HTA in EU
from National best practices to EU cooperation

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WHAT IS HEALTH TECHNOLOGY ASSESSMENT?
Health Technology Assessment (HTA) is the systematic evaluation (evidence based) of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.
Aspects considered in HTA for different health technologies

EVIDENCE USED FOR ASSESSING THE PROPERTIES AND EFFECTS OF A HEALTH TECHNOLOGY

TYPES OF HEALTH TECHNOLOGIES

- Medicines
- Vaccines
- Medical devices
- Surgical interventions
- Service delivery models
- Public health interventions
- Clinical interventions

ASPECTS CONSIDERED

- Safety
- Clinical effectiveness
- Economic consideration
- Budget impact analysis
- Organization impact
- Equity issue
- Ethical issue
- Feasibility considerations
- Acceptability to health care providers
- Acceptability to patients

Source: WHO Global Survey on HTA 2015
HTAs can be used to support many health care decisions and stakeholders:

**CLINICIANS AND PATIENTS**
- Prescribing decisions
- Practice guidelines

**PUBLIC AND PRIVATE PAYERS**
- Drug plan formularies
- Level of coverage

**HOSPITALS**
- Technology acquisition
- Hospital formularies
**HTA functions and principles**

- PROMOTING INNOVATION
- ALLOCATING RESOURCES
  - HEALTH GAIN

**HEALTH TECHNOLOGY ASSESSMENT PRINCIPLES**

*(Drummond et Al. 2008)*

1. The goal and scope of HTA should be explicit and relevant to its use
2. The HTA should be an unbiased and transparent exercise
3. The HTA should include all relevant technologies
4. A clear system for setting priorities for HTA should exist
5. The HTA should consider a wide range of evidence and outcomes
6. HTAs should consider a wide range of evidence and outcomes
7. A full societal perspective should be considered with undertaking HTA’s
8. HTA’s should explicitly characterize uncertainty surroundings estimates
9. HTAs should consider and address issues of generalizability and transferability
10. Those conducting HTAs should actively engage all key stakeholder group
11. Those undertaking HTAs should actively seek all available data
12. The implementation of HTA findings needs to be monitored
13. HTAs should be conducted in a timely manner
14. HTA findings need to be communicated appropriately to different decision – makers
15. The link between HTA findings and decision – making processes needs to be transparent and clearly defined
EU aggregate “public” health care expenditure, including government schemes and compulsory contributory health care financing schemes, in 2014 covered an amount of almost 1.095 billion € (Eurostat).
CHAPTER 2

HEALTH TECHNOLOGY ASSESSMENT IN EUROPE
### EU cooperation on HTA

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>Call for project proposals</td>
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<tr>
<td>2009</td>
<td>Call for joint action</td>
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<tr>
<td>2011</td>
<td>Call for joint action</td>
</tr>
<tr>
<td>2006-2008</td>
<td>EUnetHTA Project</td>
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<tr>
<td>2009</td>
<td>EUnetHTA Collaboration</td>
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<tr>
<td>2010-2012</td>
<td>EUnetHTA Joint Action 1</td>
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<tr>
<td>2012-2015</td>
<td>EUnetHTA Joint Action 2</td>
</tr>
<tr>
<td>2013 &amp; +</td>
<td>Draft Cross Boarder Healthcare Directive. Article 15 HTA network</td>
</tr>
<tr>
<td>2011-12</td>
<td>CBHC Directive now decided</td>
</tr>
<tr>
<td>2014-2020</td>
<td>Financial support HTA</td>
</tr>
</tbody>
</table>

- **EUnetHTA**: EU cooperation on HTA
- **DG R&I**: Draft Cross Boarder Healthcare Directive. Article 15 HTA network
- **Horizon 2020**: Calls Health Care
- **2011 FP7**: Health Care
- **2012**: Innovation – 1 New methodologies for HTA
Health technology assessment (HTA) in the EU is defined as:

“A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value”*

HTA covers different aspects (HTA core model domains), but does not include pricing and reimbursement decisions, which is a national level prerogative: evidence is global, decision is local.

