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HTA NETWORK

MULTIANNUAL WORK PROGRAMME

2016-2020

ADOPTED AT THE 6th HTA NETWORK MEETING ON 20 MAY 2016

OVERALL OBJECTIVE OF THE HTA NETWORK

The overall objective of the Health Technology Assessment (HTA) Network is spelled out in Article 15(2) of Directive 2011/24.

- *Support cooperation between national authorities or bodies responsible for HTA;*
- *Support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;*
- *Support the analysis of the nature and type of information that can be exchanged;*
- *Avoid duplication of assessments.*

In line with Article 15(7) of Directive 2011/24, measures adopted to implement this Multiannual Work Programme (MWP) shall not interfere with Member States' competence in deciding on how and when to use HTA within healthcare systems or the implementation of HTA conclusions and shall fully respect the responsibilities of Member States for the organisation and delivery of health services and medical care.

It should be noted that at the time of drafting this MWP, Members States and the European Commission are discussing and negotiating important initiatives which will have major impact in the way the EU cooperation on HTA will develop in the future, e.g., the third Joint Action EUnetHTA (JA 3). In this context it is considered important that the HTA Network continues to focus its activities on broad political and strategic objectives and yet aims at delivering concrete outputs to support achievement of its mandate. Moreover the MWP shall not duplicate the activities foreseen by the current and future Joint Actions on HTA and other possible relevant initiatives, but should aim at creating the necessary synergies.

This MWP will provide guidance for the period covering **2016 – 2020**, with a possibility of a mid-term review allowing for adjustments of the specific tasks, timing and/or possible new proposals to account for changing context of the MWP implementation.

1. OVERALL OBJECTIVES FOR THE PROGRAMMING PERIOD

2.1 Contribute to the implementation of the "Strategy for EU cooperation on HTA"

Rationale: The HTA Network adopted its Strategy for "EU cooperation on HTA" in 2014. The Strategy defines a vision for cooperation and makes specific calls to HTA Network Members as well as to other stakeholders and to the scientific bodies directly involved in HTA to implement the proposed vision. The Strategy should serve as a background document for future planning.

Recalling the vision set out by the Strategy the following areas shall be addressed:

- Broad scope of the EU cooperation on HTA (full life cycles and whole range of health technologies; all different aspects ("Domains") of HTA; support and input to a wide-range of decision makers in health care; a clear framework for priority setting),
- Fostering of cooperation between Member States and stakeholders,
- Synergies and complementarity of European activities with national activities,
- Synergies between HTA and regulatory issues,
- EU cooperation in the broader European and global context.

In each of these areas the HTA Network made specific calls for action. In addition to such specific tasks the HTA Network Members are expected to follow up on the calls made in the HTA Strategy and invited to report on any progress made in respective countries.

2.2 Contribute to the sustainability of the HTA cooperation at EU level

Rationale: such activity was included in the HTA Network Strategy. Since the adoption of the Strategy new initiatives have been planned to achieve this overall objective and respond to the calls made by the HTA Network.

The HTA Network is expected to act as key strategic forum to contribute to defining the possible scope, sustainability and governance of the European cooperation on HTA, beyond Joint Action 3 (i.e., post 2020).

2. SPECIFIC TASKS TO MEET OVERALL OBJECTIVES

3.1. Reflection paper on the interaction between regulatory and HTA issues[1]

This task was included in the previous MWP (2014 – 2015), its finalisation is planned for 2016, and a dedicated Working Group has been set up to deliver the reflection paper.

Timing: 2nd half 2016

3.2. Propose arrangements necessary to continue the cooperation after 2020

Rationale: During the coming years, one of the main objectives for the HTA Network should be to take an active role in clarifying and ensuring conditions for a sustainable functioning of the scientific and technical cooperation when the EUnetHTA JA3 ends in 2020. Consideration will need to be given to a range of issues such as overall governance of the European cooperation on HTA; the involvement of stakeholders; operational joint production and / or re-use of nationally produced work; and options for dedicated and sustainable funding. All discussions shall be undertaken in cooperation with the activities in the EUnetHTA JA3.

[1] The issue is likely to be addressed in two steps focusing on pharmaceutical first and on other medical technologies at a later stage, taking into account the discussions and revision of the Medical Devices' legislation.

Timing: starting 2nd half 2016 with further adjustments until 2020

3.3. Discussion paper on how to "facilitate appropriate involvement of all interested stakeholders in the European collaboration in HTA, notably patients, health professionals, healthcare industry, and payers"

Rationale: Stakeholders represented in the HTA Network ask for active involvement of all interested stakeholders in the European collaboration in HTA, notably patients, health professionals, healthcare industry, and payers. The stakeholders represented in the HTA Network are invited to collectively elaborate concrete proposals to be then discussed by the HTA Network. The paper shall take into account EUnetHTA collaboration with stakeholders.

