

The EUnetHTA Experience – Lessons Learned for a New EU HTA Cooperation



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EUnetHTA - AEMPS














European Network of Health Technology Assessment

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

- Joint Action 1 (2010-2012)
- Joint Action 2 (2012-2015).
- **Joint Action 3 (2016 – 2020) - 78 organisations from 29 countries**



EUnetHTA organisation

		DG SANTE and CHAFEA 					
EUnetHTA Assembly	Executive Board	WP1 Network Coordination - Dutch Health Care Institute 					
		WP2 Dissemination	WP3 Evaluation	WP4 Joint Production	WP5 Evidence Generation	WP6 Quality Management	WP7 Implementation
		Lead: AETS-ISCI III 	Lead: TLV 	Lead: NIPHNO  Co-lead: LBI  ZIN 	Lead: HAS  Co-lead: GBA 	Lead: IQWiG  Co-lead: KCE 	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			

HTA Network meeting
Wim Goettsch



WP4 – Joint Production

Production of joint assessments within the network

Horizon scanning, product selection and prioritisation

Types of Assessments:

Joint Assessments
Collaborative assessments

Rapid Relative Effectiveness Assessments (REA)
Full Assessments

Timeframe:

- Parallel with the assessment by the CHMP

Activity:

- 5/43 medical devices
- 2/37 pharma





WP5 – Evidence Generation

Objective: Provide support for evidence generation along the lifecycle of the technology.

Strand A: Early Dialogues: Advice in an early stage of clinical development

- **Parallel Consultations EMA-EUnetHTA:** Launched last June
 - Consolidated Parallel Consultations
 - Individual Parallel Consultations
- **Multi-HTA:** Only HTA participation

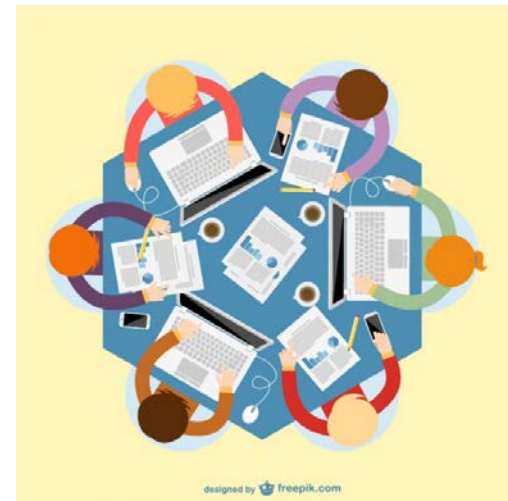
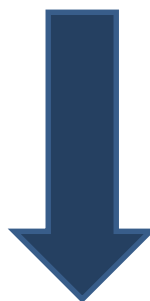
Activity:

- 2 Multi-HTA ED
- 11 Parallel Consultations EMA-EUnetHTA





Parallel Scientific Advice



Parallel Consultations EMA-EUnetHTA



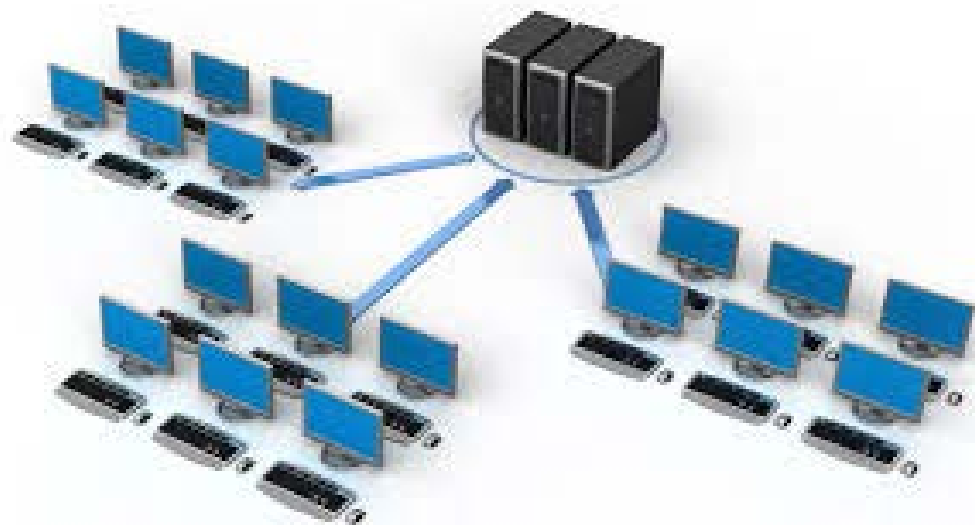
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



