



BOARD OF MEMBER STATES ON ERNS

29 APRIL 2021, 10:00-17:00

VIDEO-CONFERENCING VIA WEBEX

DRAFT MINUTES

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

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

The co-chair and DG SANTE B Director, Andrzej Rys, welcomed all participants and opened the meeting. The minutes of the last meeting of 29 January 2021 had already been approved by written procedure. The new colleagues that recently joined the Commission ERN team were introduced to the BoMS. Due to availability of the speakers, points 13 and 18 of the agenda had to be swapped. The Board accepted the change in the agenda.

2. Election of the new MS co-chair of BoMS

The BoMS thanked the current Member States co-chair Lennart Christiansson for his work and for chairing the group efficiently over the last two years. The voting procedure for the election of the new Member States co-chair was explained in detail by the Secretariat. Following the call for expression of interest five applications were received by the Secretariat and sent to the BoMS members in advance of the meeting together with the statements of intent of the respective candidates. The election took place as a secret ballot, eventually over three rounds.

The BoMS elected Mr Till Voigtländer as the new Member States co-chair of the BoMS for the next two years.

3. Update from the ERN Coordinators Group (ERN-CG)

The current ERN-CG co-chair provided an update on the activities of the ERN Coordinators Group. The new ERN-CG co-chair representing the ERNs and a new vice-chair (to be elected on 29 April 2021 at the internal ERN Coordinators meeting) will take up their new functions on 16 June 2021. The ERN-CG chair recalled the priorities that the coordinators identified with regard to the financial support of the ERN for the next years. Special emphasis was put on the need to remove the co-funding requirement of 60% for the funding received from the EU funding instruments.

The ERN-CG co-chair also raised the issues related to the composition and role of the ERN working groups should be clarified and adapted; BoMS role in addressing legal and ethical issues related to the ERN registries and uploading of patient data; the monitoring of ERNs that should be more efficient and less demanding; ERNs involvement in preparations of

future ERN projects by the Commission so as to make them more targeted to the ERN needs; and possibility of a new procedure for affiliated partners in non-covered MS. Finally, the ERN-CG co-chair wanted to thank the BoMS for their guidance in growing the ERNs from starters into adulthood.

The Commission explained that some of these questions will be addressed during the day. It was acknowledged that MS are not well represented in some working groups and the reporting from the working groups to the CG and BoMS should be improved. It was agreed that MS should make an effort to provide more technical experts for the respective working groups and it was agreed to make the composition of the WGs more flexible by allowing the invitation of external experts on an ad-hoc basis.

The Commission further clarified that the monitoring system is essential for further improvement of the ERN system and for demonstrating its added value and that it needs to be further developed whilst at the same time ensuring that the burden on the healthcare providers and ERNs remains proportionate. The Commission also clarified that the ERNs cannot directly participate in the preparation of the text of the tender calls or evaluations as this would be contrary to the applicable procurement rules. At the same the Commission recognised the importance of receiving early input from ERNs on their specific needs and requirements before launching any new project. The Commission is already applying this approach, for example in preparatory discussions regarding the future CMPS. The Commission also mentioned that the issue of new affiliated partners will be addressed only once the current assessment of the new ERN members is finished.

The new co-chair of the BoMS, proposed to have a stronger collaboration between the BoMS and ERN-CG by establishing regular and more frequent exchanges between the chairs also between the formal meetings of both groups.

4. Enlargement of the Networks – on-going call for new ERN members

The EC gave an update on the enlargement process and the online audits, indicating that the independent assessment review is currently taking place and will be finished in October 2021. A total of 843 applications were received, of which 627 obtained a favourable opinion and were transferred to the independent assessment body (IAB). The audits will be held online due to the current COVID-19 situation and will take place in May and June this year. The pilot online audit took place recently and the overall experience was successful.

