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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
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RULES OF PROCEDURE OF THE HEALTH TECHNOLOGY ASSESSMENT NETWORK

**ADOPTED BY THE HTA NETWORK
ON 10 NOVEMBER 2016**

RULES OF PROCEDURE OF THE HEALTH TECHNOLOGY ASSESSMENT NETWORK

The Health Technology Assessment Network, ("the Network")

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 (the Directive), and in particular to Article 15 and to Recital 58,

Having regard to Commission Implementing Decision 2013/329/EU of 26 June 2013 providing the rules for the establishment, the management and transparent functioning of the Network of national authorities or bodies responsible for Health Technology Assessment (HTA), and in particular to Article 4,

Considering that cooperation is necessary both at strategic level and at scientific and technical level,

Has adopted the following rules of procedure:

Article 1

Introductory provisions

1. To meet the objectives assigned to the Network by the Directive, and in line with the provisions of Article 5(2) of the Implementing Decision, the Network will be supported, by a scientific and technical cooperation mechanism.

For the time of its duration EUnetHTA Joint Action 3 ensures scientific and technical cooperation for the HTA Network. A subsequent suitable mechanism, agreed by the HTA Network, will be then put in place, to ensure continuity.

2. The Network shall focus its activities on strategic issues relevant to EU cooperation on HTA. It shall provide strategic recommendations to the scientific and technical cooperation mechanism which shall carry out its work in scientific independence and shall aim at synergies with Network's activities.

3. These rules of procedure regulate the functioning of the Network and the main principles for interaction with the scientific and technical cooperation mechanism. They are without prejudice to the specific rules of the scientific and technical cooperation mechanism, including relevant contractual obligations.

Article 2

Membership - notification and withdrawal

1. The notification referred to in Article 3(2) of the Implementing Decision shall be addressed in writing to the Commission, for the attention of the Chair.

2. Membership shall take effect ten working days after the receipt of this notification.

3. Member States shall inform the Chair in writing of the name of the organisation and the person representing them in the Network and the alternate. Continuity of representation shall be aimed at. Representatives can be accompanied by one national

expert, in duly justified circumstances more than one expert can participate to meetings, in line with Article 8 of the Commission Implementing Decision 2013/329/EU. Within a reasonable time and no later than five working days before the date of a Network meeting, the names and functions of the experts, shall be communicated in writing to the Secretariat of the Network.

4. A Member State wishing to withdraw from the Network shall send a written notification with three months' notice. When a Member State withdraws from the Network, the participating organisation from that Member State shall, where possible, finalise any work agreed to perform prior to withdrawal.

Article 3

Convening a meeting

1. Meetings of the Network shall be convened by the Chair, normally twice a year, either on their own initiative, or at the request of a simple majority of Members.
2. Meetings of the Network shall be held on Commission premises unless otherwise decided by the Network.
3. Normally dates of the meeting of the Network shall be communicated with eight weeks' notice.

Article 4

Secretariat - Agenda

1. In accordance with Article 7(1) of the Implementing Decision, the Commission shall provide secretarial support for the Network and any working group created by the Network.
2. The Secretariat shall draw up the agenda, in line with the strategic multi annual work programme adopted by the Network, in accordance with Article 5 of the Commission Implementing Decision.
3. In doing so the Secretariat shall take due account of proposals from Network Members and the scientific and technical cooperation mechanism referred to in Article 1(1) Observers, as defined in Article 8 of these Rules of Procedure, may also submit proposals.
4. Proposals for items to be included on the agenda shall reach the Secretariat at least six weeks before the meeting.
5. The agenda shall be adopted by the Network at the start of the meeting.

Article 5

Documentation to Network members

1. The Secretariat shall send the invitation to the meeting and the draft agenda to the Network Members, the scientific and technical cooperation mechanism and observers referred to in Article 8, no later than twenty working days before the meeting. The invitation shall specify also which third parties are invited to the meeting.
2. The Secretariat shall send the documents for consultation to the Network Members no later than ten working days before the date of the meeting. Observers shall be consulted on the same documents, unless decided otherwise by the Chair.
3. In duly justified cases, the time limits for sending the documentation mentioned in 1 and 2 may be reduced to five working days.
4. The scientific and technical cooperation mechanism, referred to in Article 1(1), shall report to the Network about its activities relevant to the objectives and the implementation of the work programme of the Network. Such reports and any other documentation of interest shall be submitted via the Secretariat respecting the deadlines referred to in paragraphs 2 and 3.

