by the Board via written procedure in February 2017.

The list of the 24 approved ERNs from this 2016 call is publicly available on Commission's webpage<sup>2</sup>.

All Healthcare providers for which documents were missing etc. (therefore not positively assessed in a first time) did submit complementary information during the timeframe foreseen for review and were afterwards positively assessed.

This update was followed by questions from Board members regarding costs, methodology and quality of work of the two IABs contracted under the Framework Contract.

Finally, answering to questions of Board members, the Chair A. Rys confirmed what was agreed during previous Board meetings regarding the assessment of Healthcare providers already approved (but not yet assessed by IAB): it was jointly agreed and accepted that the Commission would start in 2017 with the assessment of these already approved (but not assessed) providers using the 2017 budget of the EU Health Programme. This confirmation is important for Board members, also to plan the work on other related topics (nomination of Affiliated Partners and new ERN members, monitoring etc.).

#### **4. Feedback on the grant agreements for approved ERNs** (*DG SANTE on behalf of CHAFEA excused*) (*Chair TV*)

23 ERN Coordinators applied in due time, in 2016, for the Framework Partnerships Agreements (FPAs) to be signed for 5 years, FPAs will enable ERNs to receive annual grants (of maximum 200.000 € for each ERN Coordinator) via Single Grant Agreements (SGA) under the EU Health Programme. After approval of these 23 ERNs by the ERN Board of Member States on 15 December 2016, the Evaluation Committee of the EU Health Programme met on 16 December and formally approved this process for the 23 ERNs. The 23 ERN Coordinators then had until 24 January 2017 to send documents for the application of their Network for the agreements. In February, documents submitted were checked and exchanges took place with Coordinators regarding missing information/documents, On 8 March 2017, the state of play was:

- FPAs: 18 were fully signed, 2 were with the ERN coordinator for signature, 3 were with CHAFEA for administrative issues (mainly affiliated entities) to be solved rapidly.
- SGAs were all under review, to take into account the comments made by the evaluators. CHAFEA expected to sign the SGAs before the end of March, with the retroactive date to 1/03/2017. The IT system for finalising and signing SGAs should be operational by 10/03/2017.

SGAs will enable Coordinators to support coordination activities (meetings, but also training etc.). Each ERN Coordinator can propose different activities to be co-funded every year, and SGAs also foresee a reporting mechanism.

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<sup>2</sup> [http://ec.europa.eu/health/ern/networks\\_en](http://ec.europa.eu/health/ern/networks_en)

**5. State of play at National level – tour de table** (*members of the Board, summary DG SANTE B3*) (*Chair AR*)

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 alive (so in 2017):

1.	How MS are addressing the link of the national networks or highly specialised Centres to the future 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 future members?

Based on the 16 contributions received, a state of play was presented in December 2016, along with one national approach (FR) explained by the national representatives. Three additional contributions were sent prior to the Board meeting in March, thus allowing to have a view from 19 Member States (CY, CZ, DE, DK, ES, FI, FR, HR, IE, IT, LT, LV, MT, NL, NO, PT, SK, SE, UK).

On question 1, the “stage of implementation” is split between “done”, “ongoing” and “planned”, thus showing that this is “work in progress”. The formal and informal means proposed to address the link of national networks of highly specialised centres to ERNs are e.g. via the Ministries of Health and/or specific committees at national level; via internal procedures, "orders", legal acts at national level; via the future "national coordination hub"; via Working groups promoting networking, meetings, websites or support to national professional associations.

On question 2, the “stage of implementation” is split between “ongoing” and “planned” (sometimes "not yet discussed"), thus showing that work still needs to be accomplished in this area. Different means envisaged to connect/manage patient cases to be presented to ERNs, among which “usual proceedings”, the Cross-border Healthcare Directive and Regulation 883/2004 (Social Security scheme), internal national procedures / protocols to be put in place at national level, or novelties to be discussed with ERN members in 2017, for example "endorsed expert units", a “specific committee tasked” or the creation of a new post of rare disease / network coordinator.