Some members asked for more detailed information regarding the online audits in order to help the HCPs to prepare for the audits. The EC agreed to share more information about the methodology and the planning of the audits. Some countries asked for flexibility due to the current situation in the hospitals (e.g. some hospitals have recently been converted to COVID-19 hospitals and have to undergo an audit). The EC indicated that the difficult situation related to Covid has been taken into account throughout the whole process, including for example temporary suspension of the assessment process in 2020 or

extensions of deadlines where possible. However, it is important that the enlargement is completed this year and before the contract of the IAB ends.

5. Potential new ERNs

The EC presented the results of the survey on three potential new ERNs sent to the BoMS and ERN-CG in early 2020 concerning the potential ERNs on rare gynaecological and obstetric diseases, on rare mental diseases, and on rare infectious diseases. The results showed preliminary support of the BoMS and ERN-CG for the establishment of ERNs in the field of gynaecological/obstetric and infectious diseases, whilst in the area of mental diseases the opinions were split, partially due to the heterogeneity of this area and the overlap with other ERNs. However, the survey was considered as preliminary and non-conclusive partly because of the suboptimal participation of MS and ERNs.

There was a general agreement that for further reflections on these issues specific expertise is necessary and therefore scientific societies in the respective fields and other expert groups should be consulted before any decisions are taken. The EC clarified that no formal process for consideration of the new ERNs can start at least until 2023 when the AMEQUIS project and the evaluation of the existing networks will be finalised and the new framework contract with the IAB will be put in place.

6. Future direct ERN grants

Health and Digital Executive Agency (HaDEA) informed BoMS about the preparations of the new direct ERN grants to be launched in 2022. He explained that CHAFEA and INEA were integrated under the new agency HaDEA that was formally set up in early 2021. This new agency will be, among others, responsible for the implementation of the new EU4Health programme, including the direct ERN grants. The Regulation on the EU4Health programme was adopted in March 2021 and this represents the legal basis for the period 2021-2027. ERNs are mentioned as one of the specific objectives of the Programme. Currently the preparation of the 2021 Annual Work Programme is underway and should be adopted before the summer 2021. Regarding the new grant scheme for ERNs, it will cover 100% of the eligible costs and there will be no funding gap between the old and new grants. A “bridge” grant is being prepared also for eUROGEN that has different timing of the grants than the other ERNs. In addition, the EC announced its plan to conduct Simplified Cost Options (SCO) analysis that should feed into the preparation of the grants and which would help to reduce the bureaucratic burden for the ERNs. The SCOs analysis will require input and cooperation of HaDEA, INEA and the ERNs facilitated by an external contractor.

7. Evaluation of the Cross-border Healthcare Directive (CBHD)

The EC gave an overview of the EU legal framework for cross-border healthcare, in particular the Directive 2011/24 on patients’ rights in cross-border healthcare and informed the BoMS about the process of the evaluation of this Directive that started in January 2021. This evaluation will include also provisions on ERNs and it will assess the efficiency, effectiveness, coherence, relevance, and EU added value of the directive according to the

“Better regulation” principles. It was mentioned that some of the challenges concern the lack of awareness of patients, the incoherence of EU social security coordination, and the associated administrative burden.

The consultation strategy for the evaluation will consist of two parts: the open public consultation that will start on 4 May 2021, and a more targeted consultation with questions directed to specific stakeholders including the BoMS and ERN-CG. In addition, it was announced that there will be a workshop at the end of May on the indicators for the evaluation of the Directive.

BoMS members were invited to share their views on this topic and to engage in this consultation.

8. Managing disease areas within existing Networks

The EC presented a revised version of the draft protocol for managing disease areas within current ERN Healthcare Providers. The aim is to have in place a procedure that is simple and flexible and at the same time ensures that all relevant actors are involved and informed. The procedure should be initiated by an ERN member that will submit an application for extension of the disease coverage to its ERN board for assessment. It is left for the ERN boards to adapt the practical modalities of the assessment to the particular preferences and circumstances of each network.

