



MINUTES OF MEETING - DRAFT
BOARD OF MEMBER STATES ON ERNs
07 DECEMBER 2023, 10:00-11:00

WEBEX

Participants:

Commission: SANTE B3

Member States present online: AT; BE; CZ; DK; ES; FI; FR; IT; LT; NL; PT; SE & NO

Agenda:

9:45 - 10:00 Dial-in		
1	10.00 – 10.05	Opening of the meeting
2	10.05 - 10:15	Decision-making: the Improvement Plan of Tampere University Hospital, Finland, member of ERN EURO-NMD
3	10:15 - 10:30	Working Group on evaluation
4	10:30 – 10:50	Ombudsman case (Case 1900/2021/FA) – Proposal for a second level appeal procedure for ERNs activities
5	10.50- 10.55	Next BoMs meeting on 21-22 May
6	10.55 – 11.00	AOB/Closing of the meeting

1 | 10:00 – 10.05 | Opening of the meeting

DG SANTE welcomed participants to this extraordinary BoMs meeting which was called to make a decision on the improvement plan of the Tampere University Hospital, member of the ERN on evaluation of the ERN EURO-NMD.

DG SANTE noted that if time allows, discussion will also involve the WG on evaluation and the proposal for a second level appeal procedure for ERNs activities.

DG SANTE underlined that this agenda point on the decision making is closed for only the nominated representatives of the BoMs.

2 | 10.05 - 10:15| Decision-making: the Improvement Plan of Tampere University Hospital, Finland, member of ERN EURO-NMD

DG SANTE noted that as per Article 7 of the Rules of Procedure, the Board shall decide by consensus. Any vote shall be taken if any Board Member so requests, requiring a quorum of two thirds of the Board of Member States. In the event of a vote, the outcome of the vote shall be decided by a majority of two thirds of the Boards' Members present when the Chair proceeds to the vote. Absent Member's vote shall be taken into account if a written mandate to given to another Board Member. We have received no such communication. Therefore, we need a quorum, which means that two thirds – 19 Member States need to be present.

DG SANTE and the Co-Chair of the Board of Member States concluded that as only 13 Member States were present in the meeting, quorum was not met. As a result, it was agreed that the decision making will be followed up by written procedure, allowing 5 working days for representatives of the Board of Member States to reply. DG SANTE will then collect the replies and inform the Board of Member States of the results.

Discussion:

CZ asked where the report was available.

DG SANTE noted that it is available in CIRCA BC as per the previous transmission of reports. Details will be highlighted in where to access the report in the email for the written procedure.

AT asked about the classification of the HCP and whether the implementation of the improvement plan will be feasible given the plurality of gaps.

DG SANTE noted that the report classified the HCP as acceptable and that the HCP will be re-evaluated in one year to assess the level of implementation or not.

CZ highlighted the need to have hospital management support HCPs during the implementation of the improvement plan phase.

DG SANTE noted that it would be beneficial if the Board of Member States and the ERNs monitored the implementation process, and if it is identified that hospital managers should intervene, this could first be followed up the ERNs, then the Board of Member States and, finally, if it is needed, DG SANTE may also support.

3 | 10:15 - 10:30 | Working Group on evaluation

DG SANTE presented the proposal for the upcoming Working Group to improve the evaluation process and methodology in line with ERN legislation. Here, it was proposed that the Working Group would use the template for the mandate of the group which includes scope, goals, tasks,

timeline, and expected deliverables. Currently, it is proposed that it will take a 2-stage approach with the Working Group concluding with a report on conclusions for improvement of the methodology, followed by the revision of the Evaluation manual and the Toolkit, which may be supported by a contractor. The Group would start in February/March of 2023 and have participants from ERNs, Board of Member States and DG SANTE. Observers/Experts may also be invited, such as the Independent Evaluation Body and HADEA. The secretariat would be provided by DG SANTE, and it is proposed that DG SANTE acts as the Chair, with the ERNs and the Board of Member States nominating a rapporteur, responsible for the drafting and technical input.

