HTA in the European Union

STATE OF ART AND FUTURE SCENARIOS

Policy brainstorming I-Com, 29th November 2016

Sofitel Brussels Europe

What is Health Technology Assessment?

✓*HTA : an internationally used definition*

Systematic evaluation (evidence based) of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.

HTA : a tool to inform decision makers

EVIDENCE USED for assessing the properties and effects of a health technology

- Safety
- Efficacy
- Effectiveness
- Cost
- Cost - effectiveness
- Ethical and legal implications

both in absolute terms and in comparison with other competing technologies.

HTAs can be used to support many health care decisions and stakeholders:

Clinicians and patients	Public and private payers	Hospitals
• Prescribing decisions • Practice guidelines	• Drug plan formularies • Level of coverage	• Technology acquisition • Hospital formularies

HTA functions and principles

HTA can be instrumental in promoting **INNOVATION** that delivers better outcomes for patients and society as a whole. Evidence – based information and analysis provided are useful in making decisions on how to **ALLOCATE RESOURCES**. HTA can thus be seen as any actions whose aim it is to improve the performance of the health system in the achievement of its ultimate goal: **HEALTH GAIN.**

- ✓ Brief summary of **health technology assessment principles** proposed by Dummond et al.

1. **The goal and scope of HTA should be explicit and relevant to its use**
2. **The HTA should be an unbiased and transparent exercise**
3. **The HTA should include all relevant technologies**
4. **A clear system for setting priorities for HTA should exist**
5. **The HTA should consider a wide range of evidence and outcomes**
6. **HTAs should consider a wide range of evidence and outcomes**
7. **A full societal perspective should be considered with undertaking HTA's**
8. **HTA's should explicitly characterize uncertainty surroundings estimates**
9. **HTAs should consider and address issues of generalizability and transferability**
10. **Those conducting HTAs should actively engage all key stakeholder group**
11. **Those undertaking HTAs should actively seek all available data**
12. **The implementation of HTA findings needs to be monitored**
13. **HTAs should be conducted in a timely manner**
14. **HTA findings need to be communicated appropriately to different decision – makers**
15. **The link between HTA findings and decision – making processes needs to be transparent and clearly defined**

HTA in the European Union

In the EU, health technology assessment (HTA) is defined as:

*"A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value"**

HTA covers different aspects (HTA core models domains), but does not include pricing and reimbursement decisions, which is a national level prerogative : **evidence is global, decision is local**

	HTA Core Models DOMAINS
*Rapid REA**	1. Health problems and current use of technology
	2. Description and technical characteristics
	3. Safety
	4. Clinical effectiveness
Comprehensive / Full HTA	5. Costs and economic evaluation
	6. Ethical analysis
	7. Organisational aspects
	8. Patients and social aspects
	9. Legal aspects

Source: EUnetHTA Joint Action definition.
*Rapid REA : Relative Effectiveness Assessment

Role of HTA in Decision-Making

	PHARMACEUTICALS	MEDICAL DEVICES AND DIAGNOSTIC PROCEDURES
✓ **WHY?**	Inform National Pricing or Reimbursement	No 'routine' Reimbursement or Adoption Decision
✓ **WHEN?**	ASAP after/conjoint EMA approval	Varies: market entry later in product lifecycle
✓ **WHOM?**	HTA independent agencies, HTA governmental institutions, HTA networks	

EU cooperation on HTA

Health programme	**2005** Call for project proposals		**2009** Call for joint action	**2011** Call for joint action		**2014 - 2020** Financial support HTA
eunet**hta**	**2006-2008** EUnetHTA Project		**2009** EUnetHTA Collaboration	**2010 - 2012** EUnetHTA JA	**2012 - 2015** EUnetHTA JA	**2016 - 2020** EUnetHTA JA
Legislation		**2008-2011** Draft Cross Border Healthcare Directive. Article 15 HTA network	**2011-12** CBHC Directive now decided		**2013 & +** EU Cooperation on HTA Implementing Decision HTA Network	
DG R&I			**2011 FP7 –** Health **2012 -** Innovation – 1 New methodologies for HTA		**Horizon 2020** **Calls** **Health Care**	

Objectives and tools developed

Article 15
DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011
on the application of patients' rights in cross-border healthcare

Cooperation on health technology assessment

"The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. […]"

- Since 1993, the European Commission (EC) has supported important projects on HTA that resulted in an HTA network (EUnetHTA Collaboration) set up in 2013 that conducts project-based activities in the field of HTA. EUnetHTA coordinated the efforts of 29 European countries, including 25 Member States of the European Union (EU), in evaluating health technology in Europe

- The first two Joint Actions were co-funded through the EU Health Programme with a total budget of 15,5 million. A **third Joint Action – EUnetHTA 3, running from 2016 until 2020,** has been launched (budget EUR 20 million) on the 1st June 2016.

