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

(Text with EEA relevance)

(2014/287/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 [1], and in particular Article 12(4)(b) and (c) thereof,

Whereas:

(1) Commission Delegated Decision 2014/286/EU [2] sets out the criteria and conditions that European Reference Networks ('Networks') and healthcare providers wishing to join such Networks must fulfil.

(2) Pursuant to Article 12(4)(b) and (c) of Directive 2011/24/EU, the Commission is to decide the criteria for establishing and evaluating the Networks and the measures for facilitating the exchange of information and expertise on establishing and evaluating the Networks.

(3) Networks should be established and healthcare providers approved as Members of the Networks on the basis of an open and transparent procedure. The procedure should include: (1) the call for interest; (2) Member States' endorsement of applications of their healthcare providers; (3) the submission of applications to the Commission; (4) the verification of the completeness of applications; (5) the technical assessment by an independent body of applications to form the Networks and of applications from individual healthcare providers wishing to be Members of a Network, to determine whether the applicants fulfil the criteria; (6) the communication of the assessment outcomes; (7) the approval of the Networks and their membership by Member States; and (8) the publication of the list of established Networks and of their Members.

(4) In order to increase the coverage of the Networks, individual healthcare providers wishing to join a Network should be allowed to do so at any time. Their applications should be assessed according to the same procedure as that used to assess applications for the initial Network, including the endorsement of applications by the Member State in question.

(5) In order to guarantee that the Network has genuine European Union added value and is big enough to enable the sharing of expertise and to improve access to care for patients across the Union, only applications from the minimum required numbers of healthcare providers and Member States, submitted in line with the call of interest, should be approved. If an insufficient number of healthcare providers apply or applications cover an insufficient number of Member States, the Commission should ask Member States to encourage their healthcare providers to join the proposed Network.

(6) It might be difficult to reach the required minimum number of healthcare providers or Member States for some rare diseases or conditions due to a lack of expertise. It would therefore be a good idea to group healthcare providers that focus on related rare diseases or conditions in a thematic Network. Networks could also include providers of high technology services which usually require very high capital investment, such as laboratories, radiology services or nuclear medicine services.

[1] OJ L 88, 4.4.2011, p. 45.
[2] See page 71 of this Official Journal.

(7) Member States none of whose healthcare providers are Members of a Network should designate collaborative and associated national centres to encourage them to cooperate with the relevant Network.

(8) Each Network's and healthcare provider's application, once their completeness has been established, should be technically assessed according to the criteria set out in Delegated Decision 2014/286/EU. The assessment should, on the basis of a common assessment manual, include an exhaustive documentation review and on-site audits of a selected number of applicants. It should be carried out by an independent assessment body appointed by the Commission.

(9) Member States are invited to set up a Board of Member States which should decide on the approval of proposed Networks and on their membership. Member States' participation should be voluntary. Only a positive assessment issued by an assessment body should generally prompt Member States to approve the establishment of a Network and to grant membership of the Network.

(10) Networks' Members should be licensed to use the 'European Reference Network' logo. The logo, owned by the European Union, should constitute the visual identity of the Networks and their Members.

(11) Using a common evaluation manual, an independent evaluation body appointed by the Commission should periodically evaluate Networks and their Members. The evaluation should conclude with a technical evaluation report detailing the extent to which the objectives set out in Article 12(2) of Directive 2011/24/EU have been achieved and the criteria and conditions set out in Delegated Decision 2014/286/EU fulfilled. It should also describe the outcomes and performance of the Network and the contribution of its Members. A negative evaluation report should generally prompt Member States to approve the termination of a Network. Compliance with the requirement to have a minimum number of healthcare providers and Member States should be monitored after the evaluation so that the European Union added value of the Network can be maintained.

(12) The assessment and evaluation manuals should be based on internationally recognised practices and contain the core principles and methodologies for carrying out assessments and evaluations.

(13) The Commission should facilitate the exchange of information and expertise on establishing and evaluating the Networks. It should make general information on the Networks and their Members and the technical documentation and manuals on establishing and evaluating the Networks and their Members available to the public. It may offer to the Networks and their Members the use of specific communication media and tools. Conferences and experts meetings should be organised to provide a forum for technical and scientific debate among Networks.

