



BOARD OF MEMBER STATES ON ERNS

15 NOVEMBER 2019, 10:00-17:00

VENUE: CENTRE ALBERT BORSCHETTE, 2C

Rue Froissart 36, 1040, Etterbeek, Brussels

APPROVED MINUTES

CHAIRS: ANDRZEJ RYS (CHAIR) & LENNART CHRISTIANSSON (CO-CHAIR)

1. Welcome, approval of the agenda and minutes of past meeting

The Chair, DG SANTE B Director welcomed all participants and opened the meeting. All EU Member States, except Bulgaria and Latvia, plus Norway were represented.

Board members were asked if they had any comments to the minutes of the last meeting. Comments related to Affiliated Partners (page 8) and related to pilot projects from the Statement on relations with Industry (page 6) were mentioned. The minutes were then approved and have been made publically available on SANTE's website¹.

The Board considered the agenda prepared by the Secretariat and approved it as proposed.

2. Update on the ongoing call for healthcare providers to join existing ERNs

The Commission presented the procedure of application in details with special emphasis on the role of the ERN Board of Member States. The call for new members has been launched on 30 September 2019 and will end on 30 November 2019. The applicants apply via an online tool. The Board was informed about the high number (1200+) of draft applications. The Commission strongly encouraged Member States to be selective in the number of applications they are going to endorse and to carry out an assessment of them against the criteria specified in the call before completing the process as well as relying more on national referral networks and the consortium concept. Already well-represented countries should consider carefully the number of endorsement so to keep the ERNs manageable from the organisational and financial point of view. This request triggered an intense discussion as many Member States argued that they did not have the legal power to be selective and rejected the proposal of "adding a new criterion" (already well-represented) at this stage. Only one country informed the Board about their efforts in decreasing the number of applications while increasing quality. This being a very sensitive exercise, the idea of an ERN Board of Member State Statement which would

¹ https://ec.europa.eu/health/ern/events_en#anchor0

call for collective responsibility and commitment from Member States was raised. During the meeting such draft Statement has been prepared by the Commission, but Member States firmly rejected it. Another country suggested the Commission to link the financing with performance of ERNs. The Commission also noted that Coordinators have started to establish criterion on how to finish membership of inactive members, in addition Members States can also to withdraw them. Lastly, starting a deeper reflection in a working group on how to manage the high number of participants, commitments of the Member States and financing of the Networks was proposed.

Further, many questions about the consortium concept were raised. Clarification was needed on what this is and how in practice it should work. Regarding the ERN involvement in the assessment process, the Commission reiterated that Member States cannot ask for any kind of prior assessment, support from the ERNs. ERN Coordinators shall limit their participation to the formal step of the assessment process. The Commission also underlined that a sampling exercise cannot be avoided, given the available funding for the new call and the number of candidates. Lastly, the UK informed the Board that there was some interest among UK healthcare providers in joining the Networks and the UK is ready to endorse these applications.

3. CPMS update and discussion on the notion of "guest user"

The Commission informed the Board on the state of play regarding the **CPMS**, the **ECP** and the latest activity report.

The next release of the CPMS will be live at the end of November 2019 and will bring the following developments, among others:

- The ERN will now be able to attend ERN recurring meetings without having to disconnect between each timeslot.
- Disclaimers will appear when downloading a document.
- The video conference tool will now be supported by Safari.
- Banners will inform the coordinators of future downtime of the system.
- Guest-users will be able to record their HCP name in the system.

The CPMS users that are not active will be deactivated.

On the “**guest user**” (healthcare providers outside ERNs that can connect to CPMS for a limited period of time to enrol patient or provide expertise) which currently represents 10% of the users, the Commission called for restrained used and underlined the need to limit the “enrolling guests”. The Commission recalled that the enrolling guest category was created at the initial phase of the CPMS implementation as a way for the ERN Coordinators to support the healthcare providers and patients in the case of Member States without a member (full or affiliated partner) of the ERNs and to gather missing expertise from experts non-members of the ERN system by allowing their participation in some of the multidisciplinary panels on an ad-hoc base. Currently, after two years of the launch of the Networks, and with the integration of Affiliated Partners and the recent call for new members, the circumstances have changed considerably and there is a need to reassess the concept and use of the “guest user” licenses. Further, there are data

protection aspects of the issue. Guest users enrolling patients cannot be joint controllers in the long run. Unless someone else (e.g. coordinators) takes over the joint controllership (with additional administrative burden), the data of the patients should be deleted from the clinical part of CPMS, which can be a problem in case these patients would require additional advice from the ERNs. Only one country supported such a limitation, while some Member State underlined the interoperability problems to exchange data between treating doctors and ERN members and the need for flexibility. A more detailed analysis is needed.