WP5 – Evidence Generation

Strand B: Post-launch Evidence Generation

First pilot of a European registry in parallel with EMA



WP7 – National Implementacion

Objective: Provide support for the development of a sustainable mechanism of cooperation among HTAb.

Inform about about the stay of play, barriers for implementation, degree of uptake, mechanisms for adaptation and adoption, etc.

Activity: Case Reports





[European Commission](#) > [DG Health and Food Safety](#) > [Public health](#) > [Health technology assessment](#) > [Consultations](#)

HEALTH TECHNOLOGY ASSESSMENT



All topics

Policy

EUNetHTA Joint Actions

EU cooperation

Go back to [Health technology assessment](#) > [Consultations](#)

Public consultation on strengthening EU cooperation on Health Technology Assessment (HTA)





Policy options for strengthened EU cooperation on HTA

Key characteristics	Option 1 The status quo –voluntary cooperation on HTA (until 2020)	Option 2 Long term voluntary cooperation on HTA (beyond 2020)	Option 3 Cooperation on collection, sharing and use of <u>common tools</u> and data	Option 4 Cooperation on the production of <u>joint REA reports</u>	Option 5 Cooperation on the production of <u>joint full HTA reports</u>
Regulatory	Non-legislative	Non-legislative	Legislative	Legislative	Legislative
Participation of HTA bodies and industry	Voluntary	Voluntary	Compulsory (tools) Voluntary (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)
Uptake joint output	Voluntary	Voluntary	Compulsory for tools	Compulsory for tools and REA	Compulsory
Financing	Largely depending on EU budget	Largely depending on EU budget	Mixed funding model (EU budget + MS + industry contribution)	Mixed funding model (EU budget + MS + industry contribution)	Mixed funding model (EU budget + MS + industry contribution)
	Ending 2020	Long-term	Long-term	Long-term	Long-term
Main joint output					
a. Common Tools/templates	(✓)	(✓)	✓	✓	✓
b. Joint REA	(✓)	(✓)	(✓)	✓	✓
c. Joint Full HTA	(✓)	(✓)	(✓)	(✓)	✓
d. Early Dialogue	(✓)	(✓)	✓	✓	✓



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productos sanitarios



Oficina de apoyo
a la INNOVACIÓN
y CONOCIMIENTO
sobre MEDICAMENTOS



European
Commission

Results of the online public consultation

8th meeting of the HTA Network

DG SANTE
B4 – Medical products:
safety, quality, innovation





Public consultation

Public consultation

- Launched: 21/10/2016
- Deadline: 13/01/2017
- Extended: 30/01 (requests from MS)

Total number of replies = 249

- **Questionnaire for citizens:** 63 (from 21 MS)

Profile: Tertiary education; with background/working in HTA sector, healthcare sector or industry

- **Questionnaire for administrations, organisations, associations:** 150
- **Questionnaire for SMEs** (DG GROW – SME Network): 36 replies





Citizens



Public consultation

- **98% consider HTA useful**
- **83% consider very important or important** to assess whether a new health technology works better, equally well or worse than health technologies already available
- **Most important factors to be considered when carrying out HTA** (very high or high importance):
 - o Transparency of the HTA process (98 %) -> involving stakeholders
 - o Expertise of the assessor (96%) -> high-quality reports
 - o Independence of the assessor (94%) -> no conflict of interest
 - o Timely delivery of the assessment report (92%) -> useful for decision making
- **HTA information should be accessible to doctors and patients/patients' representatives**
- **57% consider that clinical assessment should not be performed in parallel by HTA bodies in the MS**