(14) The personal data related to establishing and evaluating the Networks should be processed in compliance with Regulation (EC) No 45/2001 of the European Parliament and of the Council [1] as appropriate.

(15) The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Article 16 of Directive 2011/24/EU,

HAS ADOPTED THIS DECISION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Decision sets out:

(a) the criteria for establishing and evaluating the Networks referred to in Article 12 of Directive 2011/24/EU; and

(b) the measures to facilitate the exchange of information and expertise on establishing and evaluating the Networks referred to in Article 12 of Directive 2011/24/EU.

[1] OJ L 8, 12.1.2001, p. 1.

CHAPTER II

ESTABLISHMENT OF EUROPEAN REFERENCE NETWORKS

Article 2

Call for interest to establish a European Reference Network

1. The Commission shall publish a call for interest to establish Networks within two years following the entry into force of this Decision.

2. Any group of at least 10 healthcare providers established in at least 8 Member States may collectively respond by the deadline indicated in the call for interest with an application containing a proposal to establish a Network in a given field of expertise.

3. The content of the application shall be as set out in Annex I.

4. On receiving an application, the Commission shall verify whether the conditions on the minimum number of healthcare providers and Member States as set out in paragraph 2 are met.

5. If either of those conditions is not met, the application shall not be entitled to assessment and the Commission shall ask Member States to encourage their healthcare providers to join the proposed Network in order to help reach the required number(s).

6. After consulting the Member States, the Commission shall decide on the appropriate timing for the publication of subsequent calls for interest.

Article 3

Membership applications

1. The application containing a proposal to establish a Network shall be accompanied by a membership application for each healthcare provider concerned.

2. The content of the membership application shall be as set out in Annex II.

3. The membership application shall be accompanied by a written statement from the healthcare provider's Member State of establishment certifying that its participation in the proposal to establish a Network is in accordance with the Member State's national legislation.

Article 4

Technical assessment of applications

1. If the Commission concludes that the requirements set out in Article 2(2) and in Article 3(2) and (3) are fulfilled, it shall appoint an assessment body to assess applications.

2. The assessment body shall verify whether:

(a) the content of an application containing a proposal to establish a Network fulfils the requirements set out in Annex I to this Decision;

(b) the content of the membership applications fulfils the requirements of Annex II to this Decision;

(c) the proposed Network fulfils the requirement to provide highly specialised healthcare in point 1(a) of Annex I to Delegated Decision 2014/286/EU;

(d) the proposed Network fulfils the other criteria and conditions set out in Annex I to Delegated Decision 2014/286/EU;

(e) the applicant healthcare providers fulfil the criteria and conditions set out in Annex II to Delegated Decision 2014/286/EU.

3. The assessment pursuant to points (d) and (e) of paragraph 2 shall only take place if the assessment body concludes that the proposal fulfils the requirements referred to in points (a), (b) and (c) of paragraph 2.

4. The assessment body shall draw up an assessment report on the application containing a proposal to establish a Network and the membership applications and send all reports to the Commission.

5. The assessment body shall send to each applicant healthcare provider the assessment report on the proposed Network and on its own membership application. The healthcare provider may send comments to the assessment body within two months of receiving the reports. On receiving the comments, the assessment body shall amend its assessment reports explaining whether the comments justify a change in its assessment.

Article 5

Approval of Networks and Members

1. On receiving an assessment report on a proposal for a Network and the proposed list of Members, drawn up pursuant to Article 4, and after verifying that the minimum number of healthcare providers and Member States set out in Article 2(2) is reached, Member States shall, within a Board of Member States as provided in Article 6, decide on the approval of the proposed Network and its Members.

2. By virtue of the approval referred to in paragraph 1, the proposed Networks shall be established as European Reference Networks.

3. If the minimum number of healthcare providers or of Member States set out in Article 2(2) is not reached, the Network shall not be established and the Commission shall ask Member States to encourage their healthcare providers to join the proposed Networks.

4. If a healthcare provider is given a negative assessment, it will be for that healthcare provider to decide whether it wants to submit its membership application, with the assessment report on the application, to the Board of Member States for review.

Article 6

Board of Member States

1. Member States are invited to set up a Board of Member States which shall decide whether or not to approve the proposals for Networks, their membership and the termination of a Network. If their decision differs from the assessment of the assessment body, the Member States shall give the reasons for this.

