



Topic 2: HTA Network Multiannual Work Programme (MWP) 2016-2020

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Chair/Rapporteur of the WG

- Working Group (**WG**) - at HTA Network meeting (**October 29, 2015**) to draft the new MWP
- **Five members** volunteered (**DE, HR, ES, SE, UK**)
- **WG meeting (22 January 2016)**, with EUnetHTA and Stakeholders' representatives
- Ms Mirjana Huic (HR) - Chair/Rapporteur of the WG
- The **WG** with the **input of Stakeholders** and **EUnetHTA** - developed a **first draft**
- To **all HTA Network** for **consultation (March 17, 2016)**
- The Rapporteur, supported by the Secretariat implemented the comments
- **Final version** of the MWP - **circulated in advance (April 29, 2016)** before 6th HTA Network meeting (May 20, 2016)



Structure of the MWP document

1. OVERALL OBJECTIVE OF THE HTA NETWORK


2. OVERALL OBJECTIVES FOR THE PROGRAMMING PERIOD

3. SPECIFIC TASKS TO MEET OVERALL OBJECTIVES

4. ADDITIONAL ACTIVITY AREAS FOR THE HTA NETWORK



1. OVERALL OBJECTIVE OF THE HTA NETWORK

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- In line with **Article 15(2) of Directive 2011/24**
 - 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
 - Shall **fully respect** the **responsibilities** of **Member States** for the organisation and delivery of health services and medical care
 - Continues to **focus** its **activities** on **broad political and strategic objectives** and yet aims at **delivering concrete outputs** to support achievement of its mandate
 - 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**
 - 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



2. OVERALL OBJECTIVES FOR THE PROGRAMMING PERIOD

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

- Vision for cooperation and specific calls to **implement the proposed vision** (to HTA Network Members, other stakeholders and scientific bodies directly involved in HTA)

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

- The HTA Network 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)



3. SPECIFIC TASKS TO MEET OVERALL OBJECTIVES

3.1 Reflection paper on the interaction between regulatory and HTA issues

- In the previous MWP (2014 – 2015)
- 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: 2nd half 2016

3.2 Propose arrangements necessary to continue the cooperation after 2020

- Active role in **clarifying** and **ensuring conditions** for a **sustainable functioning** of the **scientific and technical cooperation** when the **EUnetHTA JA3 ends in 2020**
- **Overall governance of the European cooperation on HTA; the involvement of stakeholders; operational joint production and/or re-use of nationally produced work; options for dedicated and sustainable funding**
- **In cooperation** with the activities in the **EUnetHTA JA3**

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"

- **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
- **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* and their reuse of assessments at national/regional levels

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

- The HTA Network - 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

To be examined:

- A **fit for purpose process for selecting topics** for Joint Work
- The **role of procurement processes** including possible cooperation
- The **high level of context specific information** needed for assessments
- Build on the Discussion paper **"The added value of the European cooperation in the joint HTA of medical devices"**

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"

- Examining areas in which **progress has been made**
- Identify potential areas where **further activity** may be considered
- May **focus selectively** on particular aspects of this reflection paper
- **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

Authorities responsible for HTA should aim at **HTA reports**:

- **Electronically accessible**
- **Summary in English**
- **Understandable to stakeholders**

The Reflection Paper could explore:

- **Potential tools** (e.g. templates) and **approaches** which could **support** and **promote effective communication**
- **Role of stakeholders** may have in the **preparation, review** and/or **dissemination of HTA reports**
- **Cooperation with partners with experience** in this field - the desired synergy in communicating the outcome to the public

Timing: 2nd half 2018



4. ADDITIONAL ACTIVITY AREAS FOR THE HTA NETWORK

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

- **Awareness** ↑ 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
- **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
- **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

- **Interaction with EMA**
- **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**

- Any additional clarifications on the content of the MWP



Adoption of the MWP