OBJECTIVES OF EUnetHTA PROJECT

i. To provide a robust multifaceted input to decision making
ii. To reduce duplication of work
iii. To gain a better understanding of the links between HTA and policy making in different Member States
iv. To support countries with limited HTA experience

TOOLS DEVELOPED

i. Core HTA structure/model
ii. Planned and Ongoing Projects Database (POP)
iii. Evidence database on new technologies (EVIDENT)
iv. Adaptation Toolkit

Main shortcomings

…FULL BENEFITS ARE NOT YET EXPLOITED, BECAUSE OF THE FOLLOWING **SHORTCOMINGS:**

1

The uptake of joint work at EU level into national decision-making processes has remained low, leading to duplication of work by national/regional HTA authorities

2

Significant **differences in the *procedural framework*** and administrative capacity of Member States

3

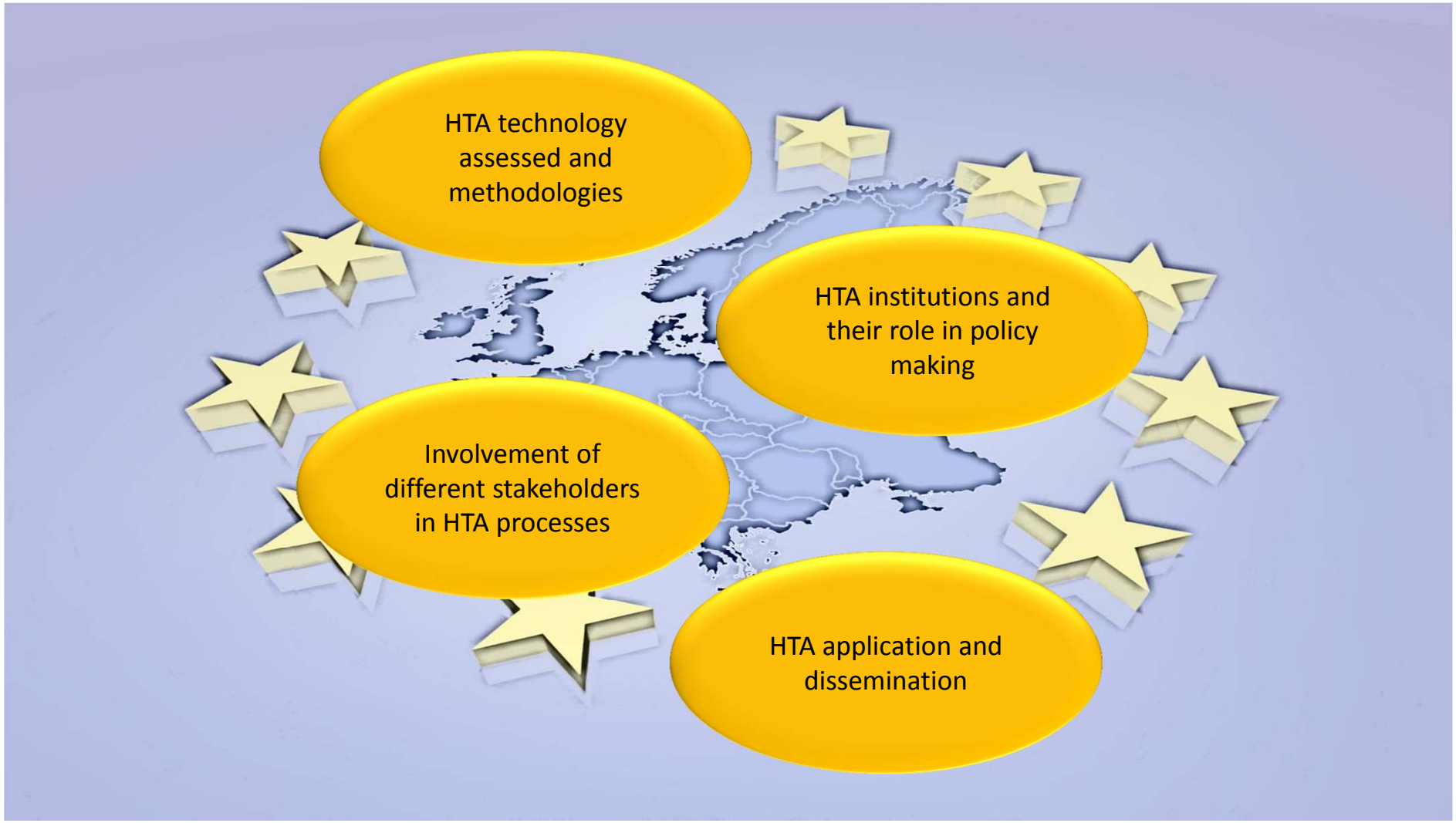
Significant **differences in national methodologies**

4

The current model of HTA cooperation at EU level is **not financially sustainable over time**

HTA differences in National Systems

The variety of traditions and socioeconomic contexts of healthcare systems of European Countries reflects in the heterogeneity of :



A comparison across countries (i)

