



Topic 2

Inception Impact Assessment *"Strengthening of the EU cooperation on HTA"*

European Commission
DG SANTE - Health Systems,
Medical Products and Innovation



Economic context

Total EU health care expenditure

- **€1 300 billion** per year, including
 - €220 billion for pharmaceuticals and
 - €100 billion for medical devices
- **10% of GDP**

The figures are forecasted to increase.

EU cooperation on HTA



HTA Network

- Policy and strategic cooperation
- Art 15 Directive 2011/24
- Set up October 2013
- Multiannual work programme
- **Permanent**

Synergy and complementarity



EUNETHTA Joint Action

- Scientific and technical cooperation
- Started in the 1990's – EUNETHTA 1 & 2
- Joint Action 3 – **2016 – 2020**



New HTA Initiative

- Cooperation beyond 2020
- Inception Impact Assessment
- Description of the status quo
- Options for the future



EU initiative on HTA – joint effort

HTA Network and EUnetHTA JA3



Key players to shape up the future
EU HTA cooperation post 2020

Major achievements

- **Trust** between HTA bodies and **capacity building**
- Development of **joint tools** (ex.: POP database, EUneHTA Core Model)
- Piloting **joint work**
- JA3: **upscaling of joint work**
- HTA Network **Strategy** for EU Cooperation on HTA



Main Shortcomings

- **Low uptake of joint work** ⇒ duplication of work by HTA bodies and industry
- **No sustainability** of current cooperation model

Policy options*

Option 1	Option 2	Option 3	Option 4	Option 5
Status quo – voluntary cooperation	Long-term voluntary cooperation (beyond 2020)	Cooperation through the collection, sharing and use of common tools and data	Cooperation on production of joint REA (relative effectiveness assessments) reports	Cooperation on production of joint Full HTA reports (REA+ economic)
Non-legislative / voluntary		Legislative / voluntary + mandatory		

+ Issues to be addressed



*Inception Impact assessment available at:

http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf

Process

➤ Inception impact assessment

- Published in September

http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf

➤ Public consultation

- **Online consultation - launched in October on "Your voice in Europe" portal**

http://ec.europa.eu/yourvoice/consultations/index_en.htm

- **Meetings with stakeholders**

➤ **Studies** to support the impact assessment process

➤ **Impact assessment** - planned for 2017



Legislative or non-legislative proposal



Open
Consultations



Suggested questions for discussion

Q. 1 "State of play" and "Issue"

- do the sections provide an accurate and fair report of the situation?

Q.2 "Option mappings"

- *Do you consider that the 5 outlined options are covering all possible scenarios?*
- *Do you see any additional options to be explored/considered?*
- *On the outlined "options" any preliminary feedback/thoughts would be very much appreciated, in particular on the following aspects:*

Q.2.1 Content - *which common tools /elements of the current EU cooperation can support MS in national HTA activities?*

Q.2.2. Scope - *are all options applicable/valuable for all type of technologies?*

Q.2.3 Implementation

Financing (where are the major challenges?). What do you see as the main guiding principles to be followed to define the adequate financing model? Any proposal?

Governance (what are the major challenges?) What do you see as the main guiding principles to be followed to define the adequate financing model? Any proposal?



**Other possible
questions/suggestions?**

Studies to support the IA

Study	Objective	Est.
Mapping of HTA national organisations, programmes and processes	The main objective of the study is to map the HTA organisations and processes in the EU and the EEA countries.	Q1 2017
Mapping of HTA methodologies	This main objective of the study is to provide a concise overview of the scientific methodologies implemented by the Member States' HTA bodies.	Q1 2017
Study on impact analysis of policy options for Strengthened EU cooperation on HTA (main study)	See next slide.	Q2 2017

Study on impact analysis of policy options for Strengthened EU cooperation on HTA

Objective

*The overall objective of the study is to provide **key input for analysing the impacts of identified policy options** to strengthen EU cooperation on HTA. The results of the study will be used to support a possible future **impact assessment** process in the Commission **on an initiative to strengthen the EU cooperation on HTA.***



The Consortium:

Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH -

Claudia Habl

London School of Economics – *Panos Kanavos*

Sogeti Luxembourg (contract management)

4 Work packages

WP 1	Definition of baseline scenario and analysis of its impact
WP 2	Definition of options and analysis of their impacts
WP 3	Literature Review
WP 4	Drafting of final report