

## COMMISSION IMPLEMENTING DECISION

of 26 June 2013

**providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment**

(2013/329/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<sup>(1)</sup>, and in particular Article 15(4) thereof,

Whereas:

(1) Article 15 of Directive 2011/24/EU assigned the Union to support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for health technology assessment ('HTA') designated by Member States (hereinafter 'the HTA Network').

(2) In accordance with Article 15(4) of Directive 2011/24/EU the Commission has an obligation to adopt the necessary rules for the establishment, management and transparent functioning of the HTA Network.

(3) Participation in the HTA Network being voluntary, Member States should be able to join at any time. For organisational purposes, Member States wishing to participate should inform the Commission of this intention in advance.

(4) Personal data should be processed in accordance with 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<sup>(2)</sup>, Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)<sup>(3)</sup> and Regulation (EC) No 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<sup>(4)</sup>, as appropriate.

(5) The Union has co-financed actions in the field of HTA through the Public Health Programme established by Decision No 1786/2002/EC of the European Parliament and of the Council<sup>(5)</sup> and the Health Programme established by Decision No 1350/2007/EC of the European Parliament and of the Council<sup>(6)</sup>, thereby supporting scientific and technical cooperation between national and regional organisations responsible for HTA with the acronym EUnetHTA<sup>(7)</sup>. It has also financed methodological work in the field of HTA through the 7th Research Framework Programme, established by Decision No 1982/2006/EC of the European Parliament and of the Council<sup>(8)</sup> and the Competitiveness and Innovation Programme established by Decision No 1639/2006/EC of the European Parliament and of the Council<sup>(9)</sup>.

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

HAS ADOPTED THIS DECISION:

*Article 1***Subject matter**

This Decision sets out the necessary rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment, as provided for by Article 15(1) of Directive 2011/24/EU.

*Article 2***Objectives**

In pursuing those objectives assigned to it by Article 15(2) of Directive 2011/24/EU, the HTA Network shall build on the experience gained in previous actions in the field of HTA supported by the Union and ensure relevant synergies with ongoing actions.

*Article 3***Membership — Designation**

1. Members of the HTA Network shall be national authorities or bodies responsible for HTA designated by the participating Member States.

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

<sup>(2)</sup> OJ L 281, 23.11.1995, p. 31.

<sup>(3)</sup> OJ L 201, 31.7.2002, p. 37.

<sup>(4)</sup> OJ L 8, 12.1.2001, p. 1.

<sup>(5)</sup> OJ L 271, 9.10.2002, p. 1.

<sup>(6)</sup> OJ L 301, 20.11.2007, p. 3.

<sup>(7)</sup> www.eunetha.eu; Commission Implementing Decision C2011/7195 on the awarding of grants for proposals for 2011 under the second Health Programme (2008-13).

<sup>(8)</sup> OJ L 412, 30.12.2006, p. 1.

<sup>(9)</sup> OJ L 310, 9.11.2006, p. 15.

2. Member States wishing to participate in the HTA Network shall notify in writing to the Commission this intention as well as the national authority or body responsible for HTA designated in accordance with Article 15(1) of Directive 2011/24/EU. Member States may designate a second national authority or body as an alternate Member.

3. If deemed necessary by the Member State, it may also designate an expert to accompany the Member.

4. The names of Member States' designated authorities or bodies may be published on the Commission web pages.

5. Personal data shall be collected, processed and published in accordance with Directives 95/46/EC and 2002/58/EC and Regulation (EC) No 45/2001, as appropriate.

#### Article 4

##### Rules of Procedure

1. The HTA Network shall adopt by a simple majority of its Members its rules of procedure, on the proposal submitted by the Commission.

2. The rules of procedure shall facilitate appropriate stakeholder consultation and liaison with Union bodies, researchers and international organisations on the work of the Network.

#### Article 5

##### Operation

1. The HTA Network shall adopt a strategic multiannual work programme and an evaluation instrument on the implementation of such programme.

2. The HTA Network shall be supported by a scientific and technical cooperation and may initiate or participate in activities involving all or some of its Members, if such involvement contributes to the objectives of the HTA Network.

3. The HTA Network may set up working groups to examine specific questions on the basis of terms of reference defined by the HTA Network. Such working groups shall be disbanded as soon as their mandate is fulfilled.

4. Members of the HTA Network and their representatives, as well as invited experts and observers, shall comply with the obligations of professional secrecy laid down by Article 339 of the Treaty and its implementing rules, as well as with the Commission's rules on security regarding the protection of EU classified information, laid down in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 amending its internal Rules of Procedure<sup>(1)</sup>. Should they fail to respect these obligations, the Chair of the HTA Network may take all appropriate measures.

#### Article 6

##### Meetings

1. The HTA Network shall be chaired by the Commission representative. The chair person shall not vote.

2. Commission officials with an interest in the proceedings may attend meetings of the HTA Network and its working groups.

3. Upon request of the Commission, the European Medicines Agency may participate in meetings of the HTA Network and its working groups.

4. The HTA Network may invite European and international organisations to attend meetings as observers.

#### Article 7

##### Secretariat of the HTA Network

1. The Secretariat of the HTA Network shall be provided by the Commission, who will draw up the minutes.

2. The Commission shall publish on its website relevant information on the activities carried out by the HTA Network.

#### Article 8

##### Expenses

1. Participants in the meetings of the HTA Network shall not be remunerated by the Commission for their services.

2. Travel and subsistence expenses incurred by participants in the activities of the HTA Network shall be reimbursed by the Commission in accordance with the provisions in force within the Commission.

3. Those expenses shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for the allocation of resources.

#### Article 9

##### Entry into force

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

Done at Brussels, 26 June 2013.

For the Commission

The President

José Manuel BARROSO

<sup>(1)</sup> OJ L 317, 3.12.2001, p. 1.