2. Member States wishing to be on the Board of Member States shall notify the Commission the national authority that shall represent them.

3. The Board of Member States shall adopt by a simple majority of its members its own rules of procedures, on the proposal of the Commission services.

4. The rules of procedure shall cover the functioning and decision-making process of the Board of Member States and specify which of its members are entitled to vote on the approval of a specific Network, which majority will determine the outcome of a vote, and what procedure to follow if the Board's decision differs from the assessment report on a Network proposal or membership application.

5. The Commission shall provide the secretariat of the Board of Member States.

6. The personal data of representatives of Member States on the Board of Member States shall be collected, processed and published in accordance with Regulation (EC) No 45/2001.

Article 7

Logo

When a Network is approved, the Commission shall license the use of a unique graphic identifier ('logo'), which that Network and its Members shall use for the activities organised by the Network.

Article 8

Applications for membership of existing Networks

1. A healthcare provider wishing to join an existing Network shall submit a membership application to the Commission.

2. The content of the membership application shall be as set out in Annex II.

3. The membership application shall be accompanied by a written statement from the healthcare provider's Member State of establishment certifying that its participation in the Network is in accordance with the Member State's national legislation.

Article 9

Technical assessment of applications for membership of existing Networks

1. If the Commission concludes that the requirements set out in Article 8(2) and (3) are fulfilled, it shall appoint a body to assess the membership application.

2. The assessment body shall verify whether:

(a) the content of the membership application fulfils the requirements set out in Annex II to this Decision; and

(b) the healthcare provider concerned fulfils the criteria and conditions set out in Annex II to Delegated Decision 2014/286/EU.

3. The assessment pursuant to point (b) of paragraph 2 shall only take place if the assessment body concludes that the membership application fulfils the requirements referred to in point (a) of paragraph 2.

4. The assessment body shall draw up an assessment report and send it to the Commission and to the applicant healthcare provider. The healthcare provider may send comments to the assessment body within two months of receiving the report. On receiving of such comments, the assessment body shall amend its assessment report explaining whether the comments justify a change in its assessment.

Article 10

Approval of new Members

1. On receiving a positive assessment report drawn up pursuant to Article 9, the Board of Member States shall decide whether or not to approve the new Member.

2. If a healthcare provider is given a negative assessment, it will be for that healthcare provider to decide whether it wants to submit its membership application, with the assessment report on the application, to the Board of Member States for review.

Article 11

Termination of the Network

1. A Network shall be terminated in the following cases:

(a) one of the minimum numbers set out in Article 2(2) is no longer reached;

(b) a negative evaluation report of the Network has been drawn up pursuant to Article 14;

(c) by decision of the Board of the Network according to its rules and procedures;

(d) if the Coordinator fails to request an evaluation of the Network within the five- year period after it was set up or since its last evaluation.

2. The termination of a Network, on the grounds listed in paragraph 1(a) and (b), must be approved by the Board of Member States referred to in Article 6.

Article 12

Loss of membership

1. A Member of a Network may lose membership for any of the following reasons:

(a) voluntary withdrawal, according to the rules and procedures agreed by the Board of the Network;

(b) by decision of the Board of the Network, according to the rules and procedures agreed by the Board;

(c) if a Member State of establishment notifies to the Member of the Network that its participation in the Network no longer complies with national legislation;

(d) if the Member refuses to be evaluated pursuant to Article 14;

(e) if a negative evaluation report on the Member has been drawn up pursuant to Article 14;

(f) if the Network where the Member participates is terminated.

2. The relevant Member State shall inform the Commission of the reasons for the notification referred to in paragraph 1(c).

3. The Board of the Network shall inform the Commission in the cases referred to in point 1(a), (b) and (d).

4. The loss of membership on the grounds listed in paragraph 1(e) must be approved by the Board of Member States referred to in Article 6.

5. In any case of loss of membership, the Commission shall verify whether the minimum numbers of healthcare providers and of Member States set out in Article 2(2) are still reached. If not, it shall ask the Network to find new Members within the next two years or terminate the Network, inform the Board of Member States of the situation and ask Member States to encourage their healthcare providers to join the Network.

6. Loss of membership shall lead to the automatic loss of any of the rights and responsibilities associated with participation in the Network, including the right to use the logo.

