

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Unit B3 Cross border healthcare, eHealth

BOARD OF MEMBER STATES ON ERNS 7 MARCH 2016, 09:30-17:00 BRUSSELS

VENUE: CENTRE CONFERENCE ALBERT BORSCHETTE RUE FROISSART 36. 1049 BRUSSELS ROOM: AB-3D

FINAL MINUTES

9:30 1.- Welcome and approval of the agenda (Chair Andrzej Rys - AR)

Director Rys welcomed all participants and thank them for coming. AR introduced Dr Tapani Piha (TP) as the new head of unit responsible for the Unit managing the ERNs process.

AR announced that the call for ERN will be launched the 16^{th} of March

AR asked to any AOB or comment to the Agenda.

24 Member States attended + Norway

The Agenda was approved by the Board of Member States.

9:45 2.- Update and state of play of the implementation of ERNs (Chair Andrzej Ry).

•9:45 – 10:15 **Enrique Terol** and **Anna Carta** made a presentation on the last development of the ERN process and update on the call.



• 10:15 - 10:30 Q&A

A number of issues were raised by the MS:

It was highlighted the importance of having included a concrete reference in the

Assessment Manual to the strategic paper issued by the BoMSs. Nevertheless, some MS stressed the importance of having a narrower list of thematic areas for the next call for ERNs and to avoid fragmentation of the Network proposals and to help potential ERNs proposals to better understand the priorities of the MS.

The EC recognised the potential importance of signalling priorities by the Board stressing the impact of the strategic paper in the current preparatory stage of the

proposals and called for a dynamic share of information between MS and the Commission on the ERNs applicants' development.

It was agreed to maintain a consistent message in all communication activities both from the EC and the BoMSs on the strategic approach of the Board against fragmented or overlapping network proposals. The EC committed to update the FAQs site of the Europa webpage and to share this information periodically with the BoMSs

10:30 3.- Relation of the ERNs with the Industry - conflict of interest etc (Chair Andrzej Rys).

10:30 – 10:45 **Prof. E. Treacy** (Ireland) gave a summary of the state of play and the different inputs and views on this matter including the view expressed in the recently published article "Position Statement on the role of healthcare professionals, patient organizations and industry in European Reference Networks". In the last slide some recommendations are showed (see ppt).



The EC suggested to form a subgroup of the BoMSs dedicated to draft a position paper of the Board on the relationship between ERNs and industry (pharmaceuticals, medical devices and other relevant).

The Member of the Board agreed that ERNs need guidelines to manage their relationship with industries. Conflict of interest goes much further than only industries; academia, research. They agree to set up a working group with the aim of exploring the conflict of interest in a wider framework, also defining what kind of stakeholders should be covered (industries, associations). In particular it has been point out that also patients associations should be considered, as patients are part of the conflict of interest. 5 MSs decided to join this subgroup FI as a chair + EI, ES, IT, UK.

11:15 4.- Proposal of a Working Group on ERN IT Chair by AR partly and TV last point

11:20 – 11:30 Tapani Piha explain the CEF tool and governance of the CEF and the IT platform of the ERN



TP asked Member States Regarding the governance if they are interested in taking an active role in the governance of the IT structure and build a dedicated subgroup. The aim will be to help define all the detailed needs and support DG SANTE in making choices concerning the ERN IT platform. Director Rys supported the idea and emphasises the importance of deciding the chair of the subgroup also to guarantee continuity and bridge between IT decisions and political decisions. 4 MSs decide to join this group. (EE chair + PT, CZ, NL)

11:50 – 12:00 **Markus Kalliola** Presentation of the Communication and Networking tool.

12:00 5.- Strategic approach of the Board to common criteria / processes to designate affiliated partners

Chair by Till Voigtländer



12:00 - 12:15 The point was introduced by **Mrs K. Damigou** (Greece) who gave an overview on the relevant legal base and the key issues related with the process of designation and integration of the affiliated partners in the future approved ERN. She presented a preliminary list of issues to be discussed with the final aim to find an agreement and common ground for the designation and communication of affiliated partners. It was highlighted that transparency and mutual trust should be the base of such agreement.