Administrations, associations, organisations (2)

Public consultation

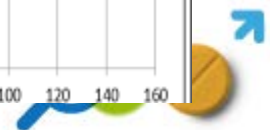


Differences between MS acknowledged by most respondents (agreement + strong agreement), including public administrations

- HTA processes 91%/96%
- HTA clinical methodology 80%/89%
- HTA economic methodology 85%/93%

Most important consequences of the different HTA procedures and/or methodologies across EU

- Diverging outcomes of HTA reports
- Duplication of work
- Decrease in business predictability
- High costs for organisations



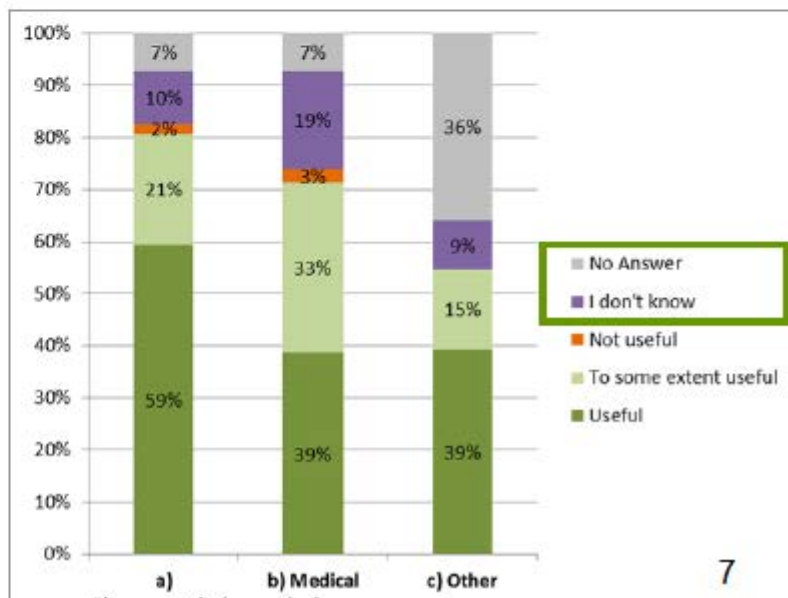
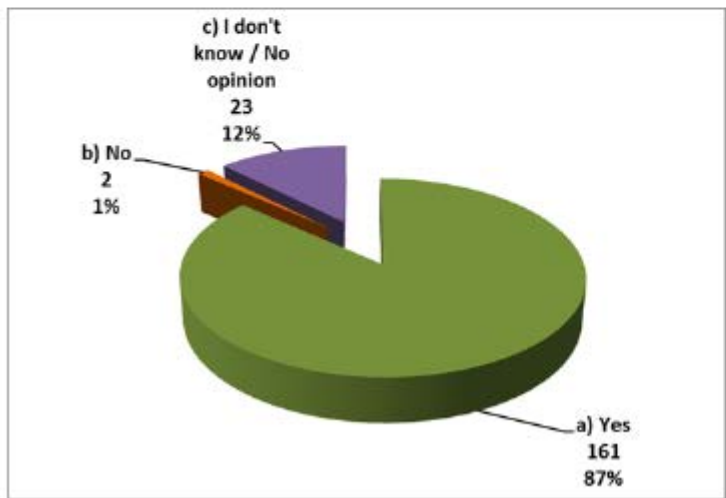


Administrations, associations, organisations (4) Public consultation



EU cooperation beyond 2020: supported by 87%

- **Scope of EU cooperation** (useful and to some extent useful) - Overall/ public administrations replies:
 - Pharmaceuticals 80%/100%
 - Medical technologies 72%/89%
 - Other technologies 54%/67%





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Oficina de apoyo a la INNOVACIÓN y CONOCIMIENTO sobre MEDICAMENTOS

Administrations, associations, organisations (4)



