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.

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness

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

5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects

Non-clinical domains (incl. economics)
- **so called *Full HTA together* with REA**

STATE OF PLAY

European Commission

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

SUSTAINABLE EU COOPERATION ON HTA

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**

1994-1997: EUR-ASSES
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 Action3
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

Abbreviated indication	Brand name (generic)	HTA recommendation					
		GEMANY	THE NETHER-LANDS	FRANCE	ENGLAND/ WALES	SCOTLAND	POLAND
Bone metastases from solid tumours	1. Denosumab	Not assessed	Equal benefit	Added benefit Equal benefit	Positive	Not assessed	Negative
Breast cancer	2. Eribulin	Equal benefit Equal benefit	Added benefit	Added benefit	Negative	Negative	Negative
	3. Pertuzumab	Added benefit	Not assessed	Added benefit	Not assessed	Negative	Positive
Colorectal cancer	4. Aflibercept	Added benefit	Not assessed	Equal benefit	Negative	Negative	Positive
Gastric cancer	5. Tegafur / gimeracil / oteracil	Not assessed	Lesser benefit	Lesser benefit	Not assessed	Positive	Negative
Melanoma	6. Ipilimumab	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	7. Vemurafenib	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	8. Dabrafenib	Equal benefit	Not assessed	Equal benefit	Positive	Positive	Positive
Non-small-cell lung cancer	9. Afatinib	Added benefit Added benefit Equal benefit Lesser benefit	Not assessed	Equal benefit	Positive	Positive	Positive
	10. Crizotinib	Equal benefit	Not assessed	Added benefit	Negative	Negative	Negative
Prostate cancer	11. Cabazitaxel	Added benefit Added benefit	Added benefit	Added benefit	Negative	Negative	Negative
	12. Enzalutamide	Added benefit Added benefit	Not assessed	Added benefit	Positive	Positive	Positive
	13. Abiraterone	Added benefit	Equal benefit	Added benefit	Positive	Negative	Positive
Renal-cell carcinoma	14. Axitinib	Added benefit	Not assessed	Added benefit	Positive	Negative	Positive

Relative effectiveness assessments of oncology medicines for pricing and reimbursement decisions in European countries. Kleijnen S, Lipska I, Leonardo Alves T, Meijboom K, Elsada A, Vervölgyi V, D'Andon A, Timoney A, Leufkens HG, de Boer A, Goettsch WG. Ann Oncol (2016) 27 (9): 1768-1775.

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

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+ Non-clinical: economic, ethical, legal, etc.)**
Non-legislative / *voluntary*		**Legislative / *voluntary + mandatory***		

+ Issues to be addressed

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

Studies supporting the Impact Assessment Overview

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.	Feb 2017
Mapping of HTA methodologies	The main objective of the study is to provide a concise overview of the scientific methodologies implemented by the Member States' HTA bodies.	Feb 2017
Study on impact analysis of policy options for Strengthened EU cooperation on HTA (main study)	Provide key input for analysing the impacts of identified policy options to strengthen EU cooperation on HTA.	May 2017

Online public consultation – overview of results (1)

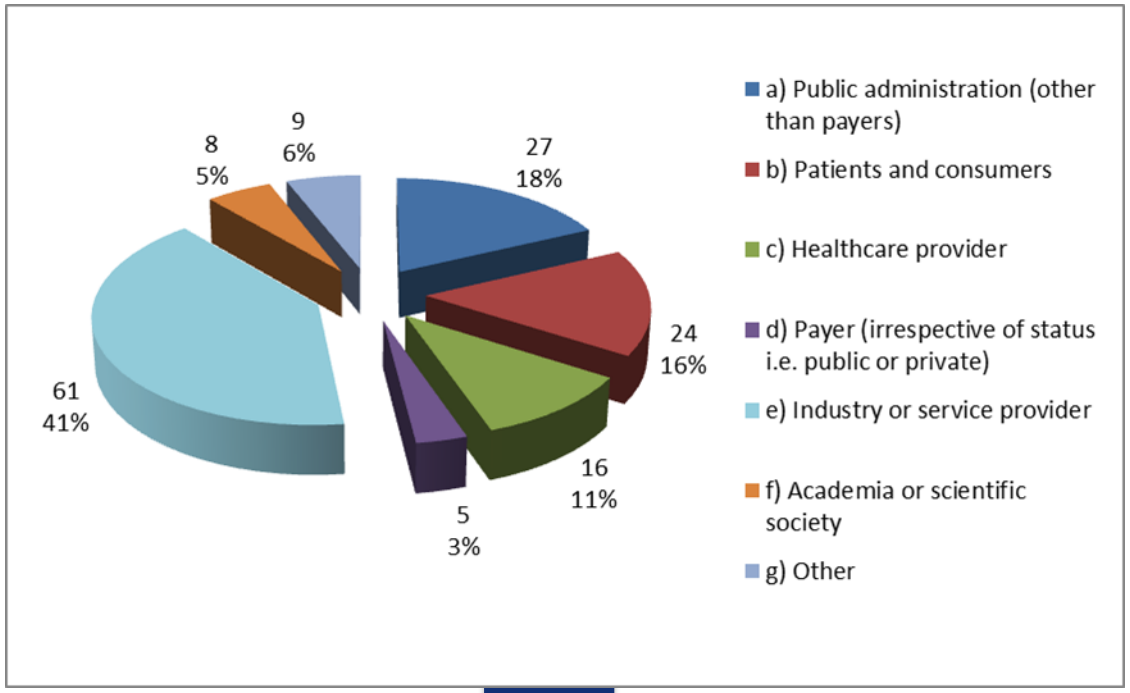
- **Questionnaire for citizens**
  - - **63** replies from 21 MS
  - - 1 to max 8 replies/MS).
  - - Highest number of replies: NL (8), IT, FR and ES (6)

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



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

Karolina.Hanslik@ec.europa.eu

Further information:

http://ec.europa.eu/health/technology_assessment/policy/index_en.htm