4. Affiliated Partners – state of play

The Commission presented the state of play, the outcomes of the designation phase and the next steps. Overall the geographic coverage with the inclusion of Affiliated Partners increased from 44% to 74%. With Affiliated Partners the number of Member States having full coverage of ERNs increased from 3 to 10. Regarding the patterns of country approaches the picture is quite heterogeneous, some rely exclusively on members, while others mainly on Affiliated Partners (notably Associated National Centres that create a link with one ERN). Obviously, small Member States tend to rely more on National Coordination Hubs (that create a link with more than one ERN at once). The designation phase at this stage has been closed, however, the exercise is still far from having been completed. The new Partners need to be integrated in the work of the ERNs. The ERNs are now requested to prepare an integration strategy detailing how Affiliated Partners will participate in the ERN work and how it will be integrated into the ERN's functioning. The individual integration strategies (one by each Network) must be approved by the ERN Board of Member States. The deadline for the Coordinators to establish those strategies has been fixed to January 2020. The ERN Board of Member States will then review and approve them.

Some countries argued in favour of reopening the affiliation process. It was agreed that once the outcomes and consequences of the exercises on affiliation and membership have been finalised and analysed, as well as the rules on termination have been established, we may come back to it.

5. Expansion of the ERNs diseases coverage

The Commission recalled that in the last months, several Networks have been raising the issue of gaps to complete the disease coverage of the Networks. In order to better understand the needs and proposals of the 24 ERNs, a survey was conducted in May 2019 on the potential disease expansion of the current 24 ERNs.

Following the discussion held on this issue in both the ERN Coordinators Group (ERN CG) and the ERN Board of Member States (BoMS) meetings on the 24-25 June, an exhaustive exercise with the ERNs looking for expansion was carried out. Based on this consultation an update of the diseases coverage (including when needed new thresholds and criteria) was published in the website of the call. Applicants of the current call can already decide to choose the new diseases, when appropriate. However, in order to update the diseases coverage of the current members and to validate the fulfilment of the

new threshold and criteria, a standardised procedure, including a peer review by the ERN Boards and further validation by the BoMS is needed.

Further, there is a need to keep on identifying gaps and overlaps in a dynamic way. To do so, on the previous day at the ERN-CG meeting, the ERNs were encouraged to maintain and review their current diseases coverage and the possible gaps to fill by using the Orphacode or any other coding systems that would facilitate the mapping of diseases. The proposed procedure for the validation is the following: once a gap has been identified by the ERN Board of the Network, it should be presented to the ERN CG who will identify the possible overlaps between networks. Criteria and thresholds will be defined by the concerned networks and they will be presented to the BoMs for approval. Afterwards, there will be a peer review by the respective Network followed by a validation from the national authorities. The BoMS will then produce an official statement about the disease and the new disease will be included on the ERN website. A written procedure will be launched by June (the latest) for the approval of the proposed standardised procedure.

6. Gaps and overlaps in ERNs disease coverage

Ana Rath, from Orphanet, has been working together with the Commission staff to map the gaps and overlaps in ERNs disease coverage by using the Orphanet classification.

The main thematic groups and broad disease categories, does not seem to have many overlaps between the ERNs. However, at the sub-thematic level or certain sub-groups of diseases, there are some overlaps. Also, most overlaps are related to different ages at presentation (e.g. PaedCan – EURACAN), or they represent complementarities between the ERNs as the concerned diseases are by nature multisystemic and would need a multidisciplinary approach. The ERNs can appear to cover similar diseases, but they actually share aspects in a complementary manner of a given disease.

Some group of very rare diseases and rare benign tumours are lacking here and there, and some major groups of diseases notably in gynaeco-obstetrics and infectious rare diseases are not addressed by any network. The needs must be clearly identified by revising the classification. Further, while there are not so many overlaps at group level, this is not the case at the disorder level.