**HTA Core Models DOMAINS**

<table>
<thead>
<tr>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Health problems and current use of technology</td>
</tr>
<tr>
<td>2. Description and technical characteristics</td>
</tr>
<tr>
<td>3. Safety</td>
</tr>
<tr>
<td>4. Clinical effectiveness</td>
</tr>
<tr>
<td>5. Costs and economic evaluation</td>
</tr>
<tr>
<td>6. Ethical analysis</td>
</tr>
<tr>
<td>7. Organisational aspects</td>
</tr>
<tr>
<td>8. Patients and social aspects</td>
</tr>
<tr>
<td>9. Legal aspects</td>
</tr>
</tbody>
</table>

*Source: EUnetHTA Joint Action definition.

*Rapid REA: Relative Effectiveness Assessment*
Objectives and tools developed

**Article 15**

*DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients’ rights in cross-border healthcare*

**Cooperation on health technology assessment**

“The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. [...]”

- Since 1993, the European Commission (EC) supported important projects on HTA that resulted in an HTA network (EUnetHTA Collaboration) set up in 2013 that conducts project-based activities in the field of HTA. EUnetHTA coordinated the efforts of 29 European countries, including 25 Member States of the European Union (EU), in evaluating health technology in Europe.

- The first two Joint Actions were co-funded through the EU Health Programme with a total budget of 15.5 million. A third Joint Action – EUnetHTA 3, running from 2016 until 2020, has been launched (budget EUR 20 million) on the 1st June 2016.

**OBJECTIVES OF EUnetHTA PROJECT**

- ✓ To provide a robust multifaceted input to decision making
- ✓ To reduce duplication of work
- ✓ To gain a better understanding of the links between HTA and policy making in different Member States
- ✓ To support countries with limited HTA experience

**TOOLS DEVELOPED**

- ✓ Core HTA structure/model
- ✓ Planned and Ongoing Projects Database (POP)
- ✓ Evidence database on new technologies (EVIDENT)
- ✓ Adaptation Toolkit
Main shortcomings

1. The uptake of joint work at EU level into national decision-making processes has remained low, leading to duplication of work by national/regional HTA authorities.

2. Significant differences in the procedural framework and administrative capacity of Member States.

3. Significant differences in national methodologies.

4. The current model of HTA cooperation at EU level is not financially sustainable over time.
HTA heterogeneity among Member States

HTA TECHNOLOGY ASSESSED AND METHODOLOGIES

HTA INSTITUTIONS AND THEIR ROLE IN POLICY MAKING

INVolVEMENT OF DIFFERENT STAKEHOLDERS IN HTA PROCESSES

HTA APPLICATION AND DISSEMINATION
A CROSS – COUNTRY COMPARISON OF HTA AMONG EUROPEAN MEMBER STATES
A cross-country comparison of HTA functions

Regulatory function

HTA or REGULATORY BODY

Advisory function

ACCESS TO THE MARKET, PRICING AND REIMBURSEMENT DECISION

(some kind of) REGULATORY

- Sweden
- Netherlands
- France
- Spain
- Poland

ADVISORY/COORDINATION

- UK
- Germany
- Denmark
- Italy

“REGULATORY BODY” i.e. an institution which have the remit to make decision about market access and / or pricing and reimbursement. Not always the two functions are performed by the same body.
### A cross – country comparison (A)