European Commission

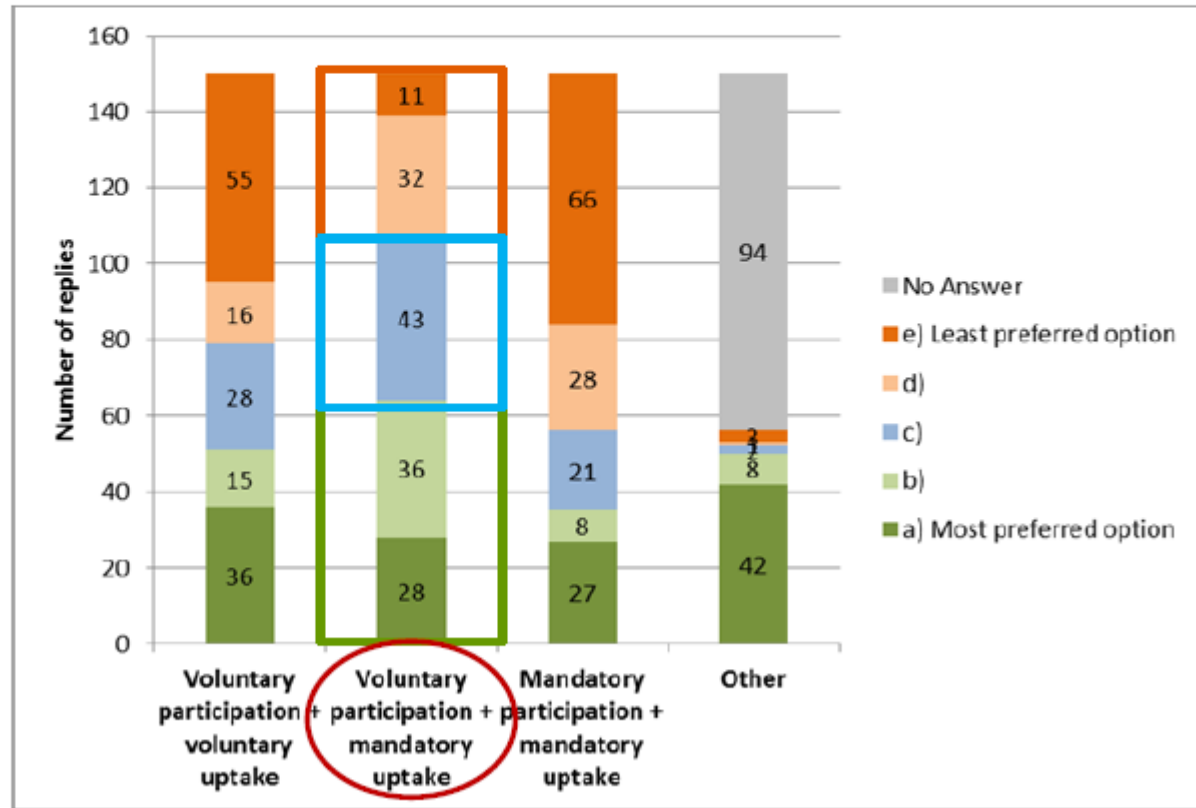
Public consultation

EU cooperation beyond 2020 – Policy options

Lowest opposition

Highest % of neutral responses

Most preferred



Is the cooperation possible?

Same aim:

- ✓ Timely access of health technologies to patients considering the limited resources

Similar methodologies:

- ✓ Same domains included in the assessment: Health problem and current use of the technology, Description of technical characteristics of the technology, Clinical effectiveness/efficacy, Safety, Non-clinical domains
- ✓ Same comparator: Comparator most likely to be replaced by the new technology
- ✓ Surrogate and composite endpoints (outcomes) are accepted in the absence of final endpoints

However... how?

- ✓ Including costs in de assessments? Country and Regional Specific Budgets
- ✓ Descentralised or Central coordination?
By a existing Agency (EMA)/ New Agency/ Comisson
- ✓ How it should be financed??
European funding /Member states/ Industry

**“Coming together is a beginning;
keeping together is progress; working
together is success” Henry Ford**



Thanks for your attention