

RULES OF PROCEDURES OF THE BOARD OF MEMBER STATES OF THE EUROPEAN REFERENCE NETWORKS (ERNs)

The Board of Member States of the ERNs (Hereinafter the Board),

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, and in particular to Article 12,

Having regard to Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil [Hereinafter 'the Delegated Decision'] ,

Having regard to Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks [Hereinafter 'the Implementing Decision'], and in particular to Article 6 and recital 9 thereof,

Having regard Decision No 153/2014 of the EEA Joint Committee of 9 July 2014 amending Annex X to the EEA agreement which incorporated Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare into the EEA Agreement.

Has adopted the following rules of procedure:

Article 1

Members of the Board - notification and withdrawal

1. Member States of the EU and EEA countries [Hereinafter 'Member States'] are invited to participate and be members of the Board [Hereinafter 'Board Member'].
2. The notification referred to in Article 6 (2) of the Implementing Decision shall be addressed in writing to the Commission.
3. Member States shall inform the secretariat of the Board in writing the names of their two representatives. Only officially nominated representatives are allowed to attend meetings and pass votes. Continuity of representation shall be aimed. Costs for travel will be covered by the Commission for one representative per Member State.
4. Representatives can be accompanied by national experts. Within a reasonable time and no later than 10 working days before the date of a Board meeting, the names and functions of the experts and the reasons for which their presence is required, shall be communicated to the secretariat of the Board.
5. A Member State wishing to withdraw from the Board shall send a written notification

with a three-month notice.

Article 2

Chair

1. The Board shall be co-chaired by a representative of a Member State participating in the Board and by the Commission's Director for Health systems and products and/or her/his alternate.
2. The Member State representative referred to in paragraph 1, shall be appointed for a period of two years, amongst the Member States representatives of the Board, according to the modalities laid out in Article 7 .
3. The Chair including the Commission shall have neither voting rights nor any casting vote, yet the Member State whose representative is holding the chair, shall nominate another representative to the Board and shall retain its voting rights as a Member of the Board.
4. The Commission will cover the travel costs for the co-chair.

Article 3

Convening a meeting

1. Meetings of the Board are convened by the Chair at least once a year, either on his/her own initiative, or at the request of a simple majority of Board Members.
2. Meetings of the Board shall be held on Commission premises unless otherwise decided by the Board Members.

Article 4

Secretariat

In accordance with Article 6(5) of the Implementing Decision, the Commission shall provide secretarial support for the Board and any sub-groups created by the Board.

Article 5

Agenda

1. The Secretariat shall draw up the agenda, after consultation of the chairs, taking into account the available assessment and evaluation technical reports and other possible points for discussion or information with direct relevance to the tasks and competences of the Board.
2. The agenda shall be adopted by the Board at the start of the meeting.

Article 6

Documentation to be sent to Board Members

1. The secretariat shall send the invitation to the meeting and the draft agenda to the Board Members no later than twenty eight calendar days before the date of the meeting.
2. The secretariat shall send to the Board Members the assessment or evaluation reports and any other documentation to be discussed by the Board no later than twenty eight calendar days before the date of the meeting.

Article 7

Voting rules and decisions making process of the Board

1. As far as possible, the Board shall decide by consensus. Abstentions shall not prevent the adoption of deliberations by consensus.
2. A vote shall be taken if any Board Member so requests. Voting requires a quorum of two thirds of the Board of Member States for both the physical and the virtual meetings. 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.
3. Each Member State represented in the Board shall have one vote no matter the number of its representatives attending the meeting. Absent Member's vote shall be taken into account if a written mandate is given to another Board Member. These mandate letters should be communicated to the secretariat of the Board in advance.

Article 8

Tasks and Decisions of the Board

1. Approval of Networks proposals and healthcare provider's membership applications included in the Network proposal: In accordance with Article 6(4) and Article 9 of the Implementing Decision the Board must decide whether or not to approve the proposals for Networks and Members.
2. Approval of healthcare providers wishing to join an existing Network: In accordance with Article 10 and Article 9 of the Implementing Decision the Board of Member States must decide whether or not to approve the applications of new Members to an existing Network.
3. Review of negative individual Member's applications if a given healthcare provider negatively assessed, decides, in accordance with Article 5 (4) or 10 (2) of the Implementing Decision, to submit its membership application and negative assessment report to the Board of Member States.
4. Termination of a Network: In accordance with Article 11 of the Implementing Decision the termination of a Network must be approved by the Board.

5. Loss of membership: In accordance with Article 12 and Article 14 of the Implementing Decision the loss of membership must be approved by the Board.

