



Brussels, 18 December 2017

BOARD OF MEMBER STATES ON ERNS

10 OCTOBER 2017, 10:00-17:00

VENUE: Permanent Representation of Poland to the EU

rue Stevin 139, 1000 Brussels

MINUTES

Chairs: Andrzej Rys (AR) & Paul Boom (PB)

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

DG SANTE B Director Andrzej Rys welcomed all participants. All EU Member States (except Bulgaria) were represented. The Chair proposed that Paul Boom, representative of the Netherlands, co-chairs the meeting in the absence of Till Voigtlander. In this context, he highlighted the need to amend the Board's Rules of Procedure, notably to clarify how to replace co-chairs in case of absence. The Chair invited Board members to send ideas to the Secretariat in case other issues could also be addressed in the amendment of the Rules.

The Board considered the minutes prepared by the Secretariat and approved them as proposed. The agenda of the day was also approved.

The Chair also draw the Board members' attention to the Cover Notes, a new working tool that the Secretariat is proposing to facilitate the debates in the Board's meetings.

Action: A) for the Secretariat to prepare and propose amendments to the Rules of Procedure B) for Board members to send ideas to the Secretariat in case other issues could also be addressed in the amendment of the Rules of Procedure.

2. Invitation process for new HCPs to join existing ERNs (*Chair AR*)

Andrzej Rys presented the rationale of the procedure envisaged by the Commission to invite new Healthcare Providers (HCPs) to join existing ERNs. He highlighted that such procedure should ensure the high quality of the applications and the enlargement of the existing ERNs to be in line with the development needs of each network. To achieve such an outcome, the Commission proposes that the selection procedure should build on the Network-specific criteria, including the thresholds, developed by each Network in 2016, which should be updated if needed. Moreover, each ERN should prepare a mapping of its development needs. According to the Commission proposal, the Networks should then carry out a pre-assessment of the applications of the HCPs wishing to join

that ERN on the basis of the ERN-specific selection criteria and of the mapping. The Commission specified that to carry out such a procedure some very limited amendments of the 2014 Commission Implementing Decision are needed.

The discussion of the Board focussed on two aspects of the proposed procedure: on one hand on the role of ERNs, on the other hand the selection criteria including the thresholds established by the ERNs.

Several Board members expressed particular concern about the role envisaged for the ERNs. While there was agreement on the need to give a pivotal role to the Networks, for some members it is not acceptable that a HCP endorsed by its Member State could fail to join a Network because of a negative assessment from such Network. One member highlighted that the final decision on membership should remain with the Board of Member States. Some members were in favour of Networks issuing instead opinions on candidatures.

One member echoed the approach presented by the EC while another member considered as unfair the fact that only those HCPs filling existing gaps would be welcomed.

The Chair explained that with the current proposal the EC aims to have clinical excellence assessed by the peers and to reduce the assessment burden on national authorities. He also clarified that already in 2016 only those HCPs which were positively assessed by the Coordinators were considered for membership. The proposed procedure is therefore not granting any new role to the Coordinators and is coherent with the 2016 approach, ensuring equal treatment for all applicants.

With regards to the Network-specific criteria including the thresholds, some Board members underlined the necessity to keep the same criteria as for the 2016 call, fearing that, otherwise, there could be doubts about the consequences that the changes could have on previously selected HCPs. Other Board members considered that the criteria shall be adapted if necessary. Further, the need to publish the criteria was mentioned several times.

The Chair concluded that the criteria and thresholds would be kept the same as for the first call and published before the beginning of the procedure. As for the role of the Networks, the EC will continue to reflect internally and will also assess the need to amend the 2014 Commission Implementing Decision.

Finally, the ERN Coordinators *Position Paper on the 2018 call for new members to existing ERNs* as well as the EURORDIS letter on the *call for New Members of Existing European Reference Networks* (dated 6 October 2017) were distributed to all participants.

Action: a) EC to continue its reflection b) Publication of the Network-specific criteria

3. Integration of ERNs into the national health system of the Member States and referral of patients to the ERNs (Chair AR)

In its presentation the EC identified several issues to be covered in the integration process and invited the Board to broaden the discussion to all these topics:

- a. Integration of the ERNs concept into the current national legal framework, including national plans for rare diseases, cancer, etc.;
- b. National endorsement of HCPs becoming ERN Members;
- c. Support by MSs to ERN Members and ERN Coordinators;
- d. Patients pathways at national level;
- e. Referral of patients to the ERNs;
- f. Reimbursement in case of patient mobility;
- g. Information on ERNs provided at MS level.