On question 3, the “stage of implementation” is largely “planned” (from 2017... to 2020), thus highlighting that the work still has to be organised and accomplished, even if sometimes “direct contacts” and “discussions” are already “planned with ERN coordinators / members at national level”. The support to ERN Coordinators or future members is envisaged a.o. via the “Ministry of Health” and/or “national networks supporting with resources” ("share the burden" for ex. on training), via “directors of hospitals” or via the (future) "national coordination hub".

Since 10 contributions are still missing, the Board agreed to ask for them prior to the next Board meeting (and updates from previous answers are also welcome). In addition, more detailed presentations of national approaches would be valuable to discuss and stimulate the exchanges of good practices, therefore Board members are invited to volunteer to present at the next Board meeting in June 2017.

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

The Chair introduced the session by explaining that ERN Coordinators had a presentation of one of the IT-tools (the ERN Collaborative Platform) via a tele-conference organised on 3 February 2017 and a small group ERN coordinators experienced with IT issues will be regularly consulted on the IT platforms. The Board will also be involved in this process, with a few representatives.

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

- the ERN collaborative platform (ECP) (for which a short video was shown).
- the clinical patient management system (CPMS),

It also included information on the ERN websites and the public website.

The ECP will support ERN collaboration activities: online communication, document management, event organisation – but is not foreseen for the exchange of clinical patient data. ERN Coordinators are invited to join the ECP and soon ERN members will be also invited (Coordinators will need to authorise their access).

The CPMS will be provided by a contractor (Software as a Service Contract), it will be built according to the clinical needs of ERNs (already expressed e.g. during workshops of the Joint Action on Rare Diseases in September 2016 or JRC Workshop on registries on 30 Nov. 2016). The delivery of the first version is foreseen for July 2017.

This general presentation and demonstration of the ECP were followed by questions of Board members on the functionalities of the tools to be provided to ERNs, on the timing foreseen for each tool, on the possibility of training sessions to be organised for these tools, on the possible links to registries.

The Chair also explained that to help ERNs and Healthcare providers in this process, forms for “patients’ informed consent” in the specific ERN context would be produced and delivered by the European Commission via a contractor.

## **7. Affiliated partners: presentation of the draft proposed to the Board for validation** (*Greek Board representative, chair of the Working group*) (*Chair TV*)

Documents from the Working group were circulated to the Board on 23 February 2017 and the aim of the presentation at the Board meeting was to reach an agreement on a final statement to be published and communicated outside of the Board (to ERNs and on Commission’s webpage, as for other statements of the Board).

The draft “Strategic document of the Board of Member States on the definition and minimum recommended criteria for Affiliated Partners designated by Member States and their link to European Reference Networks” was presented to the Board and warmly welcomed. Along with general principles for the affiliation process (priority for Affiliated Partners from Member States with no full member in a given ERN, inclusiveness of the affiliation process, fruitful relationship with ERNs etc.), three types of Affiliated Partners were identified and explained, building upon the ERN legislation:

- 1) Associated National Centres (focusing on the provision of healthcare and featuring a specifying link to an individual network),

- 2) Collaborative National Centres (healthcare providers focusing on the production of knowledge and tools to improve the quality of care, again with a specific link to an individual network),
- 3) National Coordination Hubs (option for Member States to link with all types of Networks, not necessarily an Healthcare provider).

The discussion with Board members firstly focussed on the three types of Affiliated Partners and on their respective “minimum recommended criteria for their identification and evaluation in Member States”. After thorough discussion, it was decided that the final statement of the Board would focus for now on “Associated National Centres” and “National Coordination Hubs” (“Collaborative National Centres” would be better defined by Board members at a later stage, after establishing the necessary conceptual framework and learning from the experience of integration of the two first categories into existing Networks).

It was reminded that it is up to the Member States to authorise Affiliated Partners, possibly in good intelligence with ERN Coordinators and following the approach agreed within the Board as well as their national plans/strategies developed so far in the field of rare diseases and ERNs.