<table>
<thead>
<tr>
<th>EU Member States</th>
<th>Decision making process (Review, pricing and coverage)</th>
<th>HTA authority</th>
<th>Function of HTA authority</th>
<th>General approach</th>
<th>Principal outcome measures</th>
<th>Health economic component</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sweden</strong></td>
<td>Pharmaceutical Benefits Board (LFN / TLV)</td>
<td>Pharmaceutical Benefits Board (TLV) / Swedish Council on Technology Assessment in Health Care (SBU)</td>
<td>Regulatory / Coordination</td>
<td>Systematic review and analyses of clinical and economic studies. Assessment before market entry.</td>
<td>Mortality, morbidity, quality of life, willingness to pay</td>
<td>CEA, CMA</td>
</tr>
<tr>
<td><strong>Netherlands</strong></td>
<td>Minister of Health, Welfare and Sport</td>
<td>National Health Insurance Board/Committee for Pharmaceutical Aid/Health Council</td>
<td>Regulatory/Advisory</td>
<td>Health economic information. Evidence from manufacturer dossier is required. Assessment before market entry.</td>
<td>Mortality, morbidity, quality of life</td>
<td>CEA, CUA</td>
</tr>
<tr>
<td><strong>Denmark</strong></td>
<td>Danish Medicine Agency (use of free pricing)</td>
<td>Until 2012 Danish Centre for Evaluation and HTA After 2012 decentralized at regional level</td>
<td>Advisory</td>
<td>Health economic information recommended but not required</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Germany</strong></td>
<td>Federal Association of Sickness Funds / Ministry of Health (use of free pricing)</td>
<td>G-BA/Institute for Quality and Efficiency in Health Care (IQWiG)</td>
<td>Advisory</td>
<td>Two step process. Clinical evidence (randomized controlled trials or RCT’s) followed by CBA</td>
<td>Mortality, morbidity, quality of life</td>
<td>Health economic modeling</td>
</tr>
<tr>
<td><strong>UK</strong></td>
<td>Department of Health (use of free pricing)</td>
<td>NICE/National Coordinating Centre for Health Technology Assessment (NCCHTA)</td>
<td>Advisory/Coordination</td>
<td>Clinical evidence (RCT, advanced statistical approaches, probabilistic sensitivity analysis</td>
<td>Mortality, morbidity, quality of life</td>
<td>CEA, CUA with explicit cost effectiveness threshold</td>
</tr>
</tbody>
</table>

Source: I-Com on V.V. A.A.
## A cross – country comparison (B)

<table>
<thead>
<tr>
<th>EU Member States</th>
<th>Decision making process (Review, pricing and coverage)</th>
<th>HTA authority</th>
<th>Function of HTA authority</th>
<th>General approach</th>
<th>Principal outcome measures</th>
<th>Health economic component</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>France</strong></td>
<td>Ministry of Health/ Economic and Public Health Assessment Committee (CEESP)</td>
<td>National Health Authority (HAS)/Transparency Commission</td>
<td>Regulatory</td>
<td>Evidence required from manufacturer dossier. Clinical and economics literature review recommended. Assessment before market entry.</td>
<td>Mortality, morbidity, length of life, health related quality of life</td>
<td>CEA, CUA</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td>AIFA</td>
<td>Since Fall 2014 RIHTA network coordinated by AGENAS (Regions, Autonomous Provinces and Regional Agencies)</td>
<td>Advisory</td>
<td>No guidelines. Generally considered for market entry / coverage and reimbursement: clinical effectiveness, disease relevance</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>Ministry of Health, National Health System inter - territorial Council</td>
<td>Insitudo de Salud Carlos III - Spanish Agency for Health Technology Assessment (AETS) - Regional agencies</td>
<td>Regulatory, Coordination</td>
<td>Systematic reviews of existing evidence, evidence based clinical guidelines, cost efficacy, efficiency and effectiveness analyses</td>
<td>Mortality, morbidity, length of life, health related quality of life</td>
<td>CEA (no explicit threshold, on a voluntary basis)</td>
</tr>
<tr>
<td><strong>Poland</strong></td>
<td>Economic Commission (EC), Ministry of Health</td>
<td>Health Technology Assessment Agency (AOTM)</td>
<td>Regulatory, Coordination</td>
<td>Systematic review of clinical findings, economic evaluation, and budget impact analysis</td>
<td>Mortality, cases or recoveries, health - related quality of life, adverse effects and/or medical events</td>
<td>CEA with explicit cost effectiveness threshold</td>
</tr>
</tbody>
</table>

