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BOARD OF MEMBER STATES ON ERNS

5th JUNE 2015

Summary record of the 2nd meeting
Centre Conference Albert Borschette
FINAL

SESSION II (CO-CHAIR: ANDRZEJ RYS, DIRECTOR HEALTH SYSTEMS AND PRODUCTS, DG SANTE; AND TILL VOIGTLÄNDER, AUSTRIAN HEALTH INSTITUTE)

1. WELCOME AND COMMISSION INTRODUCTION

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

The Commission highlighted that European Reference Networks (ERNs) have been the focus of a growing interest from different healthcare providers and other stakeholders. Hence, the Commission encouraged MS to engage in a common communication strategy to raise awareness about ERNs.

The proposed Agenda was adopted, adding that Sweden, Lithuania and the Netherlands will give a presentation about state of play of designation and endorsement of highly specialized healthcare providers.

A total of 25 MS attended the meeting, 24 EU MS plus Norway. The Commission communicated that a list of attendance will be circulated and the meeting would be recorded.

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, of ERNs

The *Assessment Manual and Toolkit* is under development and the deliverables are expected according to the terms of reference of the contract, some preliminary results to be presented in the meeting.

The Commission also updated the participants about the state of play and possible financial sources (Connecting European Facilities programme) related with the development of the *ERN Information and Communication Technology (ICT)* platform that the Commission intends to provide to the approved Networks in due time.

Communication and awareness activities

- The webpage has been updated with information about the ERN Board of Member States (BOARD), and about the implementation process of ERNs. The Commission encouraged MS that have still to submit information about their systems, to do so in order to include this information on the website.
- The Commission is approached by an increasing number of healthcare providers, scientific and professional associations and leaders of informal networks that are aware about the prospect of the implementation of ERNs. The Commission is informing about the state of play at EU level and directs them to their National Authorities to receive further information.

The Call for ERN is planned to be launched in December 2015 or early 2016, with the necessary length to provide sufficient time to the healthcare providers to develop a good application.

MS asked the Commission to share the information of possible interested groups or pilot networks wishing to receive information or to participate in the forthcoming call. It was agreed to work in coordination between MS and Commission in order to identify all possible proposals.

Additionally, MS asked the position of the Commission about the opening of a second call for ERN. The Commission replied that the decision to further calls is foreseen in the implementing decision and that this should be decided in consultation with the BOARD based on the outcomes and lesson learned from the first call. The Commission 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. Healthcare providers not ready at this stage would be able to submit applications to join an approved Network, as provided in the implementing decision, in a yearly base. Non mature networks should use the time until the launch of a second call to prepare solid proposals and to identify alliances with a balance and high quality group of healthcare providers across the EU.

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

The contracted consortium PACE-ERN presented the work done in the development of the Assessment Manual and Toolkit.

The Consortium started by presenting the findings and conclusions of the mapping exercise including the literature review, the outcomes of the survey to MS and the visits to some MS.

Finally the Contractor presented a draft scheme of the assessment process to be developed. MS asked for clarification in a number of issues related with the steps and contents of the assessment, and encouraged the Commission to share as soon as possible the deliverables included in the Assessment Manual and Toolkit. The Commission highlighted that the contractor is aware about the importance of respecting the deadlines and to provide the deliverables in time as established in the contract. The BOARD would need enough time to provide input to the Commission on the elements of the Assessment Manual and Toolkit.

The Commission clarified, following some questions by MS, that the criteria and steps related with the eligibility of any network or healthcare provider proposal are already established in the delegated and implementing decisions on ERN, and that the assessment operational criteria and procedures will follow these criteria and steps defined in those acts. Moreover, the Commission stated that it is for the BOARD to decide whether a positively assessed Network proposal should be approved or not as provided in the implementing decision and following the rules of procedure approved by the ERN board. This decision might be taken by the BOARD on the base of the strategic value of a concrete thematic Network proposal. In case of a negative assessment of a healthcare provider proposal, it will be for its promoters to decide on the submission of the assessment report to the consideration of the BOARD.

The Commission informed that the contractor has been asked to make a presentation on the state of play and to present some examples of possible operational criteria and steps of the assessment process to a group of clinicians and leads of pilot networks that are going to attend a Workshop on ERN, jointly organised with the EUCERD Joint Action under the framework of the Commission Expert Group on Rare Diseases.

4. FEEDBACK OF THE ACTIVITIES OF THE COMMISSION EXPERT GROUP ON RARE DISEASES RELATED WITH ERN

The Commission gave a presentation on the work developed in the rare diseases area, in particular developments in the work of the Commission Expert Group on Rare Diseases and the new Joint Action on Rare Diseases.

The Commission highlighted the EUCERD document *"Recommendations to the European Commission and the Member States on European Reference Networks"* disseminated on early 2013. These recommendations will be now updated in the light of the delegated and implementing acts. An addendum is being prepared with the best methodology to group rare diseases and improve the involvement of patients with rare diseases in the context of the ERNs.

Finally the Commission informed the participants about the upcoming workshop (1-2 July) in Brussels, organized by the EUCERD joint action. The workshop shall support the rare diseases field experts in preparing for the first call for the implementation of ERNs.