The application should be also endorsed by the Member States competent authority. Some MS indicated possible difficulties to issue national endorsements as this may not be allowed or envisaged by the national legislation in place. The BoMS therefore agreed that following the notification by the ERN member the national competent authority may either (i) explicitly endorse the extension of the disease coverage; or (ii) reject it; or (iii) take no action within 30 days, after which expiry the application could proceed to the next stage.

After a positive assessment of the ERN board the final approval will be for the BoMS. All applications for BoMS final approval should be collected by the EC as the ERN secretariat and the BoMS should consider all of them together on an annual basis. It was clarified that no dedicated IT-tool will be created.

The final revised version of the document reflecting the agreement reached during the meeting will be sent to the BoMS after the meeting for written approval.

9. Review of legislation on orphan medicinal products

The EC gave an overview of the ongoing revision of the orphan medicines legislation, which is expected to culminate in a new legislative proposal by the end of 2022. Some of the problems identified during the process were: insufficient development in areas of greatest unmet medical needs, availability and accessibility varies across MS, scientific and technological developments cannot be fully exploited, and certain procedures are inefficient and burdensome. Different options are being considered for the modification of

the legislation. Some of these were the change of the current prevalence threshold of 5 in 10.000 or adapting the market exclusivity and incentives. At this stage no decisions have been taken yet and all options will be assessed especially with regard to their potential impacts. The next steps will be the open public consultation that will start at the beginning of May and the targeted surveys in May-June 2021. The ERNs will be consulted as part of this process.

10. Update on AMEQUIS project

The EC presented an update on the AMEQUIS project, whose objective is to improve the existing system of ERNs assessment and monitoring and to set up the methodology and procedures for ERNs periodic evaluations. The first ERN evaluation should start in 2022 in line with legal requirements and should be based on the outcomes of the AMEQUIS project. The EC explained that a collection of input and consultation with all the stakeholders including the BoMS and the ERN-CG has taken place in the stage of the project, including an expert workshop organised recently. The analytical work will continue and a second expert workshop is planned for November 2021. The project will finish in the beginning of 2022.

11. ERN Working Groups and their reporting – general issues

EC explained that one of the issues detected in different working groups (WGs) was the need to ensure the right technical expertise among the WG members, particularly for the LES WG and ITAG. In addition, the representation of the Member States should be reinforced in some of the WGs. During the discussion these concerns were largely confirmed by the BoMS members.

In order to improve the situation, Member States were encourage to send more experts with the right expertise to participate in the working groups. It was further agreed that besides the core group members and ad-hoc “visiting members” could be invited to provide input on specific topics. The WG should always be chaired by the representatives of ERNs and/or Member States but the WG members can be technical experts and not necessarily ERN-CG or BoMS members. All working groups will regularly report on the progress achieved to the plenary of BoMS and ERN-CG at each meeting.

12. Report from Working group on ERN integration

The working group’s co-chair presented the WG reflections on the scope and potential work areas and deliverables of the potential Joint Action on Integration of ERNs into national healthcare systems. Five potential work areas were identified in line with the 2019 BoMS Statement on ERN integration: governance framework for ERNs, integration in the national health systems, patient care pathways, referral systems to the ERNs, and education and awareness raising on ERNs at national level and sustainability of the ERN model at HCP level. The Working Group took into account the diversity and specificities of national health systems and identified specific issues that could be addressed for each potential work area.

The EC gave an update on the EU4Health which was adopted in March this year and the preparations of the 2021 Annual Work Programme (AWP). The Joint Action will not be included in the 2021 AWP but could be considered for the 2022 AWP.

BoMS took note of the work of the WG and did not express any objections with regard to the areas identified by the WG.

13. Report from Task Force on ERN registries

The Coordinator of the ErKNET ERN presented an update on the ERN registries activities, including their funding status, amount of patients' enrolments, and heterogeneity of registry design and platforms used. The issues presented and discussed concerned the need for various sources of funding for the sustainability of ERN registries, including funding from the MS; the 'virtual platform' aiming to connect the various registries as part of the work of the EJP RD; need for standardisation and FAIRification related to the establishment of this structure; ongoing work on generic informed consent for all registries, definitions of cross-ERN domain specific common data elements, facilitating access to EUPID, and a series of webinars and workshops for ERN registries teams. There are also ERN Research fellowships available which allow young doctors and/or PhD students of ERNs to visit other centres for training. Finally, an overview of the ERICA, the European Rare Disease Research Coordination and Support Action, was provided and it was explained how the different work packages can support the ERN registries, their enlargement and interaction with several actors (e.g. Elixir, EC, EMA, Industry).

