



# **Initiative on Strengthening EU Cooperation on Health Technology Assessment (HTA)**

**DG SANTE**

**B4. Medical products:  
quality, safety, innovation**

# Economic context

## Total EU health care expenditure

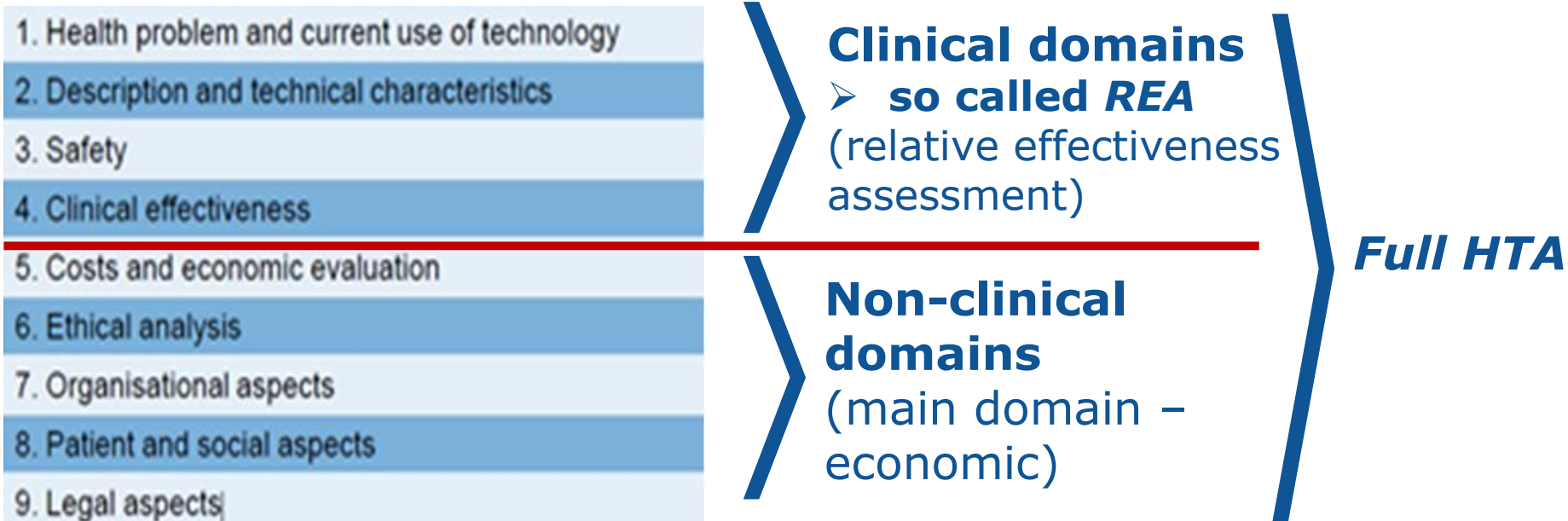
- **€1 300 billion** per year, including
  - €220 billion (23%) for pharmaceuticals and
  - €100 (11%) billion for medical devices
- **10% of GDP**

*The figures are forecasted to increase.*

## Health Technology Assessment (HTA)

### Definition

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



## What has been done at EU level ?

### ➤ Research



- AdhopHTA
- MedtechHTA
- INTEGRATE-HTA
- ADVANCE-HTA



- ADAPT SMART
- GET REAL

### ➤ 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 Action 3**

Enhanced cooperation with a focus on joint HTA work (e.g. joint assessments and uptake)



## EU cooperation on HTA – Where we are



**HTA  
Network**

**EUnetHTA  
Joint  
Action**



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



**Synergy and  
complementarity**

- **Scientific and technical cooperation**
- Started in the 1990's – EunetHTA 1 & 2
- Joint Action 3 – **Until 2020**

## EU cooperation on HTA

### Initiative on Strengthening EU cooperation on HTA

#### WHY?

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

#### WHY NOW?

- Growing support to continue cooperation on HTA
  - *Council Conclusions 2015, 2016*
  - *EP own initiative report 2016*
  - *HTA Network Strategy 2014*
- No EU-funding mechanism foreseen beyond 2020

+ Addressing shortcomings



+ Responding to Member States needs

SUSTAINABLE COOPERATION BEYOND 2020 BASED ON THE SUCCESS OF THE CURRENT COOPERATION

## Why Now?

- Growing support to continue cooperation on HTA

### Council conclusions

- Innovation for the benefit of patients (Dec 2014)
- Personalised medicines for Patients (Dec, 2015)
- Strengthening the Balance in the Pharmaceutical Systems" (June, 2016)

*"Foster enhanced cooperation between MS under the 3rd JA of the European Network for Health Technology Assessment (EUnetHTA) (...) reflect about the future of HTA cooperation at European level for the period beyond 2020 when the current Joint Action comes to an end (...)"*

## Why Now?

- Growing support to continue cooperation on HTA

<p><b>EP resolution (2015/2729(RSP))</b></p>	<p>EP calls for <i>"a step forward towards a common European Health Technology Assessment"</i> – <b>EP resolution on the Commission Work Programme for 2016.</b> (Sep, 2015)</p>
<p><b>HTA Network Strategy</b></p>	<p><i>"Calls upon the Commission to explore: how to secure support for activities necessary to facilitate joint work at EU level on a permanent basis; and(..)"</i> (Oct, 2014)</p>

- No EU-funding mechanism foreseen beyond 2020



## 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; and
4. Ensure the long-term sustainability of EU HTA cooperation.

# HTA in the context of other EU policies

## Links of HTA to Key EU Policies

1. **Internal market:** *reduce national differences and avoid duplication of efforts.*
2. **Budget/fiscal stability:** *European semester*
3. **Innovation agenda:** *Horizon 2020*

## Links of HTA to national responsibility

**Pricing and reimbursement decisions are outside the scope of this initiative**

## Initiative on Strengthening EU cooperation on HTA 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

Scope

Funding mechanism

Coordination/secretariat

\*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)

- Inception Impact Assessment published on 15 September 2016



- Online public consultation to be launched in October 2016
- Studies to support the impact assessment process
- Meetings with stakeholders
  - EC-EUnetHTA Forum 21 October
  - HTA Network 10 November
  - Bilateral meetings
- Impact Assessment process – planned for 2017

**! Close cooperation with MS, EP and all key stakeholders**



**Thank You**