Orphanet suggests several ways to address the overlaps and gaps.

The first solution would be to increase the interoperability between the ERNs. When 2 ERNs share a same disease, they need to collect data in the same way in the registries in order to be interoperable. Orphanet is currently going through every ERN to revise the Orphanet code but the existence of overlaps means that there should also be a transversal consistency.

Orphanet also suggests producing sound information for doctors and patients to be published on the Orphanet and ERN websites.

Lastly, there is also a need to design patients' pathways at national and transnational level to help them identify the ERN that would be most useful for their condition even when they are not previously aware of the existence of the ERNs.

To close, Ana Rath underlined the importance of Common Data Elements that would enable to connection of specific diseases across registries. The Joint Research Centre will organise a workshop in January to analyse the situation with the Coordinators in a bottom-up approach and develop a common data dictionary. The same data needs to be collected in a standardised manner across the different registries.

7. Presentation of the feasibility report on Establishing a European Expert Network on rare communicable diseases

The report of the feasibility study of establishing a European Expert Network on rare communicable diseases in the context of mobility and globalisation was presented. The study was funded by the EU Health Programme. The objective of such network would be the diagnosis and treatment of rare communicable diseases, not the surveillance of infectious diseases which is done by the European Centre for Disease Prevention and Control. Three options were presented, one of them could be the establishing of a European Reference Network, after the model of the 24 already existing ones.

The expansion of the ERN system to include new areas is not foreseen before 2022.

8. Presentation of the eHealth Network activities

To start the cooperation between the eHealth Network and the BoMS, the co-chair of eHealth Network, Henrique Martins was invited to present the main activities and role of the eHAction, the 3rd Joint Action supporting the eHealth Network. Co-financed by the EU Health Programme, this Joint Action is a collaborative action between Member States and also other European countries. The main aim of the eHealth action is to contribute to innovative, efficient and sustainable health systems; to promote use of information and communication technologies in health development; as well as the development of strategic recommendations and instruments to support the political discussions.

9. Feedback on the activities of the ERN Coordinators Group (ERN-CG)

Professor Irene Mathijssen, Coordinator of ERN CRANIO, Chair of the ERN Coordinators Group (ERN-CG) informed the Board on the outcome of the discussions held the day before at the ERN-CG meeting.

The presentation focused on the following areas:

- ERN enlargement;
- Overlap of diseases among ERNs;
- Registries;
- Guideline development.

Related to enlargement, the Coordinators are working on a series of strategic documents, such as the integration strategy documents for Affiliated Partners (one for each Network), the non-compliance document, the assessment of full members within the call and the

expansion of disease coverage for existing members. The ERN-CG Chair stressed the importance of expansion pointed however to some items that need further attention. In this context, underlined that some funding would be essential from Member States for Affiliated Partners. And noted that additional budgets were essential given the increase of number of healthcare providers per each Network, the potential sources of funding could be Member States, healthcare providers or industry. For the future they hope for a more dynamic and flexible system where additional calls for full members or Affiliated Partners will be foreseen. Access to CPMS for Affiliated Partners is essential so that the reach out is undertaken. Also CPMS access for non-members at national level should be more flexible, the 3-months guest user account is not enough. The ERN CG is hoping for a full coverage.

On overlaps it was underlined that the overlap of diseases between ERNs is significant. Besides the inventory based on Orphacodes, the Coordinators also made one based on included diseases. It was asked to each ERN to produce a slide demonstrating the possible overlaps they have with other ERNs. It became apparent that ERNs are not always able to identify all the existing overlaps. Certain ERNs mentioned overlaps while other did not. The issue might come from the fact that some ERNs have different systems / methods to identify the diseases covered by them. The extensive use of Orphacode and other standardised coding systems might be the best way for the ERNs to identify the existing overlaps.

It was highlighted that at present what a patient experiences, will determine to which ERN the patient will enter. How to act on overlaps? First, there is a need to identify overlaps on a disease-specific level with the use of Orphacodes. Then ERNs could initiate disease specific working groups with members of all the ERNs involved to determine care pathways and research programmes. With the vast number of overlapping diseases, the ERNs should prioritise which diseases should be handled first. They also should identify what is needed for which disease (joint clinical practice guidelines, for example).

