

# EUnetHTA

## A vision on voluntary European HTA collaboration

European network for Health Technology Assessment  
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# Content presentation

- Introduction
- Political developments regarding collaboration
- EUnetHTA until now
- The future of EUnetHTA

# European collaboration on HTA

Technologies become more 'international'  
Patients become more 'European'

Decrease duplication on HTA assessments

Increase consistency between different national  
HTA assessments

–Variety in type of assessments seems to be common:  
does this lead to different assessment results?

# European developments

## 2. Directive 2011/24/EU on cross-border healthcare

**The Directive provides a detailed legal framework focused on three main areas:**

- rules concerning the reimbursement of costs of cross-border healthcare
- responsibilities of the Member States with regard to cross-border healthcare
- cooperation between healthcare systems

**EU Objectives in HTA Article 15 Directive 2011/24:**

- Support cooperation between national HTA Authorities
- Support MS in the provision of objective, reliable, timely, transparent , comparable and transferable information [...] to enable effective exchange of information
- Avoid duplication of assessments



Commission  
European  
Commission

## 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 – EUnetHTA 1 & 2
- Joint Action 3 – **2016 – 2020**

INCEPTION IMPACT ASSESSMENT	
Title of the initiative	Strengthening of the EU cooperation on Health Technology Assessment (HTA)
Last EU measurement year / MIP deadline	SANTE 04 Date of approval: 14/06/2015
Lead / Type of initiative	Legislative or non-legislative initiative
Initiative Planning	04/2017
Abstract/ Summary	This inception impact assessment is intended for information purposes only and will be subject to change. It does not constitute the final decision of the Commission or indicate the positions of any of the Member States.
<b>A. Context, Substantive Objectives and Objectives</b>	
Context	
In the EU, total (public and private) health care expenditure remains to around EUR 1 300 billion per annum (excluding EUR 200 billion for pharmaceuticals) and EUR 130 billion for medical services. Health care expenditure also accounts on average for about 11% of the EU GDP. The expenditure is likely to increase in the coming years, considering ever-aging European population, the increase of chronic diseases and complex care technologies. <sup>1</sup> At the same time, Member States are increasingly confronted with budgetary constraints. 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.	
Definition	
Health technology refers to a medicinal product, a medical device or medical and rehabilitation procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare. <sup>2</sup>	

### New HTA Initiative

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



## Initiative on Strengthening EU cooperation on HTA

Inception Impact Assessment published on 15 September

### WHY?

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

**+ Addressing shortcomings**



### 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

**+ Responding to Member States needs**

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

## 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 reports</b>	Cooperation on production of <b>joint Full HTA reports</b>
<b>Non-legislative / voluntary</b>		<b>Legislative / voluntary + mandatory</b>		

**REA** = rapid relative effectiveness assessments – refers to the clinical assessment of a health technology  
**Full HTA** – refers to the clinical and economic assessment of a health technology

\*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)

# EUnetHTA

## Historical timeline

EUnetHTA  
Collaboration

2006

2016

EUnetHTA  
Project

Joint Action 1

Joint Action 2

Joint Action 3

Inception

Putting into  
practice

Strengthening  
practical  
application

Turning pilots  
into standard  
practice



# Achievements EUnetHTA (products)

- Tools
  - HTA Core model (full model and rapid REA)
  - EUnetHTA Planned and Ongoing Projects (POP) database
  - EVIDENT database
  - Evidence submission templates
- Methodology
  - Guidelines for REA
  - Handbook for full HTA
- Products
  - Early dialogues (EUnetHTA and SEED, medical devices and pharmaceuticals)
  - Rapid REAs (pharmaceuticals, medical devices, surgical procedures)
  - Full core HTA's (different types of interventions)

# Achievements EUnetHTA (structure)

- Strong collaboration with the HTA organisations in Europe
  - **BRAND** and **TRUST!**
- Well defined interactions with other stakeholders and other organisations
  - Structure for collaboration with regulators in pharma (EMA)
  - Interactions with other stakeholders, such as technology producers and patients in assessments, early dialogues, preparation of methodology
- Interaction with political and strategical activities
  - Link to initiatives such as HTA Network, STAMP, CAPR and MEDEV
- Embedded in the scientific HTA community
  - Link to societies like INAHTA, HTAi and ISPOR
  - Involved in multistakeholder projects in IMI such as GetReal, but also FP7 projects such as INTEGRATE-HTA, ADVANCE-HTA and ADOPTHTA

# ***Joint pilots on REA of non-pharma 2013-2015***

## **First pilot**

- Duodenal-jejunal bypass sleeve for the treatment of obesity with or without diabetes type II, authors are LBI-HTA (Austria) and AAZ (Croatia). Published in August 2013

## **Second pilot**

- Renal denervation for treatment resistant hypertension, authors are NOKC (Norway), **Avalia-t (Spain)** and CFK (Denmark). Published in December 2013

