



Brussels, 6 March 2017

**BOARD OF MEMBER STATES ON EUROPEAN REFERENCE NETWORKS
(ERNS)**

15 DECEMBER 2016, 09:00-17:30

BRUSSELS

**VENUE: Berlaymont
Rue de la Loi 200, 1040 Brussels
Room - Walter Hallstein**

MINUTES

Chairs: Till Voigtländer (TV) & Andrzej Rys (AR)

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

SANTE Director B. Andrzej Rys welcomed all participants. All Member States (except Denmark, Ireland, Romania excused) and Norway were represented.

The agenda was approved. Member States' comments to the minutes of the last Board meeting were taken on board and minutes are considered approved¹. The Chair also reminded the Board that the Board statement on ERNs and Industry, prepared by the working group and discussed at the last Board meeting, had been finalised and published on Commission's website²: the working group and its chair in particular were thanked.

The Chair reminded the Board about the importance and meaning of this meeting. It has been a long and successful process so far, with a strong participation of Member States during the whole process including several phases, in particular 1) a legal phase from 2012 to 2014 to discuss and agree on the ERN legislation (with the advice of an expert group created for that under the framework of the Directive on Cross-border healthcare); 2) Awareness and implementation of the Implementation: from 2014 to 2016 Assessment manual, contracting of the Independent Assessment Body (IAB), call for Networks, assessment process, interaction with healthcare providers and stakeholders etc.; 3) the way forward: 2017 year of the kick-off of the Networks; and 4) 2017 to 2020: functioning of the ERNs, consolidation, continuous assessment and monitoring process.

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

² https://ec.europa.eu/health/sites/health/files/ern/docs/statement_industry_conflict_of_interest_en.pdf

Finally, the co-chair of the Board (the Austrian representative) recalled to the Board that this meeting was the term of his mandate of two years as co-chair. He would co-chair as usual this meeting, but for the approval of the Networks in case of vote, he delegated its national position to the Dutch representative, in order to follow the rules of procedures. The decision on the election of the next co-chair will be taken at the next Board meeting on 8 March 2017. Till Voigtländer expressed his interest in continuing for two more years, which was welcomed by the Board, but of course other volunteers are also welcome to express their interest before the next Board meeting.

2. Outcomes of the assessment process of the first ERN call (Chair AR)

The Chair explained that the Independent Assessment Body (IAB) would present the applied methodology and the main outcomes and lesson learned from the assessment process. The following questions & answers session would not cover individual cases of healthcare providers or concrete outcomes of a specific centre, because the process from the Healthcare providers and Networks to send comments for review to the IAB was still ongoing (until 15 January 2017).

2.1. Feedback from the Independent Assessment Body (Andalusian Agency for Healthcare Quality, ACSA)

The ACSA team presented different aspects of the assessment process for Networks and ERN members, in particular the resources dedicated to the assessment (human resources, ICT, training of assessors), the technical procedures used, as well as results, successes and challenges and finally recommendations issued, providing concrete examples.

This presentation was followed by a session of questions and answers, related mainly with the site visits done for the audits (and the choice of healthcare providers audited), the quality of self-assessments in the light of the audits, and the follow-up of the recommendations formulated. ACSA explained the usefulness of being accompanied by national authorities during the audits, to better understand national specificities. Several Member States highlighted the value of the IAB work, which enables Member States to have a clearer view on the Networks.

Following this discussion, the two co-chairs announced the plan to establish within the Board a Working group dedicated to the continuous monitoring and evaluation of Networks (see below under 2.3.).

2.2. Feedback from the European Commission

The Commission's representative shortly summarised and clarified the timing for the final validation of assessment reports (for networks and healthcare providers) that would include also, when appropriate, the healthcare providers initially negatively assessed but positively assessed after appeal and review of the additional documents submitted (results in January 2017, therefore individual cases of HCPs were not discussed in the present Board meeting). Publication of the names of the individual healthcare providers (HCPs) approved to be members of an ERN would wait until finalising the appeal period (still running): only the names of the Networks approved would be published on Commission's website at this stage.