DG SANTE will follow up with a final email for expression of interest to the Board of Member States and the ERN coordinators, and that the draft mandate would be shortly shared along with a date for the first meeting of the Working Group.

Discussion:

SE and CZ asked that the meeting dates are decided as soon as possible and shared.

DG SANTE asked about the frequency of the meetings.

The Co-Chair of the BoMs highlighted that the frequency of meeting could be established in the first meeting of the Group.

SANTE confirmed that an invitation to the first meeting will be sent out shortly.

NL asked about how many participants the Group will have.

DG SANTE noted there were no restrictions in numbers, but that active participation should be sought. During the first meeting of the Group, further discussion on composition and frequency can be addressed. However, the main participants would be the ERNs and the Board of Member States with consultations of other groups such as patient organizations, hospital managers, etc.

FR underlined the importance of the involvement of the ERNs.

DG SANTE agreed and noted that they are encouraged to participate and, so far, there is a high level of interest from their side.

CZ noted that experts in quality of care assessment should also be considered and highlighted the importance of a wide perspective.

DG SANTE agreed, but suggested that the Group should be composed of a core group and that consultations could be undertaken outside of the setting of the actual Working Group.

CZ also noted the importance of considering the work of the Joint Action as regards quality of care.

4 | 10:30 - 10:50 | Ombudsman case (Case 1900/2021/FA) – Proposal for a second level appeal procedure for ERNs activities

DG SANTE recalled the European Ombudsman case and the suggestions to put in place a second level of appeal procedure for ERN activities. DG SANTE then presented a draft

decision of the Board of Member States that highlighted the different steps for such an appeal procedure.

Discussion:

The Co-Chair of the Board of Member States underlined that the timing of the procedure is important and that complaints are usually dealt with internally before going to external bodies.

CZ agreed to the need to have a mechanism in place for such complaints and asked for further information on the case that originated the European Ombudsman decision.

DG SANTE noted that further information is available in the full decision of the European Ombudsman, which is publicly available.

FR asked whether the draft procedure had been sent to the ERN coordinators and that it would be important to have their views as well. Overall, FR noted that this is an important document but that due to its legal nature, further time would be needed for consultations.

DG SANTE agreed that it would be beneficial to consult the ERNs. As a result, the draft procedure will be shared with the Chairs of the Coordinators Group and the Board of Member States. Following this, DG SANTE would revise the document and then launch a written procedure.

5 | 10:50 - 10:55 | Next BoMs meeting on 21-22 May

DG SANTE noted that for the next BoMs plenary planned for 21-22 May, it has been proposed to have this held physically in Luxembourg with hybrid possible in case presence is not possible. DG SANTE asked for the agreement of the BoMs. DG SANTE and the Co-Chair of the Board of Member States highlighted the importance of joining in person in order to facilitate discussions. The proposal for the physical meeting in May was agreed.

6 | 10:55 - 11:10 | AOB/Closing of the meeting

No further points were raised. DG SANTE closed the meeting and thanked colleagues for their participation.

Follow up action points:

- DG SANTE to follow up on the decision making of Tampere University Hospital, Finland, member of ERN EURO-NMD, by written procedure allowing 5 working days for representatives of the Board of Member States to reply;
- DG SANTE to collect replies from the written procedure and inform the Board of Member States of the results;
- DG SANTE will send final email for expression of interest to the Board of Member States and the ERN coordinators for the Working Group on evaluation;
- DG SANTE will send the draft mandate for the Working Group on evaluation and the save the date for the first meeting of the Group;

- DG SANTE will share the draft procedure for the secondary appeal process to the Chairs of the Coordinators Group and the Board of Member States. Following this, DG SANTE will revise the document and then launch a written procedure;
- DG SANTE will send the save the dates for the 2024 plenaries of the Coordinators Group and the Board of Member States.