



# EU COOPERATION ON HTA

## State of play

**Flora Giorgio**  
**Head of Sector**  
European Commission  
DG SANTE - Health Systems,  
Medical Products and Innovation

Disclaimer: the views expressed do not necessarily reflect the position of the Commission

## 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

5. Costs and economic evaluation

6. Ethical analysis

7. Organisational aspects

8. Patient and social aspects

9. Legal aspects

**Clinical domains**

➤ so called *REA*  
(rapid effectiveness  
assessment)

**Non-clinical  
domains**

(economics)

➤ so called *Full HTA*  
together with REA



## 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, later EUnetHTA
- Now Joint Action 3 – **2016 – 2020**



### New HTA Initiative

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

## Major Achievements (JA1 and JA2)

- **Trust** between HTA bodies and **capacity building**
- Development of **joint tools** (POP, EUnetHTA core model)
- Piloting **joint work**
- JA3 – **upscaling of joint work**



## Shortcomings

- **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 NETHERLANDS	FRANCE	ENGLAND/WALES	SCOTLAND	POLAND
Bone metastases from solid tumours	1. Denosumab	Not assessed	Equal benefit	Added benefit	Positive	Not assessed	Negative
Breast cancer	2. Eribulin	Equal benefit	Added benefit	Added benefit	Negative	Negative	Negative
	3. Pertuzumab	Equal benefit	Added benefit	Added benefit	Not assessed	Negative	Positive
Colorectal cancer	4. Afibercept	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	Not assessed	Equal benefit	Positive	Positive	Positive
		Added benefit					
		Equal benefit					
Prostate cancer	10. Crizotinib	Lesser benefit	Not assessed	Equal benefit	Positive	Positive	Positive
	11. Cabazitaxel	Equal benefit	Not assessed	Added benefit	Negative	Negative	Negative
	12. Enzalutamide	Added benefit	Added benefit	Added benefit	Negative	Negative	Negative
	12. Enzalutamide	Added benefit	Not assessed	Added benefit	Positive	Positive	Positive
Renal-cell carcinoma	13. Abiraterone	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	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, Vervolvy V, D'Andon A, Timoney A, Leulkens HG, de Boer A, Goettsch WG. *Ann Oncol* (2016) 27 (9): 1768-1775.

## I IA - Why?

### WHY?

- Support MS to ensure sustainability of healthcare
- Contribute to patient access to innovation
- Support innovation in EU

In close  
cooperation  
with  
EunethTA  
and HTA  
Network

+ Addressing  
shortcomings



**SUSTAINABILITY BEYOND 2020 BASED  
ON THE SUCCESS OF THE CURRENT COOPERATION**

### WHY NOW?

- Growing support to continue cooperation on HTA
  - *Council Conclusions 2015, 2016*
  - *EP own initiative report on access to innovative medicines 2016*
- No EU-funding mechanism beyond 2020

+ Responding to Member States needs



## Policy options\*

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

+ 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](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](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](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







# Stakeholders' involvement

# Stakeholders' involvement



## 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, later EUnetHTA
- Now Joint Action 3 – **2016 – 2020**

## New HTA Initiative

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

INCEPTION IMPACT ASSESSMENT			
Title of the initiative	Strengthening of the EU cooperation on Health Technology Assessment (HTA)		
Lead DG - RESPONSIBLE UNIT or IP/Member	DATE/EM	Date of approval	14/01/2016
Legal base or reference	Legislative or non-legislative initiative		
Initiative PL number	04/2017		
Author(s) Name(s)			
<p>This inception impact assessment is provided for information purposes only and is not an official document. The Commission is not responsible for the content of any website or other information published on the internet.</p>			
<b>A. Context, Substantive Choice and Objectives</b>			
<b>Context</b>			
<p>In the EU total (public and private) health care expenditure remains at around EUR 1 300 billion per year (including EUR 220 billion for pharmaceuticals) and EUR 130 billion for medical devices. Health care expenditure thus amounts on average for about 17% of the EU GDP. The expenditure is likely to increase in the coming years, including even after Europe's ageing population, the increase of chronic diseases and complex care technologies.<sup>1</sup> At the same time Member States are increasingly constrained with budgetary conditions. These developments will require Member States to further improve the efficiency of health budgets – focusing on effective technologies which maximising a Member State's expenditure.</p>			
<b>Definition</b>			
<p>Health technology refers to a medicinal product, a medical device or medical and surgical/diagnostic procedures as well as services for disease prevention, diagnosis or treatment used in health care.<sup>2</sup></p>			



## Stakeholders' involvement



### HTA Network

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

***EC to set up a stakeholder Pool → to contribute to policy developments on HTA***

- gather the list of organisations interested in HTA
- propose to the HTA Network its representatives to participate as observer: 8 in total.
- work via different methods: ad hoc consultations on specific topics, written consultations or ad hoc meetings, etc.



## Process

- Call for expression of Interest to identify relevant stakeholders → **to be launched in December - until January**
  - The EC services will identify the organisations based on eligibility and added value criteria
  - 4 categories (patients/consumers; healthcare providers/academia; payers; industry)
  - EU umbrella organisations/transparency register
  - Membership (the organisation)
  - Demonstrated interest in HTA related activities



# EUnetHTA



## EUnetHTA Joint Action

- **Scientific and technical cooperation**
- Started in the 1990's, later EUnetHTA
- Now Joint Action 3 – **2016 – 2020**

- From a Stakeholder Forum and consultation approach in EUnetHTA 2, to engage stakeholders more actively in the Work Packages of EUnetHTA 3 in "**HTA production**"
- Stakeholders will be asked to participate as experts in the joint production (e.g REA, ED, Full HTA, methodology developments etc.)



## EU cooperation on HTA



### New HTA Initiative

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

- ***Public consultation is open until 13 Jan- we welcome your input!***

[http://ec.europa.eu/health/technology\\_assessment/consultations/cooperation\\_hta\\_en.htm](http://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en.htm)

- ***Bilateral meetings (All minutes of meetings with stakeholders are published on our website)***

[http://ec.europa.eu/health/technology\\_assessment/latest\\_updates/index\\_en.htm](http://ec.europa.eu/health/technology_assessment/latest_updates/index_en.htm)



# Thank you

Further information available under:

[http://ec.europa.eu/health/technology\\_assessment/policy/index\\_en.htm](http://ec.europa.eu/health/technology_assessment/policy/index_en.htm)