2.3. Monitoring and assessment of ERNs (Commission)

As discussed already during the Board meetings of July and September 2016, the Commission formalised the proposal to enhance the future assessment process of the Networks by strengthening the following 4-step assessment process: 1) continuous monitoring system of the ERNs activities; 2) periodical self-assessment of the ERNs and HCPs; 3) stronger involvement of Member States (MS) in the assessment: by instances checking criteria of their own healthcare providers when a similar exercise is carried out at national level for other reasons (accreditation or certification of HCPs etc.); 4) further assessment by the IAB on specific criteria of the approved HCPs not assessed in the initial process (timing and method to be discussed with the MS).

To this purpose, it was proposed by the chairs the creation of a working group of MS with the aim of making a proposal for an integrated monitoring and assessment process for the future. The group will discuss the best approach to adopt, with the support of the Commission and with a dynamic interaction with some ERN coordinators. The Board agreed on this principle, and a number of MS volunteered (AT, ES, FI, FR, NL, NO). Works would start in January 2017, and a first draft statement would be presented on 8 March 2017. Final document to be presented to the Board in June 2017.

3. Decision on the approval (or refusal) of ERN applications of the first call (introduction by Commission, Chair TV)

Board members were reminded about the “rules of procedures”³ of the Board about voting and decisions making process. Voting followed the alphabetical order of the ERNs acronyms.

All of the following ERN applications were approved, one by one, by consensus:

- European Reference Network on Rare Bone Disorders (BOND)
- European Reference Network on Rare craniofacial anomalies and ENT disorders (CRANIO)
- European Reference Network on Rare Endocrine Conditions (Endo-ERN)
- European Reference Network on Rare and Complex Epilepsies (EpiCARE)
- European Rare Kidney Diseases Reference Network (ERKNet)
- European Reference Network on Rare Eye Diseases (ERN-EYE)
- European Reference Network on Rare inherited and congenital anomalies (ERNICA)
- European Reference Network on Rare Respiratory Diseases (ERN-LUNG)
- European Reference Network on Rare Neurological Diseases (ERN-RND)
- European Reference Network on Rare and Undiagnosed Skin Disorders (ERN-Skin)
- European Reference Network on Rare Adult Cancers (solid tumors) (EURACAN)
- European Reference Network on Rare Hematological Diseases (EuroBloodNet)
- European Reference Network for Rare Neuromuscular Diseases (EURO-NMD)

³ https://ec.europa.eu/health/sites/health/files/ern/docs/board_procedures_en.pdf

- European Reference Network on GENetic TUmour RIsk Syndromes (ERN GENTURIS)
- Gateway to Uncommon And Rare Diseases of the HEART (GUARD-HEART)
- European Reference Network on Rare Congenital Malformations and Rare Intellectual Disability (ITHACA)
- European Reference Network for Rare Hereditary Metabolic Disorders (MetabERN)
- European Reference Network for Paediatric Cancer (haemato-oncology) (PaedCan-ERN)
- European Reference Network on Rare Hepatological Diseases (RARE-LIVER)
- Rare Connective Tissue and Musculoskeletal Diseases Network (ReCONNET)
- Rare Immunodeficiency, Autoinflammatory and Autoimmune Diseases Network (RITA)
- European Reference Network on Transplantation in Children (incl. HSCT, heart, kidney, liver, intestinal, lung and multiorgan) (TRANSCHILD)
- European Reference Network on Rare Multisystemic Vascular Diseases (VASCern)

It was proposed to change the acronym of the ERN “TRANSCHILD”. This proposal was taken into account by the ERN and the acronym was later changed to “TRANSPLANT-CHILD”.