This was followed by a presentation of the Lithuanian representative on Rare disease healthcare services in Lithuania.

Lastly, the representative of the Netherlands raised the issue of the legal bases for HCP endorsement at national level and requested Member States to share their experience in this regard.

Following a short discussion, the Chair proposed to create a working group to address all the topics to be covered in the integration process. The Working Group shall make recommendations (potential solutions) to the Board.

The Board noted the creation of the new Working Group to be led by the Dutch representative of the Board and composed of LT, HU, DE, FR, ES, NO members + 1-2 Coordinators + 1 representative of the ERN Coordinators Cross-border Working Group. A first report on activities will be elaborated for the forthcoming meeting of the Board (tentatively taking place in December).

Action: a) set up the Working Group. b) Board members interested to join the Working Group to contact the Working Group Chair. c) prepare for the next meeting a first report on activities.

4. Affiliated Partners: procedure for their nomination and integration into ERNs (Chair AR)

The new 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*” prepared by the Affiliated Partners working group was circulated to the Board on 9 October 2017.

The aim was to agree on a final version of the document.

The Greek representative of the Board, Chair of the Working Group presented the updated version of the Strategic document, which is the outcome of a one-year reflection process of the Board on a more detailed definition and characterization of Associated National Centres and Coordination Hubs and on the procedures to be developed and implemented in order to integrate these new partners into ERNs. She stressed that the work on the definition of a set of minimum recommended criteria was done and that the Working Group had therefore completed its mandate.

It was agreed that both the intended timelines of the affiliation process and the details on the termination procedures will be taken out of the document. The designation time would be discussed in the next Board meeting while the procedures for termination would be defined in due time. The Chair concluded therefore that there was consensus on the document and asked the secretariat to finalise the agreed redrafting of the statement before its publication.

One Board member expressed the wish that the ERN Coordinators Group could produce a "Position Paper" on the process of Affiliated Partners designation.

The Chair put forward two questions for Board members:

- a. By when Member States would be ready to start the Affiliation process?
- b. What is the estimated magnitude / number of potential Affiliated Partners?

Action: a) for the Secretariat to finalise the agreed redrafting and to circulate a new version of the Strategic document before its publication.

5. Financing possibilities of the European Investment Bank (Chair PB)

The representative of the European Investment Bank (EIB) presented the EIB lending activities in the health sector, addressed the eligibility criteria and lastly showed some case studies.

Since 2007, EUR 8.5bn has been invested in the life science sector. Going forward, it is expected that more than EUR 1bn will be invested annually in this sector. The EIB financing can potentially be used to support ERNs and its members' activities. Health infrastructure, innovation, fundamental medical research, medical education and training, integrated care and community involvement and health informatics / eHealth are the areas of intervention in the field of health.

Health sector projects may be supported in the form of individual loans, framework loans or programmes. Both classic procurement and PPP structures are possible. Health sector projects are eligible under EFSI.

6. Feedback on the activities of the ERN Coordinators Group (Chair PB)

The elected Spokesperson of ERN Coordinators Group presented a summary of the activities being carried out by the different ERN working groups, notably by the:

- a. Working Group on IT & data-sharing;

- b. Working Group on Research;
- c. Working Group on Ethics & legal issues;
- d. Working Group on Cross-border healthcare and business continuity;
- e. Working Group on Monitoring & assessment.

For each Working Group the agreed objectives, the progress report, next steps and the needs were addressed.

The EC welcomed the intensive work carried out by the ERNs and the significant progresses achieved. The importance of the continuous interaction between the Board and ERN Coordinators and their respective working groups was also underlined, just like the necessity to avoid overlaps with the working groups of the Board.

The Spokesperson, asked by a member of the Board, listed the following areas being of particular concern in the immediate future:

- a. Integration of ERNs into the national health system of the Member States. A draft strategy is being prepared.
- b. Need to define a legal entity for the ERNs.
- c. Sustainability of the project.
- d. Sustainability in relation to orphan drugs.

