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Health systems and products  
**Healthcare systems**

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

**7 October 2015**

**Summary record of the 3<sup>rd</sup> meeting**

**Gulbenkian Foundation, Room 1**

**Av. De Berna, 45a / 1067-001 Lisbon (Portugal)**

**CO-CHAIR:** **ANDRZEJ RYS**, DIRECTOR HEALTH SYSTEMS AND PRODUCTS, DG SANTE;  
**TILL VOIGTLÄNDER**, AUSTRIAN HEALTH INSTITUTE

### **1. WELCOME AND COMMISSION INTRODUCTION**

Andrzej RYS acting as co-chair welcomed all the Member States (MS) in the meeting.

The proposed Agenda was adopted,

A total of 28 members of the board attended the meeting (27 EU MS plus Norway). The list of attendance was circulated.

The minutes of the previous meeting were approved. One MS asked for clarifications concerning the process of membership of individual healthcare providers wishing to join an existing Network and to address this issue in the next meeting of the ERN Board of Member States (The Board).

### **2. STATE OF PLAY OF THE IMPLEMENTATION OF ERNS (ACTIVITIES AND TIMELINE) (COMMISSION)**

The Commission updated MS about the activities developed by the Commission and the implementation timeline for the next months on ERNs.

#### *The Assessment Manual and Toolkit*

It is under development and some of the draft versions of the deliverables (mapping exercise, Independent Assessment Manual and Operational criteria) have been distributed to the MS for comments. The contractor will present the contents later in a specific point of the meeting.

The Commission informed on the extension of the deadline for the call for tender for Independent Assessment Bodies (IAB) until 23<sup>rd</sup> of November, due to a corrigendum.

The Commission also informed the participants about the state of play and possible financial sources and highlighted the decisive role of the Member States in the decision making process of the approval of funding and support to the activities of the future ERNs by way of the respective MS committees of the Health Programme, Connecting European Facilities, Horizon 2020 RTD. It was mentioned as well the capacity of MS to activate Structural Funds projects as a tool of the MS to finance some of the activities of the future Networks.

#### Communication and awareness activities

The Commission presented the communication activities related with the advertising campaign in scientific journals, the update of the webpage contents and other awareness initiatives. It also mentioned the value of the 2nd ERN conference for raising awareness and helping possible applicants to prepare their applications. MS have an important role to play in the interaction with healthcare providers, patients and professionals organisations.

The webpage has been updated with information about The Board, the ERN implementation process and a new tab has been added on the assessment process including some draft deliverables of the Assessment Manual. The Commission reminded MS that they have still to submit information about their systems in order to include this information on the website, as only 12 member states have replied yet.

#### Interaction with interested healthcare providers and possible candidates for the Call for ERNs

The Commission reported about the technical workshop on ERN for interested healthcare providers organised jointly on 1-2 July with the EUCERD joint Action in Brussels. As previously requested by MS, the Commission is sharing in a dynamic way the information of possible interested groups or pilot networks wishing to receive information or to participate in the forthcoming call. The Commission encouraged MS to do so as well by sharing with the Board the information they are receiving in order to identify all possible future proposals. A possible way would be to collect the information at the Board meetings and to put it on CIRCABC.

Several MS raised the fact that they have been approached by an increasing number of possible applicants who were requesting information on the national endorsement procedures for proposed ERN applications and on the criteria to be followed by The Board for the approval of Networks.

#### The Call for ERN

The Commission plans to launch the call on the first quarter of 2016 and stressed that the priority for the upcoming call should be focused on stimulation of the participation of mature and strong proposals ensuring high quality standards. Non mature networks should use the time until the launch of a second call to prepare solid proposals and to identify well-balanced alliances and high quality group of healthcare providers across the EU.

The Board agreed that this message to the possible applicants would need to be made explicit through a common approach.

### **3. ASSESSMENT MANUAL AND TOOLBOX (PRESENTATION OF THE ONGOING WORKS AND TIMELINE)**

The contractor consortium PACE-ERN presented the work done since June 2015 in the development of the Assessment Manual and Toolkit.