Article 13

Assessment manual

1. In consultation with Member States and interested parties, the Commission shall draw up a detailed manual regarding the content of, documentation and procedure for the assessment referred to in Articles 4 and 9.

2. The assessment procedure shall include the verification of the documentation submitted by the applicants and on-site audits.

3. The body appointed by the Commission pursuant to Articles 4(1) and 9(1) to assess a proposal for a Network and applications for membership of the Network shall use the assessment manual.

CHAPTER III

EVALUATION OF EUROPEAN REFERENCE NETWORKS

Article 14

Evaluation

1. All Networks and their Members shall be periodically evaluated, at the latest every five years after their approval or last evaluation.

2. On receiving the request for evaluation from the Coordinator of a Network, the Commission shall appoint a body to evaluate the Network and its Members.

3. The evaluation body shall verify and assess:

(a) the fulfilment of the criteria and conditions set out in Delegated Decision 2014/286/EU;

(b) the accomplishment of the objectives set out in Article 12(2) of Directive 2011/24/EU; and

(c) the outcomes and performance of the Network and the contribution of each Member.

4. The evaluation body shall draw up an evaluation report on the Network and send it to the Commission, the Board of the Network and the Members of the Network.

5. The evaluation body shall draw up an evaluation report on each Member of the Network and send it to the Commission and the Member in question.

6. The Coordinator and Members of the Network may send comments to the evaluation body within two months of receiving the report. On receiving the comments, the evaluation body shall amend its evaluation report explaining whether the comments justify a change in its evaluation.

7. Any termination of a Network or loss of membership on account of a negative evaluation must be approved by the Board of Member States referred to in Article 6. The Board of Member States may offer the Network or the Member in question one year to remedy the shortcomings identified before carrying out a new evaluation. That period of time shall only be offered to a specific Network or Member of a Network if the Board of the Network presents an improvement plan.

Article 15

Evaluation manual

1. In consultation with Member States and interested parties, the Commission shall draw up a manual regarding the content of and documentation and procedure for the evaluation of the Networks and their Members referred to in Article 14.

2. The evaluation procedure shall include the evaluation of the documentation submitted, including the self-evaluation reports, and on-site audits.

3. The body appointed by the Commission pursuant to Article 14(2) to evaluate a Network and its Members shall use the evaluation manual.

CHAPTER IV

EXCHANGE OF INFORMATION AND EXPERTISE

Article 16

Exchange of information on establishing and evaluating the Networks

1. The Commission shall facilitate the exchange of information and expertise on establishing and evaluating the Networks by:

(a) making general information on establishing and evaluating the Networks, including information on the assessment and evaluation manuals referred to in Articles 13 and 15 publicly available;

(b) publishing a regularly updated list of the Networks and their Members, together with the positive assessment and evaluation reports of the Networks and the decisions of the Board of Member States, in accordance with its rules of procedure;

(c) organising conferences and experts meetings for technical and scientific debate among the Members of Networks, if appropriate;

(d) providing electronic media and communication tools to the Networks, if appropriate.

2. For the purpose of publishing the list referred to in paragraph 1(b), any change in the Member acting as Coordinator of a Network or in the person nominated as Coordinator of a Network shall be communicated to the Commission by the Board of the Network.

CHAPTER V

FINAL PROVISIONS

Article 17

Revision

The Commission shall evaluate the functioning of this Implementing Decision five years after its entry into force.

Article 18

Entry into force

This Decision shall enter into force on the tenth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

CONTENT OF THE APPLICATION TO ESTABLISH A NETWORK

The application to establish a Network must be submitted according to the call for interest published by the Commission and must include:

(a) the name of the proposed Network;

(b) the completed application form, with the self-assessment questionnaire and additional documentation required in the assessment manual;

(c) evidence that all applicant healthcare providers share the same area of expertise and focus on the same health condition or conditions;

(d) the name of the healthcare provider that will act as Coordinator of the Network and the name and contact details of the person who will represent the proposed Coordinator;

(e) the names of all applicant healthcare providers.

ANNEX II

CONTENT OF THE MEMBERSHIP APPLICATION

The application of healthcare providers must include:

(a) the title of the relevant proposed Network or existing Network;

(b) the completed application form, with the self-assessment questionnaire and additional documentation required in the assessment manual;

(c) the name and contact details of the healthcare provider's representative.