In response to further questions, the Spokesperson argued that in the next call for new healthcare providers to join existing ERNs the active participation of the Networks is essential to make use of their knowledge / expertise. This could materialise, for example, in the elaboration of a "map of needs". Furthermore, it was stated that ERNs need "ambassadors" as they are highly dependent on Member States' politics.

7. Relations between Industry and ERNs (*Chair PB*)

The Chair of the Working Group on Industry updated the Board representatives on the state of play of the activities carried out so far and put some questions on the table.

Already in November 2016 the Working Group on Industry (FI (Chair), EL, ES, IT, UK, FR) elaborated a Statement on the relationship of ERNs with the Industry, which was published on the Commission's website. At the last meeting the Board decided to continue this work and to strengthen the Working Group by adding more members to it. The question on how to best collaborate with the ERN Coordinators Working Group on Ethics & legal issues was also raised.

The Chair of this Working Group informed the Board about its draft policy paper on managing Conflict of Interests circulated to the Board on 6 October 2017. The document includes a number of questions to be answered, for example:

- a. How does this policy relate to the COI procedures HCP professionals already follow?
- b. Who needs to disclose?

- c. Who is overseeing? What are the roles of ERN Coordinators, DG SANTE and the Board?
- d. To whom will be reported (Internal, External)?
- e. Who will evaluate and on what criteria?
- f. Who will do the management?

After finalising the draft Conflict of Interest policy paper the Working Group will start preparing a draft Code of Conduct.

The EC underlined that the Board Working Group on Industry was set up with the objective to establish principles. As for the ERN Working Group on Ethics & legal issues the EC suggested that the Board should analyse its draft Code of Conduct, even if not necessarily endorse it.

The Co-chair suggested looking into already existing protocols, guidelines of professional organisations. In her response, the Chair of the ERN Working Group on Ethics & legal issues confirmed that they have already done so.

8. IT: update of progress and outlook of 2018 planning (Chair PB)

The representative of the IT Unit in DG SANTE updated the Board on the latest developments as regards both IT tools supplied to ERNs: the ERN Collaborative Platform (ECP) and the Clinical Patient Management System (CPMS). The ECP is already in use and aims to support online communication, document exchange and event organisation. However, it is not foreseen for exchange of clinical patient data. From an IT perspective, an interactive approach is proposed: start with working first version and continuously improve after uptake phase. The number of ECP users for 24 ERNs increased from 533 in June to 1303 in October. Some ERNs are using it very intensively. The videoconferencing tool (Webex) and a more specific document sharing tool (CIRCABC) are also available for ERNs.

The CPMS is the ERN tool for diagnosis and treatment of patients through a virtual consultation system. The system has been open for user testing and feedback since 7 July 2017, when test plans and comprehensive information were sent to all ERNs. There is now a 1 year period to evaluate and assess the current solution, make an improvement plan and decide on next steps. In line with the European Data Protection legislation the CPMS is under prior check by the European Data Protection Supervisor. Once the prior check will be finalised the roll-out / deployment can start. As for the next steps there is a need to develop a strategy for ERN-specific patient data and registries to guide future development.

Following a short discussion, the EC representative noted that all concerns experienced during the testing phase should be transmitted to the IT Advisory Board. The new data protection rules (GDPR) coming into force in May 2018 may trigger some adjustments in the system and that the direct integration of the CPMS in national data systems is at present unrealistic due to the sensitivity of the dossier. Manual inscription of data is the most effective way to go forward. Further, one representative shared a concern regarding

the codification in CPMS. A unique patient code for all ERNs (unique identifier) should be given instead of using different codes by clinical case consultations.

9. Update on research activities and the 2017 call for Patients Registries (*Chair PB*)

The representative of DG Research & Innovation gave an update on EU research activities relevant for ERNs. The presentation focused on the elements possibly of interest for ERNs from the pre-publication of Horizon 2020 Draft Work Programme 2018-2020, notably:

- a. Rare Disease European Joint Programme Co-fund (indicative deadline: 18/04/2018);
- b. Innovation Procurement: Next generation sequencing for routine diagnosis;
- c. HTA research to support evidence-based healthcare;
+ other topics offering rare disease funding opportunities.

DG RTD presentation was followed by a short update prepared by CHAFEA on the ERN Patient Registries call.

Any Other Business (*Chair PB*)

The next Board meeting is foreseen for 5 December 2017.

END OF THE MEETING