Timing: 1st half 2017

3.4. Reflection paper on efficient joint cooperation on HTA of Medical Technologies[2] and their reuse of assessments at national/regional levels

Rationale: The HTA Network will act as platform for discussion and development of concrete actions needed to facilitate efficient cooperation and joint work on Medical Technologies and reuse of assessments at national/regional levels. As part of this work, a number of specificities related to medical technologies will need to be examined. These include: the need for a fit for purpose process for selecting topics for Joint Work, the role of procurement processes including possible cooperation and the high level of context specific information needed for assessments. The reflection paper shall build on the discussion paper "The added value of the European cooperation in the joint HTA of medical devices", discussed by the HTA Network in October 2015, and identify possible ways forwards.

Timing: 2nd half 2017

3.5. Identification of areas of progress and further action as a follow up on "Reflection paper on reuse of joint work and national/regional work produced in another country/region, in national HTA activities"

Rationale: The HTA Network shall follow up on the reflection paper on "Conditions to facilitate take up and reuse at national level of joint HTA production", by examining areas in which progress has been made and identify potential areas where further activity may be considered. This work may focus selectively on particular aspects of the above mentioned reflection paper. The activity should be based on the work that will be done in EUnetHTA JA3.

Timing: 1st half 2018

3.6 Reflection Paper on effective communication on HTA reports to a broader audience

Rationale: The HTA Network Strategy recommends that authorities responsible for HTA should aim at HTA reports that are electronically accessible, including a summary in English,

[2] For the purpose of this paper, the Medical Technology = Medical Devices, In-vitro Diagnostics, Medical Imaging and Health ICT

and understandable to stakeholders. The Reflection Paper could explore potential tools (e.g. templates) and approaches which could support and promote effective communication, as well as the role stakeholders may have in the preparation, review and/or dissemination of HTA reports. For this, cooperation with partners with experience in this field could create the desired synergy in communicating the outcome to the public.

Timing: 2nd half 2018

3. ADDITIONAL ACTIVITY AREAS FOR THE HTA NETWORK

In defining and carrying out its activities, the Network shall aim at acting as a key platform to exchange information on strategic issues between key players in the European HTA community.

In line with this objective, the following areas are proposed for possible further activity. Such activity could be undertaken via bringing the topics from the list below on the agendas of the regular HTA Network meetings, or via organisation of the joint meetings (where possible and appropriate) with relevant parties, or via contribution to the discussions at the meetings of the parties with which the HTA Network cooperates.

4.1. Act as a platform to monitor and share experiences between Member States aimed at strengthening cooperation in areas of common interest, for example:

- Awareness raising of the essential role that HTA can play in decision making processes.
- Support and guidance to health authorities and healthcare providers in HTA capacity building.
- Horizon scanning initiatives and/or regular exchange of work plans (mechanism of cooperation with other projects).
- Discussion on "other technologies" (that is, technologies others than pharmaceuticals and medical devices) for which application of HTA may be useful (mechanisms for this reflection is to be explored).
- Economic assessments of new technologies, for example on common core economic models which could increase transferability among EU Member States.[3]
- Comprehensive mapping on HTA in Europe based on existing materials (or updating of the maps of HTA activities in Europe in cooperation with other relevant actors).
- Mapping on how ethical issues are handled within EU regarding prioritization and decision-making.

[3] The EUnetHTA guideline on "Methods for health economic evaluations" could serve as a basis for the discussion, which could also involve other experts in the health-economic field.

- Sharing experiences on the impact of the use of HTA in decision making regarding both the introduction and disinvestment of health technologies.

- Evaluation of the impact of EU cooperation on HTA (including awareness on HTA methods and conclusions, improved transparency, decreased complexity and costs for developers).

- Share experiences of approaches to situations where evidence is limited and/or are major uncertainties.

4.2. Act as a platform to identify, create and when possible strengthen cooperation with relevant EU bodies and fora, other relevant key players, including relevant stakeholders, for example:

- Interaction with EMA and possible exchange of relevant information on a regular basis for HTA purpose in close cooperation and alignment with the activities and developments in the EUnetHTA JA3.

- Follow up and interact where and when relevant with the Innovative Medicines Initiative (IMI) and relevant initiatives funded under H2020.

- Regular exchange of information with the relevant EU Fora (the Network of Competent Authorities in Pricing and Reimbursement (CAPR), the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) and others.

END