Strengthening of the EU cooperation on HTA

Update

DG SANTE
Unit B4: Medical products: quality, safety, innovation
Health Technology Assessment (HTA)

**Definition**

HTA assesses the added value (relative effectiveness) of a given health technology over and above existing ones.

**Clinical domains**
- so called *REA* (relative effectiveness assessment)

**Non-clinical domains**
- so called *Full HTA* together with REA
STATE OF PLAY

SUSTAINABLE EU COOPERATION ON HTA

Scientific & technical

- Joint production
- Quality Management
- Early dialogues & Real world data generation
- National implementation and impact

Strategy

- Strategy for EU Cooperation on HTA
- Reflection Paper on synergies between regulatory and HTA issues

Sustainability

- Inception Impact Assessment
- Public consultation
- Studies to Support the impact assessment
- Impact assessment

2016

2020
Stakeholders' involvement

- **HTA Network Stakeholder Pool**
  Call of expression of interest establishing the **HTA Network Stakeholder Pool** representing: patients/consumers, health providers, payers and industry at EU level
  → 9 patients/consumers' organisations

- **HTA Network – Observers**
  → 8 stakeholders' organisations (4 categories)
What has been done at EU level?

Public Health
- Projects
  - 1999-2001: ECHTA/ECHAI
  - 2006-2008: EUnetHTA
- Joint Actions
  - 2010-2012: EUnetHTA Joint Action 1
    Scientific/technical cooperation on methodologies and tools.
  - 2012-2015: EUnetHTA Joint Action 2
    Further development of cooperation and piloting of joint assessments.
  - 2016-2020: EUnetHTA Joint Action 3
    Enhanced cooperation with a focus on joint HTA work
    (e.g. joint assessments and uptake)

Research
- AdhopHTA
- MedtecHTA
- INTEGRATE-HTA
- ADVANCE-HTA
- ADAPT SMART
- GET REAL
Major Achievements (EUnetHTA JA1 and JA2)

- **Trust** between HTA bodies and capacity building
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)
- JA3 – **upscaling of joint work**
Shortcomings of current EU cooperation on HTA

- Low uptake of joint work ⇒ duplication of work by HTA bodies and industry
- Differences in the procedural framework and administrative capacities of Member States
- Differences in national methodologies
- No sustainability of current cooperation model

Recommendation oncology drugs (MA 2011-2013) per country

<table>
<thead>
<tr>
<th>Abbreviated indication</th>
<th>Brand name (generic)</th>
<th>GEMANY</th>
<th>THE NETHERLANDS</th>
<th>FRANCE</th>
<th>ENGLAND</th>
<th>WALES</th>
<th>SCOTLAND</th>
<th>POLAND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone metastasis from solid tumours</td>
<td>Denosumab</td>
<td>Not assessed</td>
<td>Equal benefit</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Positive</td>
<td>Not assessed</td>
<td>Negative</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>Enbrel</td>
<td>Equal benefit</td>
<td>Equal benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Pertuzumab</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Added benefit</td>
<td>Not assessed</td>
<td>Negative</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>Afirilex</td>
<td>Not assessed</td>
<td>Equal benefit</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Negative</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Gastric cancer</td>
<td>Tegafur / gimeracil / oteracil</td>
<td>Not assessed</td>
<td>Lesser benefit</td>
<td>Less benefit</td>
<td>Less benefit</td>
<td>Not assessed</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Ipilimumab</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Vemurafenib</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Dabrafenib</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Not assessed</td>
<td>Equal benefit</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>Non-small-cell lung cancer</td>
<td>Afatinib</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Not assessed</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Orzolimib</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>Cabazitaxel</td>
<td>Equal benefit</td>
<td>Not assessed</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Enzalutamide</td>
<td>Added benefit</td>
<td>Equal benefit</td>
<td>Not assessed</td>
<td>Added benefit</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Abiraterone</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Not assessed</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Renal-cell carcinoma</td>
<td>Axitinib</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Added benefit</td>
<td>Not assessed</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
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Initiative for EU cooperation on HTA
Why now?

Need for a sustainable mechanisms (post 2020) to build on the success of the current cooperation (EUnetHTA JA3) whilst addressing identified shortcomings.
Initiative for EU cooperation on HTA
Impact on rare diseases

• Small target population
• Challenges related to evidence requirements – importance of patients' involvement in HTA processes
• Timely patient access to innovative health technologies

Importance of EU collaboration - to agree on the how the value of products to treat rare diseases will be assessed in HTA
Policy Objectives of the HTA initiative

GENERAL OBJECTIVES:
1. Enable Member States to strengthen their cooperation on HTA in a sustainable manner
2. Ensure a better functioning of the internal market of health technologies
3. Contribute to a high level of human health protection, as stated in Article 168 TFEU and Article 35 of the Charter of Fundamental Rights

SPECIFIC OBJECTIVES:
1. Reduce duplication of efforts for HTA bodies and industry
2. Promote convergence in HTA procedures and methodologies
3. Improve the uptake of joint work in Member States
4. Ensure the long-term sustainability of EU HTA cooperation
Policy options

Inception impact assessment

<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+ Non-clinical: economic, ethical, legal, etc.)</td>
</tr>
<tr>
<td>Non-legislative / voluntary</td>
<td>Legislative / voluntary + mandatory</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

+ Issues to be addressed

- Scope
- Funding mechanism
- Coordination / secretariat
## Studies supporting the Impact Assessment Overview

<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Est.</th>
</tr>
</thead>
<tbody>
<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>Feb 2017</td>
</tr>
<tr>
<td>Mapping of HTA methodologies</td>
<td>The main objective of the study is to provide a concise overview of the scientific methodologies implemented by the Member States' HTA bodies.</td>
<td>Feb 2017</td>
</tr>
<tr>
<td>Study on impact analysis of policy options for Strengthened EU cooperation on HTA (main study)</td>
<td>Provide key input for analysing the impacts of identified policy options to strengthen EU cooperation on HTA.</td>
<td>May 2017</td>
</tr>
</tbody>
</table>
Online public consultation – overview of results (1)

- **Questionnaire for citizens**
  - 63 replies from 21 MS
  - 1 to max 8 replies/MS).
  - Highest number of replies: NL (8), IT, FR and ES (6)

**Preliminary results:**
- 98% consider HTA useful
- 57% consider that it’s not necessary that national/regional HTA bodies perform clinical/medical assessments of the same health technologies in parallel, independently from each other
Online public consultation – overview of results (2)

- Questionnaire for administrations, organisations and associations
  - 150 replies

![Pie chart showing the distribution of responses by category:]
- a) Public administration (other than payers): 41%
- b) Patients and consumers: 18%
- c) Healthcare provider: 16%
- d) Payer (irrespective of status i.e. public or private): 11%
- e) Industry or service provider: 5%
- f) Academia or scientific society: 3%
- g) Other: 8%
Online public consultation – overview of results (3)

- Questionnaire for administrations, organisations and associations

Preliminary results
- 40% of respondents participated to EU-funded projects and Joint Actions aimed at strengthening cooperation on HTA across the EU and 52% are aware of such activities
- 35% of respondents found EU cooperation useful and 45% to some extent useful
- 92% consider that EU cooperation should continue beyond 2020
Timeline

• Publication of the public consultation report
• Conclusion of studies supporting the impact assessment
• Impact assessment
• Consultation meetings (MS MoH, HTA Network, EUnetHTA, Stakeholders)
Thank You

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Further information: