

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

**VERSION OF 15 March 2024**

The Board of Member States of the ERNs [Hereinafter 'the Board'],

Having regard to Article 12 of 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<sup>1</sup> [Hereinafter 'Cross-border healthcare Directive'],

Having regard to the Article 4 and Recital 3 of 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<sup>2</sup>,

Having regard to the 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<sup>3</sup>,

Having regard to the Commission Implementing Decision 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU 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<sup>4</sup>,

Having regard to the Decision No 153/2014 of the EEA Joint Committee of 9 July 2014 amending Annex X to the EEA agreement which incorporated the cross-border healthcare Directive into the EEA Agreement<sup>5</sup>.

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 of the European Reference Networks [Hereinafter 'Members of the Board'].

2. The notification referred to in Article 6(2) of the Commission Implementing Decision 2014/287/EU concerning the notification of the Member States to the Commission on the national authority that

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<sup>1</sup> 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 (*OJ L 88, 4.4.2011, p. 45*).

<sup>2</sup> 2014/286/EU: Commission Delegated Decision 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 (*OJ L 147, 17.5.2014, p. 71*).

<sup>3</sup> 2014/287/EU: Commission Implementing Decision 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 (*OJ L 147, 17.5.2014, p. 79*).

<sup>4</sup> Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU 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 (*OJ L 200, 29.7.2019, p. 35*).

<sup>5</sup> Decision of the EEA Joint Committee No 153/2014 of 9 July 2014 amending Annex X (Services in general) to the EEA Agreement (*OJ L 15, 22.1.2015, p. 78*).

shall represent them on the Board of the Member States, shall be addressed in writing to the Commission.

3. Member States shall inform the Secretariat of the Board of Member States in writing the names of their two representatives. At least one of the representatives should be nominated from the national health Competent Authority. Only officially nominated representatives or their alternates are allowed to attend meetings and pass votes. Costs for travel will be covered by the Commission for one representative per Member State, following Commission reimbursement rules.

4. Representatives can be accompanied by national experts. Within a reasonable time and no later than 5 working days before the date of a Board of Member States 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 of Member States. The Secretariat must confirm the participation of the national experts.

5. Members States must inform the Secretariat of the change of their members in the Board, by means of a written notification, as their earliest convenience.

## *Article 2*

### **Chairs**

1. The Board of Member States shall be co-chaired by a representative of a Member State participating in the Board of Member States and by the Commission's representative or their alternate.

2. The Member State representative referred to in paragraph 1 shall be appointed for a period of 2 years, amongst the Member States representatives of the Board of Member States, according to the modalities laid out in Article 7 of the Rules of Procedure. The appointment shall take effect on the first day of the month following the appointment.

3. The Chair, including the Commission, shall have neither voting rights nor any casting vote. However, the Member of the Board whose representative is holding the Chair shall nominate another representative to the Board of Member States and shall retain its voting rights as a Member of the Board of Member States.

4. The Commission will cover the travel costs for the Co-Chair.

## *Article 3*

### **Convening a meeting**

1. Meetings of the Board of Member States are convened by the Co-Chairs at least once a year, but preferably twice a year. Board of Member States meetings should be held back-to-back to ERN-Coordinators Group (ERN-CG) meetings to facilitate their collaboration and exchange of views.

2. The Co-Chairs may also request the Board of Member States to convene for *ad-hoc* meetings. In such cases the delivery of the agenda and supporting documents may be closer to the meeting than the 10 working days envisaged for ordinary meetings.

3. Physical meetings of the Board of Member States shall be held on Commission premises unless otherwise decided by the Co-Chairs.

#### *Article 4*

##### **Secretariat**

In accordance with Article 6(5) of the Commission Implementing Decision 2014/287/EU, the Commission shall provide secretarial support for the Board of Member States and any Working Groups created by the Board of Member States.

#### *Article 5*

##### **Agenda**

1. The Secretariat shall draw up the agenda after consulting the Chairs and sent it out to the Board of Member States no later than 15 working days before the meeting.
2. The agenda shall be adopted by the Board of Member States at the start of the meeting.

#### *Article 6*

##### **Documentation to be sent to the Members of the Board**

1. The Secretariat shall send to the Members of the Board the documents to be discussed by the Board Member States no later than 10 working days before the date of the meeting.
2. CIRCA-BC will be the official repository of the Board of Member States documents.

#### *Article 7*

##### **Voting rules and decision-making process of the Board of Member States**

1. The Board of Member States shall decide by consensus, as far as possible. Consensus requires a quorum of two thirds of the Board of Member States for both the physical and virtual meetings. Abstentions shall not prevent the adoption of deliberations by consensus.
2. A vote shall be taken if any Board Member States so requests. Voting requires a quorum of two thirds of the Board of Member States for both the physical and virtual meetings. The outcome shall be decided by a majority of two thirds of the present Members of the Board when the Chair proceeds to the vote.
3. Each Member State represented in the Board of Member States shall have one vote no matter the number of its representatives attending the meeting. Absent Member's vote shall be accepted if a written mandate is given to another Member of the Board. This written mandate shall be communicated to the Secretariat of the Board of Member States no later than 5 working days before the meeting.
4. It is highly advisable that the Members of the Board ensure the representation of their Member State during the meetings of the Board of Member States. If physical participation is not possible, virtual participation shall be ensured during the meetings of the Board of Member States. This is especially important for all cases where voting is scheduled on the agenda to reach the required quorum and to have as many Member States as possible expressing their views.

## *Article 8*

### **Tasks and Decisions of the Board of Member States**

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 2014/287/EU, the Board of Member States must decide whether to approve the proposals for European Reference Networks for rare diseases (ERN) and their members.
2. Approval of healthcare providers wishing to join an existing ERN: in accordance with Article 10 and Article 9 of the Implementing Decision 2014/287/EU, the Board of Member States must decide whether to approve the applications of new Members to an existing ERN.
3. Review of negative individual Member's applications: in accordance with Article 5(4) or Article 10(2) of the Implementing Decision 2014/287/EU, a given healthcare provider negatively assessed by the Independent Evaluation Body can submit their membership application and negative assessment report to the Board of Member States for review.
4. Termination of a Network: In accordance with Article 11 of the Implementing Decision 2014/287/EU, the termination of a Network must be approved by the Board of Member States.
5. Loss of membership: In accordance with Article 12 and Article 14 of the Implementing Decision 2014/287/EU, the loss of membership must be approved by the Board of Member States.
6. When the decision of the Board of Member States as regards the above paragraphs (1) (2) (3) (4) and (5) differs from the technical assessment of the Independent Evaluation Body and in accordance with Article 6(1) and (4) of the Implementing Decision 2014/287/EU, the Board of Member States 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 2014/287/EU, when the minimum number of healthcare providers of Member States is not reached to set up a network, Member States will encourage their healthcare providers to join the proposed Networks in view of reaching the minimum number.
8. Member States with no Member of a given approved Network shall inform the Board of Member States 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 2014/286/EU and Implementing Decision 2014/287/EU. The Board of Member States will take note of those designations.
9. Evaluation of the Networks: In accordance with Article 14(7) of the Implementing Decision 2014/287/EU any termination of a Network must be approved by the Board of Member States.
10. The Board of Member States may offer the Network or the ERN 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 2014/287/EU.
11. In accordance with Article 13(1) of the Implementing Decision 2014/287/EU, the Board of Member States might decide to participate in the consultation process on the content of the Assessment Manual to be draw up by the Commission.

12. The Board of Member States shall be notified of any change in the coordination in the ERN networks.

13. The Board of Member States can be consulted on complaint reviews regarding the ERNs.

#### *Article 9*

##### **Admission of third parties**

1. The Chairs may invite, on an *ad-hoc* basis, experts from outside the Board of Member States with specific competence in a subject on the agenda to participate in the meeting of the Board of Member States.

#### *Article 10*

##### **Written procedure**

1. If necessary, the Board of Member States's opinions, conclusions, recommendations, or reports on a specific question may be delivered via a written procedure. To this end, upon request of the Chairs, the Secretariat will send the Members of the Board the document(s) on which the Board of Member States is being consulted and sets a time limit for observations or decision, including votes.

2. The Secretariat shall inform the Board of Member States of the outcome(s) of the written procedure.

3. However, if a simple majority of the Members of the Board requests that the question should be discussed at a meeting of the Board of Member States, the written procedure shall be terminated without result and the Secretariat shall convene a meeting of the Board of Member States as soon as possible.

#### *Article 11*

##### **Summary minutes of the meetings and publication of the Board of Member States decisions**

1. Summary minutes on the discussion on each point on the agenda and the opinions and decisions adopted by the Board of Member States shall be drafted by the Secretariat and sent to the Board Member States no later than 15 working days after the meeting.