The discussion among the Member States touched several points among which:

- It was reminded that MSs are fully competent to designate affiliated partners.
- The internal process involving the designation of affiliated partners at national level should be complemented with a transparent and agreed procedure for the communication of the designated partners to the Board and later to the relevant approved Networks.
- The connection and integration of the affiliated partners into the ERNs would need a dynamic interaction between National authorities, Network Coordinators and the designated affiliated partners.
- TRUST and transparency should be the driving principles of the process.
- The BoMSs need to reach a common understanding and a clear pathway of how the affiliated partners would gain their status.
- It would be desirable to agree on a common set of basic information and designation letter for all Affiliated partners.

A subgroup of MS working on this topic has been proposed and agreed. 9 MSs joined this group: EL (chair), AT, MT, KY, ES, UK, LUX, LT, SI.

13:00 - 14:00 Working Lunch

14:00 7.- Health Programme – Work Programme 2016: Call for Grants jointly with the ERN Call for interest (CHAFEA)

Chair by Mr Till Voigtländer

CHAFEA, the EC agency dealing with the Health Programme connected by video link from Luxemburg. **Vera Zazvonov** and **Hristina Mileva** explained the details of the call for grants for ERNs.

14:40 6.- Proposal of agreement on a common template for the endorsement of Health Care Providers Chair by Till Voigtländer



12:45 – 12:50 E. Terol presented the template.

MSs commented that a compulsory section common to all national certificate are of utmost importance. Moreover, it has been suggested to envisage a same template certificate endorsement for full member and for affiliated partners.

It was agreed that all endorsement certificates would include a common set of information.

14:30 8.- State of play at National level – tour de table (all members of the Board) Chair by Mr Till Voigtländer

A tour de table showed that all member states have addressed the endorsement process. Most of MS are addressing the set-up of special procedures for the endorsement of individual healthcare providers willing to join a Network proposal. A majority of MS confirmed that procedures were already decided and in place. Nevertheless a formal publication and communication of the procedures were still ongoing in a number of MS. All committed to finalise the procedures in time.

Main issues reported by the MS:

- The different timing and complexity and the linkage between the national procedures for the designation of centres of expertise/reference and the process to endorse the HCP wishing to participate in a Network proposal.
- Risk of tension where the scope of the network proposals have not been addressed at national level due the lack of national criteria or procedures in certain thematic areas.
- Lack of definition or communication by the potential network applicants of the specific criteria to be fulfilled by their future members. This situation creates uncertainty.
- MS with experience and well defined systems of national designation would in general endorse all previously designated national centres without any further procedure. In several cases the candidates HCP have already received the endorsement letter.

- The majority of MS with federal or highly decentralised healthcare systems have already reach agreements with the federal or regional authorities in order to speed-up and simplify the process of endorsement.
- MS with a high number of already designated Centres of Expertise were discussing the strategy on how to balance the over representation in the Networks and how to link the future ERN to their national networks.
- The creation of consortia of centres with different locations but functionally linked and sharing patients, resources or techniques was also discussed as a good alternative in certain circumstances (by instance the functional relation of a paediatric hospital with an adult provider; specific diagnostic or treatment facilities located outside the main healthcare provider, medical or surgical units sharing patients and complementing each other etc.)
- Some MS expressed their intention to use some of the criteria and information requested for the ERN call as the documentation to decide the endorsement at national level.

A presentation of the state of play in Hungary was made by Mr Pflieger representative of Hungary in the Board (see ppt)



The Board agreed on maintaining a dynamic exchange of information with the Commission and to provide as soon as possible written information to be posted in the ERN webpage.

15:35 9.- AOB

Chair by Mr Till Voigtländer

Next meeting of BoMSs to be scheduled by the end of June.

The Chairs summarised the conclusions of the meeting encouraged the National representatives to send the information on their national designation procedures in writing as quick as possible.

Till Voigtländer, Andrzej Rys,

Co-chair Co-chair