## **Third pilot**

- Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction, authors are FinOHTA (Finland) and HIQA (Ireland). Published in February 2015

## **Fourth pilot**

- Biodegradable stents for benign refractory esophageal stenosis, authors are **ISCII (Spain)** and SAGEM (Turkey). Published in August 2015

## **Fifth pilot**

- Implantable devices for the treatment of mitral valve regurgitation, authors are Agenas (Italy), AAZ (Croatia) and Ministry of Health (Slovakia). Published in September 2015

## **Sixth pilot**

- Mechanical thrombectomy in acute ischaemic stroke. Authors are HIQA (Ireland), University of Erlangen (Germany). Planned publication in December 2015

# EUnetHTA Joint Action 3

Aims to build a **sustainable model** for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe

# Specific Objectives of JA3

- To increase production of high-quality HTA joint work
- To increase uptake and implementation of joint HTA work at the national, regional, and local level
- To support evidence-based, sustainable, and equitable choices in healthcare and health technologies

# EUnetHTA JA3 Participants

**79** partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

**Project Coordinator:**  
Dutch National Health Care  
Institute (ZIN)



# Organisational and governance structure

DG SANTE and CHAFEA



## Work Package 1 Network Coordination - Dutch Health Care Institute

**Work Package 2**  
Dissemination

Lead:  
AETS-ISCIII



**Work Package 3**  
Evaluation

Lead:  
TLV



**Work Package 4**  
Joint Production

Lead:  
NIPHNO  
Co-lead:  
LBI  
ZIN



**Work Package 5**  
Evidence  
Generation

Lead:  
HAS  
Co-lead:  
GBA



**Work Package 6**  
Quality

Lead:  
IQWiG  
Co-lead:  
KCE



**Work Package 7**  
Implementation

Lead:  
NICE  
Co-lead:  
Agenas



Spain

Sweden

Norway

Austria

Netherlands

Germany

United Kingdom

Belgium

Croatia

Cyprus

Czech Republic

Denmark

Finland

France

Greece

Hungary

Ireland

Latvia

Malta

Poland

Portugal

Romania

Slovakia

Slovenia

Italy

Estonia

Lithuania

Bulgaria

Switzerland



# Summary of select activities in JA3

## WP4 Joint Production

- To produce **43** rapid REA on other technologies and **37** on pharmaceutical
- To provide a system for topic selection and prioritization

## WP5 Evidence Generation

- To conduct Early Dialogues (joint HTA or parallel/joint with regulators)
- To link additional data collection to on-going activities

## WP6 Quality Management

- To provide quality management for EUnetHTA joint products
- To further develop methodologies and tools for joint work if necessary

## WP7 National implementation and impact

- To facilitate the uptake of joint products at the national/local level
- To measure the impact of joint work in collaboration with other work packages



# Work Packages EUnetHTA JA3

## Work Package 1 Network Coordination

**Work Package 4**  
Joint production  
(Pharmaceuticals &  
Other Technologies)

**Work Package 5**  
Evidence  
generation

**Work Package 7**  
National  
implementation

**Work package 6**  
Quality  
management,  
Scientific  
Guidance, &  
Tools

**Work package 2**  
Dissemination

**Work package 3**  
Evaluation

# Issues on how to proceed with joint HTAs in JA3 (rapid vs full)

- Focus on rapid (single technology) assessments as is there the most urgent need
- Not only focus on pharma but also other technologies (med devices)
- Priority on the first four domains (clinical domains) because transferability of the other domains (6-9) is debated (maybe more relevant in the national situation)
- Comparative (multiple technology) assessments may be relevant as reassessments (for instance in conditional reimbursement)
- Divergent views on the use of the Economic and Cost domain
  - Relevant and helpful for many, especially less experienced, organisations
  - However, very context specific and difficult to transfer between countries

# Issues on how to proceed with joint HTAs in JA3 (implementation)

- Implementation in national practice is an issue for all technologies
  - Implementation barriers assessed in 're-use report' HTA network
  - Legal barriers may be important in some countries
  - Organisational issues like the structure of the core report; independent assessment vs critique of submission
  - The language issue!
- Topic selection is a more urgent issue for med-tech
  - Very dependent on national process of priority setting
- Timeliness is most important for pharma, 90-days after MA.
  - However it will be very difficult to shorten the current joint procedure
  - Earlier start, more in line, with the regulatory assessment?
  - Data exchange with EMA is an issue

# Specific issues relevant for the involvement of Spain in EUnetHTA JA3

- Linking to the activities of the Spanish HTA Network
  - Learning from the implementation of joint reports in the Spanish practice
  - Discussing HTA activities in relation to clinical guidelines
- Focus both on pharma and medical devices
- Support the structure in which both national organisations and regional organisations (may also include academical institutions) benefit from EUnetHTA collaboration
- Use the new option of 'affiliated entities' in EUnetHTA
  - Provides structural links between nominated bodies and other organisations that contribute to the scientific work in EUnetHTA JA3

# Thank you

## Any Questions?