The contractor started by presenting a short review of the development process of the Assessment Manuals & Technical Toolboxes for European Reference Networks (ERN). This was followed by presenting the 6 stage process of the technical assessment underlining the most important decision points and the proposed decision guidelines and rating scale. The contractor described the structure and methods followed for the definition of the operational criteria and presented a few examples of criteria.

It was stressed that prior to this meeting The Board had already been invited to share comments on the operational criteria and on the two manuals for applicants and for the Independent Assessment Bodies.

In the discussion it was emphasised that the defined operationalization of the assessment procedure measurements was very important to reach uniformity and comparability in the technical assessments of the proposed ERN. MS expressed the wish to link the national assessments procedures to the technical ERN assessment to avoid duplication in administrative procedures.

Several MS stressed the need to improve the current content of the Assessment Manual and the operational criteria. The Commission informed that the deadline for comments of The Board to the draft proposals was extended until 20th of October 2015 as only few MS (three) had sent comments in written so far.

Regarding applications for Membership to an Existing Network some MS stated that calls should take place periodically (annually recommended) to ensure that any health care provider that meets the criteria requirements can apply to be a member of an existing network and that the criteria to be fulfilled are the same as those initially required at the creation of the ERN.

With regards to the Operational criteria MS mentioned that the document should be organised following the criteria requirements as per Annex I and II of the Commission Delegated Decision 2014/286/EU one by one in order to bring clarity to the document and make it easier to follow. In particular they stressed that for each criterion, the following elements should be included in a more specific and clear way a) Elements to be evaluated for each criteria, b) Tools and methods used to assess these elements and c) Measurement and rating of each element to get the specific criteria score. In addition, some MS reminded the need to emphasize the criteria linked directly to health-care focussing on diagnostic and treatment services and to balance the number of criteria currently proposed addressing other elements such as research.

MS also stressed that operational criteria should be so clear that any assessment body can evaluate the Health Care Providers in the same way in order to achieve greater uniformity across the assessments undertaken by different bodies. The contractor was asked to improve the proposal along that line.

In the discussion following the presentation several strategic issues emerged. An important debate dealt with the access of The Board to the reports produced by the IAB in case of negative assessment of health care providers and ERN proposals. Several MS expressed their interest on having this information. Commission raised the issue of avoiding the "blame and shame situation" for the health care provider but different board representatives felt that it was an important information member states should know. The Commission will consult its legal services on this matter.

Further it was mentioned that the assessment of associated and collaborative partners were not included in the current assessment process as the process to designate those centres was a national competence. Nevertheless, it was pointed out that the operational criteria and the application of the call should address how the future ERNs would interact with such centres including a strategy or plan on how the possible relevant associated and collaborative partners would be easily integrated and supported by the ERN. The working group on small MS of The Board will make a proposal to The Board on how to address the process at national level and how to link the designated Associated and Collaborative Centres to the approved ERNs.

The Commission reminded that, as provided in the implementing decision and following the rules of procedure approved by the ERN board, The Board is competent, , to decide whether a positively assessed Network proposal should be approved or not. This decision might be taken by The Board on the base of the strategic value of a concrete thematic Network proposal. MS agreed on the need of a transparent decision based on some strategic statements of The Board. The Commission reminded that following a decision of The Board such criteria could be included in the Rules and Procedures of The Board for public knowledge.

#### **4. STATE OF PLAY AT NATIONAL LEVEL (DESIGNATION, ENDORSEMENT, STRATEGIC VIEWS...)**

A tour de table showed that important progress in all member states could be reported since the last meeting. More than half of the member states are addressing the set-up of special procedures either for the national designation procedures of highly specialised healthcare providers at national level or for the endorsement of individual healthcare providers willing to join a Network proposal. Other MS are still on the analysis phase and in some member states procedures are about to be elaborated and reported to encourage highly specialised centres of expertise to become associated or collaborative centres. All of them are expressing their confidence to be ready to support the implementation process of ERNs for next year for the upcoming call.