The discussion then focused on the timing proposed for the integration of Affiliated Partners into new approved ERNs:

- a. Development of an affiliation strategy (by ERNs and Member States) and identification of Affiliated Partners (by Member States) for the 2<sup>nd</sup> and 3<sup>rd</sup> quarters 2017;
- b. Integration of Affiliated Partners identified and designated on the national level into their respective ERNs for the 4<sup>th</sup> quarter 2017.

This challenging timing meets both expectations of Member States not yet represented in some/all ERNs and of ERNs willing to associate Healthcare providers which did not join/meet the criteria for the 2016 call. In addition, some Board members highlighted the need of thinking to the size of Networks and therefore of possibly limiting access to Affiliated Partners (so that ERNs can start/continue working properly while integrating these new partners) as well as the need to make clear the differences between Affiliated Partners and full members in terms of obligations and rights within the ERNs (to be further discussed within the Board).

This timing is also pre-conditioned by the adoption of this Board statement, after minor adaptations, prior to (or at the latest during) the next Board meeting on 20 June 2017 and due communication to ERNs (to support the development of their affiliation strategies).

Finally, as this question is related to Affiliated Partners and the Board asked for clarification regarding the timing for new full members joining recently approved ERNs, it was proposed that the call for new ERN full members would be announced in December 2017 with deadline for submission until Summer 2018, to enable both inclusiveness and an appropriate time window for applicants to properly apply.

**8. Monitoring and assessment of ERNs: First feedback from the Working group created in December 2016 and established in January 2017 (TV, Austria, chair of the Working group) (Chair AR)**

As agreed during the Board meeting on 15 December 2016, a new Working Group was created within the Board regarding monitoring and assessment of ERNs, building upon Commission's proposal. To achieve a robust ERN monitoring and assessment system, four dimensions need to be taken into account:

1. Continuous monitoring,
2. Periodical self-assessment and reporting of the ERNs and Healthcare providers (HCPs),
3. Strong involvement of Member States in the assessment,
4. Further assessment by the IAB of HCPs not assessed in the initial process (see point 3 of the agenda).

While the Board of Member States is welcome to provide useful inputs on these 4 dimensions, it is certainly expected to deliver on the 3<sup>rd</sup> dimension: "strong involvement of Member States in the assessment" (for example on general criteria for the assessment of HCPs, as clearly defined in the Assessment Manual).

After preliminary email exchanges within the new Working Group prior to the Board meeting, the Chair of the Working Group presented a first outline of his proposal to the Board. This outline would also be presented to ERN Coordinators before the next Board meeting in June 2017, during which an advanced draft would be discussed and possibly approved.

**9. Conference on 9 March and side events (DG SANTE B3) (Chair TV)**

The Commission briefly summarised all events foreseen after this Board meeting on 8 March in Vilnius, e.g. the Kick-off Conference of the ERNs on 9 March 2017 in LitExpo, to be opened by the EU Commissioner for Health and Food Safety Vytenis Andriukaitis, attended by ca. 500 participants and with many speakers involved in the ERN process (ERN Coordinators, patients' representatives and also Board members). Discussions and exchanges of views are expected on the challenges and next steps for ERNs, before the formal Award Ceremony.

On 10 March 2017, each of the 24 approved ERNs will have a room at its disposal for its kick-off meeting with its present members.

**10. Communication strategies and tools regarding ERNs (DG SANTE 02) (Chair TV)**

The representative of the Communication Unit in DG SANTE presented the tools developed for ERNs and the communication strategies foreseen for ERNs, starting with the main ambitions (involve (future) partners, inform beneficiaries, manage expectations and show added value of EU cooperation). The key messages are primarily about what ERNs are, how ERNs work for HCPs and for patients and about their concrete results. Priority target audiences were defined and Member States/National authorities (Board members) are key players in the communication process. Material available was presented (flyers, video clip shown<sup>3</sup>, social media campaign, webpage<sup>4</sup> and the

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<sup>3</sup> <http://ec.europa.eu/avservices/video/player.cfm?sitelang=en&ref=I134312>

communication toolkit<sup>5</sup> prepared specifically for ERNs). These tools and presentation were warmly welcomed by Board members.