It was also highlighted the need to harmonise names and acronyms of the ERNs in order to keep consistency with the ERNs official name included in the ERN logo and in the license contract to be established between the Commission and each Coordinator for the use of the logo. Such a harmonisation would be proposed to and discussed with ERN Coordinators⁴.

Regarding communication activities, it was agreed to publish only the names of the Networks approved as stated above.

A Board representative stressed the importance of the ERNs to develop their policy regarding industry following the statement of the Board⁵.

To close the morning session, the **Director General of DG SANTE, Xavier Prats Monne**, joined the meeting, welcomed the decision of the Board and stressed the high added-value of ERNs at EU level by bringing concrete results to patients with rare or low prevalence diseases and conditions. He thanked Board members and confirmed its commitment to continue supporting ERNs in the future.

4. Update on the process for the remaining ERN application: 2nd wave of the 2016 call (Commission) (Chair TV)

⁴ See list : https://ec.europa.eu/health/ern/implementation/call_en

⁵ https://ec.europa.eu/health/sites/health/files/ern/docs/statement_industry_conflictinterest_en.pdf

It was informed that a contracted Independent Assessment Body (Accreditation Europe) was performing the assessment of the 24th ERN application, eUROGEN (ERN on urogenital diseases following the established methodology).

Board members agreed on following a written procedure for the eventual approval of the ERN eUROGEN in case of positive assessment report by the IAB. The assessment report would be circulated on 30 January.

5. Next steps on the grant agreements for approved ERNs (CHAFAEA) (Chair TV)

The call and evaluation of grants projects was summarised and next steps (procedural and timeline) were presented: the Evaluation Committee would meet on 16 December 2016, submission of further documents in January 2017, grant agreements of positively evaluated projects to be signed at the end of February or early March.

Board members and Commission also highlighted the need to explore and seek for other sources of funding, including the use of the current reimbursement procedures (Cross-Border Healthcare Directive or Social Security Regulation, which are possibly both relevant for ERN activities).

Finally, the possibility of exchange of professionals (via the Erasmus+ programme?) will be investigated.

6. State of play at National level (Chair TV)

The Commission's representative summarized the 17 contributions received from Board members on the three following questions, already presented to Board members in September 2016:

1. How MS are addressing the link of the national networks or highly specialised centres to the future ERNs?
2. How MS are envisaging the connection/case management of patient cases to be presented to the ERNs?
3. How MS are addressing the support to the Network coordinators or future members?

For the first question and on the stage of implementation, showed work is still in progress. Several examples of formal and less formal means on how to link national networks and centres to ERNs were provided. On the other two questions, answers showed less progress (ongoing/planned), but still a few useful examples were provided. Board members agreed to share their answers within the Board, to learn from others. These issues will become more and more important with the kick-off of the Networks.

French representatives took the floor to present their national approach on rare diseases (and on ERNs), well established, the 3rd "national plan" being in preparation. France explained the connections between and activities of their 23 national networks ('filières'), 131 reference centres and 800 'competence centres'.

7. ERN IT Platform and related activities: update on the developments (Commission) (Chair AR)

Commission presented the state of play of the ERN IT tools that are crucial for ERNs to start working properly: the ERN clinical platform (to exchange clinical data amongst Networks) and the communication & collaboration tool (for members of networks to communicate and plan their common work). Timeline was presented: contract to be signed with selected contractor in December, January to July 2017 to adapt the platform to the needs of the ERNs. July to be functional. Commission asked MS to participate in this fine tuning of the IT services and will provide information on related activities, when available (report from JRC Workshop on Registries, work on informed consent etc.).

8. Affiliated partners: state of play (Chair TV)

8.1. Related actions planned by the Maltese Presidency

Malta presented their coordination hub model based in their long experience of bilateral coordination with the UK and the highlights for Health of the Maltese Presidency. The chair of the working group on affiliated partners acknowledged the Maltese strategy as a good example to be considered by the future Affiliated partners.