Regarding registries, it was underlined that ERN-wide registries are high priority for all ERNs. There are 5 ERNs registries ongoing and other 19 ERNs have submitted an application. With complete registration of all patients within the registry monitoring will be covered and unique data are collected on epidemiology and for research. There is a need for good IT tool to facilitate registration, at least on national level.

Related to the Clinical Practice Guidelines programme Coordinators are asking for clarification with regard to the legal status for the ERN-based guidelines.

Lastly the BoMS was informed that 2 journals (Eur J Hum Genet and Eur J Med Genet) have an ERN dedicated corner.

10. Presentation of the recommendations / conclusions of the Joint Action on Rare Cancers (JARC)

Paolo. G. Casali, coordinator of the Joint Action on Rare Cancers (JARC) presented the main outcomes and recommendation of the JARC. The JARC was funded by the Health Programme and is a multistakeholder collaboration between 18 Member States coordinated by the Fondazione IRCCS Istituto Nazionale dei Tumori of Milan. The collaboration started in 2016 and was finalised in September 2019.

It included 34 partners comprising Ministries representatives (Cyprus, Czech Republic, France, Ireland, Italy, Malta, Poland, and Spain), universities, public health institutions,

population-based cancer registries, oncological institutes, patients' organisations (ECPC, EURORDIS, CCI-Europe) and other societies/organisations (including the Organisation of European Cancer Institutes – OEI, the European Society for Paediatric Oncology – SIOPE, and the European Organisation for Research and Treatment of Cancer - EORTC).

The four ERNs addressing Cancer (ERN EURACAN, ERN PaedCan, ERN EuroBloodNet and ERN GENTURIS) were involved in the project.

The JARC has established a framework for all stakeholders to work together to: a) prioritise rare cancers, in the agenda of the EU and Member States and b) develop innovative and shared solutions, mainly to be implemented through the ERNs on rare cancers.

Lastly, it was underlined that Member States need to speed up the integration of the ERNs into their national healthcare systems with real implementation of patient pathways and referral systems at national level.

11. Member States sharing experience on integration and the way forward (e.g. country presentations)

The Commission stressed that in the context of exchanging good practices on how to link, integrate ERNs into the national health system, it is essential to continue with the series of country presentations. The aim of the exercise is to get a better understanding of the different national arrangements and learn from each other. More specifically, to address the sets of policies falling under the scope of integration as stated in the Board Statement on Integration and present what countries are doing or plan to do in these areas so as to enhance the integration process. Unfortunately, this time nobody volunteered to make such presentation. Members of the Board were encouraged to exchange good practices and were asked to signal their willingness to the ERN Secretariat.

Related to the EUROPA website the Working Group on Integration was mandated to prepare a template for the section dedicated to national information. Currently the information there is outdated (mainly related to the 2016 Call) or missing for most of the Member States. This section should ideally provide information on the ERNs from national websites, or to explain the link with national rare diseases strategies or policies. It is the space where Member States can better explain how the ERNs are linked with the national health systems. Currently only 7 Member States do have information related to the ERNs there.

12. Monitoring – state of play of data collection

The Commission presented the results of the data collection exercise for 2018 and of the first semester of 2019. The numbers show the progress of the ERN initiative across Europe in patient care, knowledge generation and dissemination and the effect of the revision of the 18 ERN indicators. Some aspects still need to be clarified with the main issue being the difficulty of the data collection of new patients. The Monitoring working group will discuss any possible need of changes/clarification on the indicators definitions and the next steps to be developed. As already agreed, the collection of the pending data corresponding to the second semester of 2019 and the complete year in the case of some ERNs should start in February 2020. If the conclusion on the quality of the data is positive, the idea would be to make public and use the results of the monitoring exercise in the upcoming months to show and to demonstrate the value of the work of the ERNs.

13. AOB

The Commission proposed for a second time to change the number of meetings of the BoMS from 3 to 2 meetings of 1,5 day per year so as to put it back to back with the ERN-CG meetings (they are having only 2 meetings a year) and leave more time to implement the decisions taken during the meetings, but members of the Board argued in favour of having 3 meetings a year.

END OF THE MEETING