## **11. Any Other Business (Chair AR)**

Short updates were provided on different topics:

- Update on EU policies in the field of rare diseases (Expert Group: mandate recently expired, but ongoing Joint Action on Rare diseases will continue to support ERNs, e.g. with different Workshops on interoperability, indicators etc.).

- Update on Research policies at EU level, in particular in the field of rare diseases: plan to launch a European Joint Programme (EJP) Co-fund under Horizon 2020. Indeed the ERNs are expected to have a major structuring effect on research and care by linking centres of expertise through their cooperation. Research and in particular clinical and translational research is a central element of the ERNs. They will help to gather data and expertise on rare diseases and bring research results to the benefit of the patient in terms of diagnosis and treatment options. DG Research (RTD) and DG SANTE work closely with Member States to integrate the role of ERNs in research in a new integrated strategy on research. A first meeting was held in October 2016 with Member States to explore the possibilities and a potentially EJP Cofund action. To follow-up, Member States representatives established a small drafting group to develop the concept, objectives and priorities of a potential new Programme to support the implementation of a research and innovation pipeline from bench to bedside for rare diseases. The FR delegation volunteered to lead the drafting group composed of representatives of 8 countries and the E-Rare consortium and of complementary experts.

These discussions will feed into the preparation of Horizon 2020 Work Programme 2018-2020 for Health, demographic change and wellbeing. Further (audio) meetings are planned in the next months, ERNs Coordinators and Board will be kept informed.

- Update by Maltese Board representative on the Workshop organised under the Maltese Presidency on "Structured cooperation in highly specialised healthcare" a week prior to the Board meeting.

- Supporting to the financing of ERN activities: in addition to previous points (Research, "national approaches" etc.), the Chair of the Board proposed to summarise and map, at the next Board meeting, possible "financing options" such as the Social Security Regulation, and Cross-border healthcare Directive.

- Establishment of a group of ERN Coordinators: the Commission explained that after the official kick-off of ERNs on 8 March, it was proposed to establish an "ERN Coordinators' Group" (ECG). This group would have its first physical meeting in

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<sup>4</sup> <http://ec.europa.eu/health/ern>

<sup>5</sup> [http://ec.europa.eu/health/ern/toolkit\\_en](http://ec.europa.eu/health/ern/toolkit_en)

Brussels end of April 2017 and would meet again in June, back-to back with the next Board meeting (20-21 June 2017, tbc).

- Update on the study funded under the EU Health Programme for ERNs, by PWC: the final report was delivered and shared with Board members, Board members who contributed to this work were thanked.

- Network agreement (formerly called “Consortium agreement”): the draft, developed with the support of a Board member for voluntary use by ERNs, was shared with Board members on 1 March 2017. This proposed draft will also be shared and discussed with ERN Coordinators in April 2017.

- ERN logo: The Commission decision on the use of the ERN logo was adopted on 23 February 2017<sup>6</sup>. Next step is to sign “Licensing agreements” between the European Commission and all 24 ERN Coordinators (once signed, each Coordinator will be entitled to sign “Sublicensing agreements” with its ERN members, draft to be provided by the Commission). In parallel, all extended versions of the logo (for each Network and each Coordinator/member, with the official names confirmed by Board members in Oct.-Nov. 2016) are being prepared by a contractor and will be delivered to each ERN Coordinator, once the Licensing Agreement has been signed.

- JRC Workshop on registries (Luxembourg, 30 Nov.): A final report and conclusions were finalised and shared with participants. It was shared also with ERN Board members.

- Next Board meeting foreseen on 20 June 2017 in Brussels (to be confirmed), back-to-back with a meeting of the ERN Coordinators’ Group (ECG).

END OF THE MEETING

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<sup>6</sup> 2017/C 60/06, Commission Decision of 23 February 2017 as regards the granting of individual licences to all Coordinators of the European Reference Networks to use the European Reference Network trademark