5. STATE OF PLAY AT NATIONAL LEVEL (DESIGNATION, ENDORSEMENT, STRATEGIC VIEWS)

The Commission proposed MS to reflect on a number of key issues related with MS responsibilities and strategic views about the implementation process of the ERNs, and in particular regarding the designation of providers at national level, the endorsement of applications and the strategic value of the future Networks. A presentation was made by Lithuania, Netherlands and Sweden on how they were addressing these key questions. (Presentations are attached to these minutes)

The presentations raised the interest of the BOARD and several MS asked a number of questions about details and criteria related with the national practices of the mentioned three MS.

Representatives of a number of low populated MS expressed their concern about the inclusiveness of the process of establishing a Network and on the access and approval of healthcare providers in certain cases. The risk that the requisites on volume and or technology could establish a barrier to health care providers based in small MS was highlighted.

Furthermore, some MS identified the need for clarification on how the interaction between the Networks, the full members of an approved Network and the national coordination hubs or associated or collaborative health care providers would be organised. A discussion by the BOARD members on alternatives and recommendations to assess and approve such providers or hubs at national level was also deemed necessary.

The Commission reminded about the content of the legal acts were it is clearly established that it is National competence to decide on this designation and that no assessment or approval of such providers is foreseen under the framework of the ERN assessment process.

The Commission's view is that the relation and interaction of those providers with each of the Networks could vary depending on the thematic field and that it would need to be addressed and clarified in each of the Networks proposals. Commission encouraged a close collaboration and communication between interested MS and coordinators of Network proposals. Further discussion by the members of the BOARD would be needed in order to discuss and eventually reach a common approach to this matter.

The Co-chair proposed the creation of a sub-group of MS aiming to study and propose options to address the issues above mentioned. The subgroup would present their conclusions to the BOARD plenary. This proposal was agreed by unanimity by the BOARD and the Commission was mandated to facilitate the interaction of the subgroup.

6. ERN 2015 CONFERENCE

The Commission gave practical information about the 2nd ERN conference (“*from ERN planning to implementation*”), to be held in Lisbon on the 8-9th of October 2015.

The Commission is in charge of the organization (an enterprise has been contracted to help in the administrative and organisational aspects) in coordination with the Ministry of Health of Portugal who will host the event and the Luxembourgish Presidency who has included the event in the official Programme of their upcoming Presidency of the EU. The identification and registration of speakers, experts and participants is ongoing. A draft agenda of the event is already available (see [here](#)),

The 2nd ERN conference aims to:

- Present and illustrate the activities and projects regarding ERNs to demonstrate how EU wide collaboration in this area can contribute to better and safer healthcare and thus be beneficial to EU citizens.
- Encourage the commitment and participation of the targeted audience in the implementation process of ERNs allowing them to take advantage of the outcomes and activities funded by the Health Programme.
- Lead and help the participants through the process of consolidating a network and formalising an application to be approved as an ERN.

For the first day more than 400 participants are expected (clinical experts, healthcare professionals, patient organizations, national authorities and other interested stakeholders. The second day will be more focused on clinical experts and leaders of informal networks willing to participate in the call for ERNs.

The conference will be preceded by a meeting of the BOARD on the 7th of October in Lisbon, the agenda and venue will be announced in due time.

The BOARD was requested by the Commission to identify and propose a list of healthcare providers at national level who might be interested in participating in the implementation process of the Networks. A balanced number of participants in terms of thematic areas and territorial distribution would later receive the invitation to participate in the conference. The Commission requested MS not having sent their proposals to do it urgently as only the proposals received in time (deadline has been extended from 20 of May to 15 June) would be considered for registration due the high number of requests already received.

7. - SUPPORTIVE AND RESEARCH ACTIVITIES UNDER THE WP 2015 OF THE HEALTH PROGRAMME AND OTHER POSSIBLE SOURCES

The Commission gave an overview of the potential *funding support sources for the future Networks* (Public Health Program 2015, Connecting European Facilities, Horizon 2020, Structural Funds, etc...) that could be used to cover the administrative cost, and incentivise research in an ERN. The Public Health program WP 2015 has been already approved including some resources allocated to the assessment process, technical support and awareness activities related with the ERN implementation.

The Commission also addressed the issue of the future sustainability of the ERN. Currently there is no legal basis that mandates the Commission to provide administrative financial support to the Networks besides the third Public Health Programme 2014-20. The Commission encouraged the BOARD to reflect about this issue and to discuss on the future steps to establish, in a medium term, a sustainable support to the ERNs operations considering inter alia a legal base for this aim.

8. AOB AND CONCLUSIONS

The Co-Chair, Till Voigtländer raised the question to the BOARD, if MS saw any incompatibility of his role as Co-Chair and representative of Austria. He explained that due to human resources constraints there was a limitation of having two representatives from Austria, one as Chair with no voting capacity and a second one as nominated authority of Austria. He proposed to have the approval of the BOARD to be able to provide information on the activities and state of play in Austria and to participate in the discussion if there were no issues for voting and decision making purposes. None of MS objected this proposal.

The Co-Chair concluded the meeting mentioning that the Commission will share the information of possible informal networks with MS. The assessment manual and toolkit available deliverables will be shared as soon as possible and discussed in detail in the next BOARD meeting.

Finally, the BOARD will create a sub-group to explore how healthcare providers of small MS could have access and interaction with the future approved Networks while respecting the legal base, and which models could be used for the discussion or referrals of patient cases from these MS. The Commission will facilitate the creation of the subgroup.

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
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
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
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