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**

**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*

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
<th>Option 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status quo – voluntary cooperation</td>
<td>Long-term voluntary cooperation (beyond 2020)</td>
<td>Cooperation through the collection, sharing and use of common tools and data</td>
<td>Cooperation on production of joint REA (relative effectiveness assessments) reports</td>
<td>Cooperation on production of joint Full HTA reports (REA+ economic)</td>
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</tbody>
</table>

| Non-legislative / voluntary | Legislative / voluntary + mandatory |

+ Issues to be addressed

*Scope*  
*Funding mechanism*  
*Coordination/secretariat*

Process

- **Inception impact assessment**
  - Published in September
  

- **Public consultation**
  - Online consultation - launched in October on "Your voice in Europe" portal
  
  - Meetings with stakeholders

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

- **Impact assessment** - planned for 2017

  Legislative or non-legislative proposal
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

## Objective

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

<table>
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<th>4 Work packages</th>
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<td><strong>WP 1</strong></td>
<td>Definition of baseline scenario and analysis of its impact</td>
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<tr>
<td><strong>WP 2</strong></td>
<td>Definition of options and analysis of their impacts</td>
</tr>
<tr>
<td><strong>WP 3</strong></td>
<td>Literature Review</td>
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<tr>
<td><strong>WP 4</strong></td>
<td>Drafting of final report</td>
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