2. The Members of the Board shall send any comments they may have on the draft summary minutes to the Secretariat in writing within 10 working days of receiving these.

3. The summary minutes and the decisions of the Board of Member States shall be published according to Article 16(1)(b) of the Commission Implementing Decision 2014/287/EU.

#### *Article 12*

##### **Attendance list and Conflicts of interest**

1. At each meeting, the Secretariat shall draw up an attendance list of Member State representatives in the meetings of the Board of Member States.
2. At the beginning of each meeting, either Board of Member States meetings or Board of Member States Working Groups meetings, any Member State representative, as well as experts and representatives of third parties who have been invited to attend the meetings, shall inform the Co-Chairs of any conflict of interest regarding a particular item on the agenda.
3. Conflict of interest is defined as any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's ability to act independently and in the public interest when participating in the Board of Member States meeting.
4. In the event of such a conflict of interest, the person concerned shall, at the request of the Co-Chairs, withdraw from the meeting whilst the relevant items of the agenda are being dealt with.
5. Conflicts of interest shall be reported in writing, e.g., in the summary minutes of the Board of Member States meeting.
6. Paragraphs 1, 2, 3 and 4 shall also apply to deliberations taken by the Board of Member States in written procedures.

### *Article 13*

#### **Working Groups**

1. The Board of the Member States may decide to set up Working Groups [Hereinafter 'WGs'] to carry out a specific task of interest or importance to the Board of Member States or the Commission, defined when the WG is set up.
2. The Board of Member States may decide that the WG will be set up jointly by the Board of Member States, the ERN-CG and the Commission.
3. Each WG will be led by an elected WG Chair. The WGs Chair may be a Board of Member State representative, an ERN Coordinator, or a Commission representative.
4. Each WG shall finalise, no later than 4 weeks after its activation, a draft mandate describing the scope, goals, tasks, timeline and expected deliverables of the WGs. The Board of Member States shall approve the mandate of the WG. In the case of a joint WG, both the Board of the Member States, the ERN-CG and the Commission shall approve the mandate of the WG according to the decision-making rules set up in their respective Rules of Procedures.
5. The Chair of the WGs shall lead, organise, and supervise the work of the WGs based on their mandate. This might include organising web conferences or, when necessary, ad hoc meetings of the WGs.
6. Once a mandate of a WG is fulfilled or when so decided by Members of the Board and, if relevant, the ERN-CG and the Commission, the WGs shall be terminated.
7. External experts can also participate in the WGs, provided that they are nominated by a Member State or, if relevant, by an ERN Coordinator and the Commission. The names and functions of the external experts and the reasons for which their presence is required, shall be communicated to the

Secretariat of the Board of Member States within the deadlines set by the Secretariat. The Secretariat must approve the external experts' participation.

8. The list of the WGs, including a description of their mandate will be published on the ERNs webpage of the Commission.

9. A member of a WG wishing to withdraw from it, shall send a written notification to the Secretariat of the Board of Member States.

10. WGs should convene at least twice a year. Any further meetings are voluntary, if the group so wishes, based on the needs and ongoing priorities.

#### *Article 14*

##### **Correspondence**

1. Correspondence relating to the Board of Member States shall be addressed to the Secretariat, for the attention of the Co-Chairs.

2. Correspondence for Members of the Board shall be sent to the e-mail address or addresses which they provide for that purpose.

#### *Article 15*

##### **Access to documents**

Requests for access to Board of Member States documents shall be handled in accordance with Regulation (EC) No 1049/2001<sup>6</sup>. 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<sup>7</sup>.

#### *Article 16*

##### **Confidentiality of deliberations**

1. The Board of Member States' deliberations shall be confidential.

2. The Board of Member States may, by a simple majority of its Members of the Board, decide to open its deliberations to the public.

#### *Article 17*

##### **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 relevant EU legislation where applicable Regulation (EU) 2018/1725 on the

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<sup>6</sup> 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*).

<sup>7</sup> Commission Decision of 5 December 2001 amending its rules of procedure (notified under document number C(2001) 3714) (*OJ L 345, 29.12.2001, p. 94*).

protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies<sup>8</sup> and Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data<sup>9</sup>.

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<sup>8</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (*OJ L 295, 21.11.2018, p. 39*).

<sup>9</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (*OJ L 119, 4.5.2016, p. 1*).