Source: I- Com on V.V. A.A.
## Most common methodologies used in Health Technology Assessment

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Sweden</th>
<th>Netherlands</th>
<th>Denmark</th>
<th>Germany</th>
<th>United Kingdom</th>
<th>France</th>
<th>Italy</th>
<th>Spain</th>
<th>Poland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>EPI and observational analyses</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Cost and economic analyses</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Comparative analyses</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Post-marketing surveillance</td>
<td></td>
<td>X</td>
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<td></td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Modelling</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Expert-opinion</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Group judgement</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Systematic review</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Meta-analyses</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
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CHAPTER 4

CHALLENGES TO HTA HARMONISATION IN EUROPE
EUROPEAN COMMISSION INCEPTION IMPACT ASSESSMENT
“Strengthening of the EU cooperation on Health Technology Assessment (HTA)”
2016

**OPTION 1**
The status quo with Joint Action until 2020. HTA is regulated and organised at national/regional level. Voluntary cooperation mechanism through the current JA and the HTA Network until 2020.

**OPTION 2**
Long-term voluntary cooperation, financed by the EU beyond 2020. This option foresees the continuation of the current cooperation model, but on a longer-term basis.

**OPTION 3**
Cooperation on collection, sharing and use of common tools and data. Introduction of a legal framework for HTA cooperation to enable the efforts by national bodies to be compatible, shared and used. This will ultimately allow for the production of joint REA reports on a voluntary basis.

**OPTION 4**
Cooperation on production of joint Relative Effectiveness Assessments (REA) reports and their uptake. Mutual recognition of HTA assessment opinions applying joint REAs at national level. Establishment of a central structure in charge of managing the preparation, coordination and follow-up reports.

**OPTION 5**
Cooperation on production of joint Full HTA reports and their uptake. Joint production of Full HTA reports, comprising not only the assessment of clinical/medical domains but also the assessment of economic, ethical, legal and organisational domains.
What should we harmonise in the HTA at European level?

- Reduce differences between national HTA approaches with regards to procedures and methodologies, and make it easier for national HTA bodies to share results produced by them individually or jointly.

- **Option 1 and 2** would probably leave the situation unchanged with respect to differences among Member States and problems in applying REA’s results in transnational setting.

- **Option 3 and 4** - extending the cooperation to joint assessments of the clinical/medical part of HTA would improve the cost efficiency of national bodies’ resources, by allowing them to save time in order to generate more reports and further improve the average quality of HTAs in terms of management, relevance, transparency. Implementation, economic evaluation and other HTA context – specific aspects would remain a National responsibility thus respecting the subsidiarity principle.

- **Option 5** seem to be far from be possible and or desirable, given existing differences between national contexts (relevant to health care, innovation and budget constraints).

- In general, Joint assessments would reduce costs and administrative burden for the industry, due to the reduction in the number of submissions to be performed and a greater harmonisation in data requirements.

- A uniform regulatory framework for HTA among Member States would guarantee that HTA takes part of National decision making processes with similar administrative procedures to be followed, being performed by independent bodies, with benefits for patients, industries and governments.
What should we harmonise in the HTA at European level?

Also if most HTA agencies agree that the

**DOMAINS MOST EASILY APPLICABLE AND ADAPTABLE ACROSS COUNTRIES AND DIFFERENT POLICY SETTINGS ARE:**

1. Technology use;
2. Safety;
3. Effectiveness;

**5 POTENTIAL BARRIERS preventing the adoption of joint reports on European REA:**

1. Inconsistency between the EU REA and national HTA timelines and incorporation of joint reports in national processes
2. Changes required in national laws and regulations
3. Differences between EU REA and national HTA methodology
4. Regionalisation of the HTA decisions
5. Position of relevant stakeholders