14. Report from Working group on knowledge generation

The working-group co-chair presented an overview of the main tasks of the knowledge generation WG, of which the most important one is the development of Clinical Practice Guidelines and Clinical Decision Support Tools to support ERNs. Another important task is the preparation of the future ERN and EHDS virtual academy which will be a platform for online training materials produced by ERNs and also related to the European Health Data Space (EHDS).

With regard the Programme on development of ERN Clinical Practice Guidelines the contractor supporting the ERNs (AETSA) explained their activities and the state of play of the project. They emphasized the role of the consortium to support the ERNs during the development of these guidelines and tools considering the needs of each ERN. The work packages which are provided by them are focused on the organisational structure, methodology, training and practical support during the development of the guidelines and tools.

The EC gave an update on the ERN Professional Mobility Programme which allows health professionals from ERNs to visit other centres for training and learning purposes. Due to COVID-19, the first mobility round was postponed to June/July this year. The EC encouraged the MS to support their ERNs be actively involved in this programme.

15. Report from Working group on legal and ethical issues (LES)

The working group co-chair reported on the activities of the WG on LES. The main issues discussed recently by the Working Group on legal, ethical and stakeholder issues include the implementation of the 2019 BoMS statement on the ERN relationship with the industry, in particular with regard to the ERN conflict of interest policy and conflict of interest form; survey on existing ERN projects involving industry partners; ERN governance structure for future projects involving industry..

The BoMS was invited to reflect whether it would be willing to reconsider the 2019 BoMS Statement in particular with regard to the “no direct funding of ERNs by industry” clause. This is in particular relevant for the ERN registries and their sustainability. BoMS were also encouraged to increase the participation of MS in this WG and to ensure more legal expertise.

16. Report from ERNs IT Advisory Group (ITAG)

The EC gave an overview of the activities of the group and encouraged interested MS to participate as their contribution was at the time rather limited. The current tasks of the WG are the collection of feedback on the future new CPMS version and the preparatory work for the future ERN Virtual Academy.

Several brainstorming meetings with the ERN community were organised and showed support for the possibility that the future CPMS might have a mobile interface in addition to the current desktop. This would imply big changes to the platform but would be a unique opportunity to simplify the user interface.

The EC explained that the Service Directory (SD) and Indicators (IND) are stable tools now and that the Healthcare Provider Application was up and running.

In addition, the EC outlined that in the near future the CPMS will be based on a pay per user instead of pay per ERN and block of users model, which will increase the sustainability of the tool.

Regarding long-term goals, the future CPMS is intended to be modular and open-source, with a loosely-coupled architecture and flexible management. The backwards compatibility, security measures, and GDPR compliance will be maintained in the future CPMS; and the IT governance will stay in the hands of the ERN community and will be supported by the Commission. This structure will allow the different ERNs to adapt the CPMS to their own needs with little IT effort. This flexibility is not possible with the current CPMS. The new CPMS won't be launched before Q2 2023.

It was announced that the results of the data privacy impact assessment (DPIA) of the current CPMS will be presented on the 4th of May this year, and the BoMS were invited to follow the presentation.

During the discussion it was explained that the input needed from MS is not technical but on the governance and user features level.; the BoMS could, for example, provide their input regarding preferred monitoring functions to implement in the future CPMS in view of the integration of the ERNs in the national health systems.

17. CPMS activity report

The EC presented an overview of the usage of CPMS. The analysis showed a very limited use of CPMS in the last 3 years. It was pointed out that some possible reasons for this low use are the lack of reimbursement of CPMS sessions, inappropriate integration of CPMS, and a too complex system. The EC encouraged the MS to help improve these results.

Furthermore, the EC explained that the current licensing scheme of CPMS will be modified in the new contract, starting in June 2021 and will be more efficient.

During the discussion EC confirmed that a seamless connection with the ERN registries is being considered as well as the connection with the future EHDS. The results on the use of CPMS per ERN were also presented and showed an uneven use of CPMS. Some MS argued that the analysis should also be done in relative terms, using per MS population or number of ERN centres. The EC clarified that this was the initial idea but that it could not be performed because the available spatial data were not reliable.

18. Report from Working group on monitoring

The EC presented the main actions of the monitoring WG: improvement of the indicators system, awareness and training. It was explained that the goal of the monitoring exercise is primarily to assess the overall performance of the ERNs and not to compare the ERNs. The data collection in 2020 experienced limitations due to COVID-19 and Brexit. It was also stated that it is yet to be decided how to make the data public and what data to publish. It was shown that there has been a continuous growth of the ERN patient population, with currently 1.67 million patients being treated by the ERN members. In addition, there has been an increasing number of patient organisations participating in ERN activities.

The indicator concerning ERN training activities showed a participation of 92% of the ERN members in the activities. Similar trend was observed for research activities, and it was commented that this number was probably underestimated because of missing acknowledgment of ERNs in this area. Furthermore, it was commented that the development of ERN clinical practice guidelines (CPGs) and clinical decision making tools (CDMTs) was in progress and that the HCP participation was 89% at present.

During the discussion it was stated that it would be desirable to have a stronger cooperation with the WG on ERN integration. It was announced that the next steps of the WG on monitoring are to perform a survey on the data collection process and possible improvements, and to assure consistency between the report and the uploaded information. The data collection exercise will continue to take place twice a year, in March and October.

19. European Health Data Space and ERN registries

The EC presented the ongoing work on the creation of the European Health Data Space (EHDS), including the need to involve the ERNs in the collaboration and preparatory

discussion concerning the EHDS. The EC finalised a study on the assessment of MS legislation on health data processing and GDPR, and is conducting studies on existing regulatory gaps, and on infrastructure for the future EHDS. An impact assessment study supporting the future legal proposal on the EHDS will start in May. An online public consultation on the EHDS will be launched in the beginning of May.

The EC also presented the roadmap for the legislative proposal on EHDS and presented the pilot project on the infrastructure for the EHDS focusing on secondary use of health data. This pilot is built around health data space nodes, each of them being a trust anchor. Each node can be a HCP, MS authority, EU agency, research infrastructure, etc. The objective is to enable queries from one trusted node to another. An option currently under consideration is the creation of an “EU health data permit authority” which could be the gate to the EHDS for other organisations who are not attached to any node, for example for the ERN registries.

The potential advantages of this EHDS structure for the ERN registries were presented. Various options could be considered. For example, the ERN registries could have the possibility to orchestrate permit requests for access to data, have a secure cloud to store their registries, have the possibility to simplify registry implementation, receive access to tools for analytics and AI, and the IT provider will be managed by the EHDS. These options will be assessed as part of the impact assessment analysis.

To bring this forward it was suggested to have closer interaction between the ERN registries and the team working on the EHDS. At the same time, duplications of work and efforts should be avoided.

20. Any Other Business

Preliminary date of the next regular BoMS meeting is 11/11/2021, but the date will be confirmed later. In addition, an extraordinary meeting of the BoMS to approve the new ERN members will be organised before the end of 2021.

Meeting participants

Country	
Austria	Ireland
Belgium	Italy
Bulgaria	Latvia
Croatia	Lithuania
Cyprus	Malta
Czech Republic	Netherlands
Denmark	Norway
Estonia	Poland
Finland	Portugal
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	Sweden

Organisation
DG SANTE (Director, B3, B2, A4, B5)
HADEA
ERNs (CG co-chair, ERN RITA, ERKNet, GENTURIS, ERN EYE)
AETSA consortium