6. When the decision of the Board on regards to the above paragraphs (1) (2) (3) (4) and (5) differs from the technical assessment of the independent assessment bodies and in accordance with Article 6 (1) and (4) of the Implementing Decision, the Board must decide what procedure to follow and give the reasons for its decision which will be communicated to the interested parties and managed according to Article 11 of this Rules of Procedures.

7. In accordance with Article 5 (3) of the Implementing Decision, when the minimum number of healthcare providers or of Member States is not reached, Member States will encourage their healthcare providers to join the proposed Networks.

8. Member States with no Member of a given approved Network shall inform the Board on any healthcare providers they might wish to designate to cooperate with the relevant Network as Associated or Collaborative National Centres or as a national coordination hub as mentioned in the Delegated Decision and Implementing Decision. The Board will take note of those designations.

9. Evaluation of the Networks: In accordance with Article 14 (7) of the Implementing Decision any termination of a Network must be approved by the Board.

10. The Board may offer the Network or the Member with a negative evaluation and presenting an improvement plan, one year of extension before carrying out a new evaluation as provided in Article 14 (7) of the Implementing Decision.

11. In accordance with Article 13 (1) of the Implementing Decision the Board might decide to participate in the consultation process on the content of the Assessment Manual to be draw up by the Commission.

Article 9

Admission of third parties

1. Representatives of the Independent Assessment body (ies) on charge of the technical assessment of the Network proposals, membership applications and evaluation of the approved Networks will attend, following the request of the Chair, regularly the meetings of the Board. Those rapporteurs shall present, summarise and clarify the outcomes of their assessments and evaluations.

2. The Chair may invite on an ad hoc basis experts from outside the Board with specific competence in a subject on the agenda to participate in the work of the Board.

Article 10

Written procedure

1. If necessary, the Board's opinions, conclusions, recommendations, or reports on a specific question may be delivered via a written procedure. To this end, upon request of the Chair, the

secretariat sends the Board Members the document(s) on which the Board is being consulted and, where appropriate, sets a time limit for observations.

2. The secretariat shall inform the Board of the outcomes of the written procedure.

3. However, if a simple majority of Board Members asks for the question to be examined at a meeting of the Board, the written procedure shall be terminated without result and the Secretariat shall convene a meeting of the Board as soon as possible.

Article 11

Summary minutes of the meetings and publication of the Board's decisions

1. Summary minutes on the discussion on each point on the agenda and the opinions and decisions delivered by the Board shall be drafted by the secretariat and send out to the Board Members without delay and no later than 15 working days after the meeting.

2. The Board Members shall send any comments they may have on the draft summary minutes to the secretariat in writing within 15 working days.

3. The summary minutes and the decisions of the Board shall be published according Article 16.1 (b) of the Implementing Decision.

Article 12

Attendance list and Conflicts of interest

1. At each meeting, the secretariat shall draw up an attendance list specifying the authorities and organisations to which the persons designated by the Member States to represent them belong.

2. At the beginning of each meeting, any person designated by the Member States, as well as experts and representatives of third parties who have been invited to attend the meeting, shall inform the chair of any conflict of interest¹ with regard to a particular item on the agenda.

3. In the event of such a conflict of interest, the person concerned shall, at the request of the chair, withdraw from the meeting whilst the relevant items of the agenda are being dealt with.

4. Conflicts of interest shall be reported in writing, e.g. in the summary minutes of the Board's meeting.

5. Paragraphs 1, 2, 3 and 4 shall also apply to deliberations taken by the Board in written procedure.

Article 13

¹ As an example, Article 52(2) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 248, 16.09.2002, p. 1) contains a specific definition of a conflict of interest.

Correspondence

1. Correspondence relating to the Board shall be addressed to the secretariat, for the attention of the Chair.
2. Correspondence for Board Members shall be sent to the e-mail address or addresses which they provide for that purpose.

Article 14

Access to documents

Requests for access to Board's documents shall be handled in accordance with Regulation (EC) No 1049/2001². It is for the Commission to take a decision on requests for access to those documents pursuant to its Rules of Procedure as amended by Decision 2001/937/EC, ECSC, Euratom³. If the request is addressed to a Member State that Member State shall apply Article 5 of Regulation (EC) No 1049/2001.

Article 15

Confidentiality of deliberations

1. The Board's deliberations shall be confidential.
2. The Board may, by a simple majority of its Members, decide to open its deliberations to the public.

Article 16

Protection of personal data

All collecting, processing and publishing of personal data for the purposes of these rules of procedure shall be in accordance with Regulation (EC) No 45/2001⁴ and Directive 95/46/EC⁵ where applicable.

² Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001 p.43).

³ Commission Decision of 5 December 2001 amending its rules of procedure (2001/937/EC/ECSC, Euratom, OJ L 345, 29.12.2001, p. 94).

⁴ Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1 2001, p.1).

⁵ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).