8.2. Reporting of the Working Group (WG) of the Board of MS (*Chair of the WG*)

The chair of the working group presented a strategic approach to common criteria and processes to designate affiliated partners. The strategy consists in a stepwise approach, which includes key aspects (selection and priority criteria for Member States with no full member in a given ERN, clear definitions of the three different sub-types of affiliated partners defined in the legislation, establishment of a win-win relationship between affiliated partners and the ERNs, inclusiveness and openness of the affiliation process), as well as a timeline / roadmap of the affiliation process. Further to the Board statement⁶ adopted in May 2016, the Board agreed on the following timeline: agreement on a statement (based on the above mentioned first statement, as well as the roadmap presented in this meeting) during the next Board meeting on 8 March 2017, then six months for newly created ERNs to start operating (during this period, ERNs will also be asked to develop an integration strategy for affiliated partners identified and designated by the Member States that finally should be presented to and approved by the Board, and in parallel Member States will be requested in the 2nd and 3rd quarter 2017 to identify and designate appropriate healthcare providers, for one or more sub-types of affiliation, based on recommended minimum criteria following a transparent and explicit procedure), with the aim of opening in the 4th quarter of 2017 an inclusive and effective process for applications and subsequent integration of nationally designated affiliated partners. The Board agreed with this timeline. The working group will now need to prepare the detailed proposal for agreement in March 2017.

9. Joint Action (JA) on Rare Cancer: Activities and planned actions and events (*Commission, DG SANTE CI*) (Chair TV)

A general overview of the Joint Action goals and work packages was presented. The JA was launched few weeks ago in Luxemburg. One of the main goals of the JA is to

⁶ https://ec.europa.eu/health/sites/health/files/ern/docs/boms_strategicview_affiliatedpartners_en.pdf

provide ERNs with support and technical inputs in different areas (in particular on clinical guidelines development). Furthermore, the JA will support the work to establish strong links between the ERNs addressing rare cancers (adult, paediatric and onco-haematology).

10. Information on the 3rd ERN Conference (9-10 March 2017 in Vilnius) (Chair TV) (*Commission and representative of the Ministry of Health, Lithuania*)

An overview was provided of the 3rd ERN Conference (9 March) and of the kick-off meeting of the ERNs (10 March) organised by the European Commission. The Conference, hosted by the Lithuanian Ministry of Health and included under the auspices of the Maltese Presidency of the Council, was presented. The Board would meet in Vilnius as well on 8 March. A working dinner of the ERN Coordinator Group and the ERN Board members will be organised on the 8th March in order to foster strong links between the two groups.

11. Any Other Business (AOB) (Chair AR)

- Co-Chair of the Board as of 2017: The two years of mandate of the current co-chair (Member State's representative, from Austria) expiring in December 2016, the election of the next co-chair will happen during the next Board meeting. The present co-chair was warmly thanked by the Board and expressed his willingness to continue, if Board members so agree. Volunteers can also express their interest prior to the next meeting.

- A Network agreement draft (voluntary tool to help networks organising their work) is currently being finalised, it will be shared with Board members, and also with coordinators of approved Networks.

- Licence contract for ERN trademark (logo): The Commission thanked Board members for checking the names of the healthcare providers to be mentioned on the different versions of the logo, and explained that a draft contract would be signed for the use of the logo with coordinators, who would be entitled to sign a sub-licensing contract with their members.

- Creation of the ERN Coordinators Group: After the approval of the Networks, this Coordinators Group will be formalised starting with a first meeting in the ERN March Conference. Further meetings will be planned back to back with some of the ERN Board of MS meetings in order to facilitate and strengthen the interaction and discussion at technical and strategic level.

- Workshop on Registries and ERNs: Organised by JRC on 30 Nov. 2016 in Luxembourg with the support of SANTE colleagues, this meeting enabled to explore, also with some Board members, ERN representatives and experts, the question of registries and ERNs. The report will be shared once made available.

Till Voigtländer,
Co-chair

Andrzej Rys,
Co-chair