Article 6

Decisions of the Network

1. As far as possible, the Network shall make decisions by consensus. Abstentions shall not prevent the adoption of decisions by consensus.
2. A vote shall be taken if any Network Member so requests. In the event of a vote, the outcome of the vote shall be decided by a majority of two thirds of the Networks' Members present at the start of the vote. Each Member State shall have one vote. An absent Member State's vote shall count in the vote if a written mandate is given to another Network Member.
3. The Network's decisions shall normally be made public. However, in duly justified circumstances¹, the Network may decide that certain decisions can be kept confidential or be subject to explicit public consultations.

Article 7

Working groups

1. When the Network decides to set up working groups, referred to in Article 5 of the Implementing Decision, it shall define terms of reference and appoint a Chair. Such working groups shall be disbanded as soon as their mandate is fulfilled.
2. The working groups shall report to the Network.

¹ For example, when decisions may have an impact on public health, or when commercially sensitive information are referred to.

3. The scientific and technical cooperation mechanism shall be consulted on questions to be examined by the working groups in order to help ensure coherence and reduce any unintended duplication.

4. Insofar as possible, the working groups shall conduct their work, including meeting, electronically.

Article 8

Admission of third parties

1. EUnetHTA, as the scientific and technical cooperation mechanism, shall be invited to attend the Network's meetings and its working groups, without voting rights.

2. In accordance with Articles 4(2) and 6(4) of the Implementing Decision, the Chair shall invite observers to attend meetings of the Network. Part of the meeting may be reserved for Network Members only.

3. Third parties have no voting rights.

4. The Network may give observer status to:

- a. Authorities competent for HTA of EEA/EFTA countries and of accession countries. In appointing their representatives EEA/EFTA countries shall take into account Article 2(3) and 2(4) of these Rules of Procedure.
- b. European and international organisations, whose activities are relevant to meet the objectives of the Network.
- c. Stakeholders' representatives.

5. Following proposals from the Network Members, the Secretariat will draw up a list of observers as defined in paragraph 4 (b) and (c), for adoption by the Network. This list will be subject to revision, as appropriate.

6. In addition to the above, the Chair may invite, on an ad hoc basis, experts with relevant competence in a subject, to participate to one or more items on the agenda of the meetings of the Network or a working-group.

Article 9

Written procedure

1. If necessary, the Network's decisions may be delivered via written procedure. To this end, upon request of the Chair, the Secretariat will send to the Network Members the document(s) on which the Network is being consulted and sets a time limit for comments.

2. The Secretariat shall inform the Network of the outcome of the written procedure.

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

Article 10
Minutes of the meetings

1. Minutes on the discussion on each point on the agenda shall be drafted by the Secretariat and sent out to the Network members without delay and no later than ten working days after the meeting.
2. The Network Members shall send any comments they may have on the draft minutes to the Secretariat in writing within ten working days.
3. The minutes shall not mention the individual position of the Members and observers during the Network's deliberations. The minutes will be made public on the Commission website. In duly justified circumstances², parts of the minutes may remain confidential.

Article 11
Attendance list and Conflicts of interest

- 1 At each meeting, the Secretariat shall draw up an attendance list including the authorities and organisations to which the persons designated by Member States and third parties as per Article 8 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 potential conflict of interest³ with regard to a particular item on the agenda. The Chair shall decide if a conflict exists.
3. In the event of such a conflict of interest, the person concerned shall withdraw from the meeting whilst the relevant items of the agenda are being dealt with.
4. Conflicts of interest shall be reported in the minutes of the Network's meeting.
5. Paragraphs 1, 2, 3 and 4 shall also apply to working groups and to deliberations taken by the Network in written procedure.

Article 12
Correspondence

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

² For example when discussions are of a confidential or sensitive nature, including on proprietary topics, such as individual products, data exclusivity, or commercially sensitive information.

³ 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.

Article 13
Access to documents

Requests for access to Network's documents shall be handled in accordance with Regulation (EC) No 1049/2001⁴. 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, Euratom⁵. If the request is addressed to a Member State that Member State shall apply Article 5 of Regulation (EC) No 1049/2001.

Article 14
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 45/2001⁶ and Directive 95/46/EC⁷ where applicable

Article 15
Revision clause

These Rules of Procedure may be revised by the Network when necessary.

⁴ 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).

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

⁶ 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).

⁷ 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).