MS raised some strategic issues and risks related with the implementation process of ERN which are not considered under the legal base as for instance:

- How to avoid fragmentation, overlapping and too limited scope of the Network proposals?
- How to avoid competition and promote cooperation between similar interested groups in a common thematic field?
- How to ensure the benefits of ERN in the case of Member States where there is no centre of expertise through the designation of associated/collaborative centres at National level and how to connect them to the approved ERN?
- How to “indicate” the priorities, thematic areas or strategic value that the MS would like to promote?

It was highlighted the need of a common strategic vision on those issues for which the legal base is not providing criteria or a mandate to the Commission and therefore there is a limitation to address them in the call for ERN or in the technical assessment process of future ERN.

The Board agreed on maintaining a discussion and eventually on finding a common position to those issues under their mandate. To be able to lead this discussion a strategic working group (SWG) on ERN of The Board was created to work on the above listed strategic questions and to propose possible solutions. It was suggested to present these possible solutions in a proposal for the consideration of The Board for its next meeting on the 9th of December. Spain, UK, Portugal, Austria, Lithuania, Cyprus and Sweden volunteered during the meeting and afterwards to become members of this SWG representing a good balance of larger MS, medium-sized and small Member States..

The representatives of Cyprus and Lithuania also members of the working group on small MS would ensure the integration of the conclusions of both groups.

The Commission offered its support to the work of the group with the use of CIRCABC, and the organisation of audio meetings and web conferences if needed.

## **5. FEEDBACK OF THE SMALL MEMBER STATES WORKING GROUP**

The representative of Malta presented on behalf of the working group of the small MS a non-paper "European Reference Networks - maximising participation and benefit for small EU member states". The document consisted of a swot analysis for small member states to join and benefit from prospective ERNs. Malta stressed that this demand to include small member states in the ERN process is based on the objective of article 12 of the Directive 2011/24/EU (h) to help Member States with an insufficient number of patients with a particular condition or lacking technology or expertise to provide highly specialised services of high quality.

Several solutions as the creation of a European policy, a targeted communication with the ERN applicants concerning small member states, increased communication and support by the technical assessment procedure were raised. The Co-chair concluded that this issue also would have to be dealt in the SWG mentioned above.

## **6. AOB AND CONCLUSIONS**

The Co-Chairs closed the meeting by reminding the National representatives to send their comments on the draft versions of the Assessment Manual and Operational Criteria in written by the 20th of October 2015 and thanking Portugal as host of the meeting and encouraging national representatives to interact with the participants of the 2<sup>nd</sup> ERN Conference taking place on the 8<sup>th</sup> and 9<sup>th</sup> of October.

Till Voigtländer,

Co-chair

Andrzej Rys,

Co-chair

## **Annex 1 - List of Participants**

AUSTRIA	Austrian Health Institute
BELGIUM	FPS Health, Food Chain Safety and Environment
BULGARIA	Ministry of Health
CROATIA	Croatian Health Insurance Fund
CZECH REPUBLIC	Ministry of Health
CYPRUS	Ministry of Health
DENMARK	The National Health and Medicines Authority
ESTONIA	Ministry of Social Affairs
FINLAND	Ministry of Social Affairs and Health/The National Health and Medicines Authority
FRANCE	Ministère des Affaires Sociales, de la Santé et des Droits des Femmes, Institut Nationale de Cancer
GERMANY	Thüringen Ministry for Labour, Social Affairs, Health, Women and Family Affairs
GREECE	Ministry of Health
HUNGARY	Permanent Representation
IRELAND	Mater Misericordiae University Hospital
LATVIA	Ministry of Health
LITHUANIA	Lithuanian University of Health Sciences
LUXEMBOURG	Direction de la Santé
MALTA	Ministry for Energy and Health
NETHERLANDS	Ministry of Health, Welfare and Sport/Radboud universitair medisch centrum
NORWAY	Ministry of Health and Care Services, Norwegian Directorate of Health
POLAND	Children's Memorial Health Institute
PORTUGAL	Ministry of Health
ROMANIA	Ministry of Health
SLOVAK REPUBLIC	Ministry of Health
SLOVENIA	Ministry of Health
SPAIN	Ministry of Health, Social Services and Equality
SWEDEN	National Board of Health and Welfare
UNITED KINGDOM	Department of Health