EU Member States	Decision making process (Review, pricing and coverage)	HTA autorithy	Function of HTA authority	General approach	Principal outcome measures	Health economic component
Sweden	Pharmaceutical Benefits Board (LFN / TLV)	Swedish Council on Technology Assessment in Health Care (SBU)	Regulatory / Coordination	Systematic review and analyses of clinical and economic studies. Assessment before market entry.	Mortality, morbity, quality of life, willingness to pay	CEA, CMA
Netherlands	Minister of Health, Welfare and Sport	National Health Insurance Board/Committee for Pharmaceutical Aid/Health Council	Advisory	Health economic information. Evidence from manufacturer dossier is required. Assessment before market entry.	Mortalty, morbidity, quality of life	CEA, CUA
Denmark	Danish Medicine Agency (use of free pricing)	**Until 2012** Danish Centre for Evaluation and HTA **After 2012** decentralized at regional level	Advisory	Health economic information recommended but not required	N/A	N/A
Germany	Federal Association of Sickness Funds / Ministry of Health (use of free pricing)	Federal Joint Committee/Institute for Quality and Efficiency in Health Care (IQWiG)/German Agency for Health Technology Assessment (DAHTA).	Advisory	Two step process. Clinical evidence (randomized controlled trials or RCT's) followed by CBA	Mortality, morbidity, quality of life	Efficiency frontier analysis
UK	Department of Health (use of free pricing)	NICE/National Coordinating Centre for Health Technology Assessment (NCCHTA)	Advisory / Coordination	Clinical evidence (RCT, advanced statistical approaches, probabilistic sensitivity analysis	Mortality, morbidity, quality of life	CEA, CUA with explicit cost effectiveness threshold

Source: I- Com on V.V. A.A.

A cross – country comparison (ii)

EU Member States	Decision making process (Review, pricing and coverage)	HTA autorithy	Function of HTA authority	General approach	Principal outcome measures	Health economic component
France	National Health Authority (HAS)	Economic and Public Health Assessment Committee (CEESP)/Transparency Commission	Regulatory	Evidence required from manufacturer dossier. Clinical and economics literature review recommended. Assessment before market entry.	Mortality, morbidity, lenght of life, health realted quality of life	CEA, CUA
Italy	AIFA	**Since Fall 2014** RIHTA network coordinated by AGENAS (Regions, Aunonomous Provinces and Regional Agencies)	Advisory	No guidelines. Generally considered for market entry / coverage and reimbursmente : clinical effectiveness, disease relevance	N/A	N/A
Spain	Ministry of Health, National Health System inter - territorial Council	Insitudo de Salud Carlos III - Spanish Agency for Health Technology Assessment (AETS) - Regional agencies	Regulatory, Coordination	Systematic reviews of existing evidence, evidence based clinical guidelines, cost efficacy, efficiency and effectiveness analyses		CEA (no explicit threshold, on a voluntary basis)
Poland	Economic Commission (EC), Ministry of Health	Health Technology Assessment Agency (AHTAPol)	Regulatory, Coordination	Systematic review of clinical findings, economic evaluation, and budget impact analysis	Mortality, cases or recoveries, health - related quality of life, adverse effects and/or medical events	CEA with explicit cost effectiveness threshold

Source: I- Com on V.V. A.A.

A cross – country comparison (iii)

Most common methodologies used in Health Technology Assessment

UE Member States	Clinical trial	EPI and observational analyses	Cost and economic analysis	Comparative analysis	Post - marketing surveillance	Modeling	Expert opinion	Group judgment	Systematic review	Meta - analysis
Sweden	DM	D	DM	DM	D	DM	DM		DM	DM
Netherlands	DM	DM	DM	DM	D	D	M	DM		
Denmark	DM		DM	DM		DM	DM	DM	DM	DM
Germany	DM		DM	DM		DM			DM	DM
United Kingdom	D	D	DM	DM			DM	DM	DM	D
France	M	M	M	M	M		M		M	
Italy	D	M	DM	M	DM		M	M	DM	DM
Spain	DM	DM	DM	DM	M		M	D	DM	DM
Poland	DM	DM	DM	DM			DM	DM	DM	

M Medical Devices
D Drugs

What is needed to be successful?

Challenges to harmonization?

1. HTA Process and value dossier format requirements
2. HEOR modelling methodology platform to uniform algorithms and data used
3. Mutual recognition of HTA assessment opinions: applying joint REA at a national level
4. Centralised European HTA agency

Possible European framework development:

European Commission Inception Impact Assessment

"Strengthening of the EU cooperation on Health Technology Assessment (HTA)" – 2016

Options Mapping

1. The status quo – Joint Action until 2020;
2. Long-term voluntary cooperation (financed by the EU beyond 2020);
3. Cooperation on collection, sharing and use of common tools and data;
4. Cooperation on production of joint REA reports and their uptake (cooperation on clinical/medical matters);
5. Cooperation on production of joint Full HTA reports and their uptake (cooperation on cost-effectiveness).

Source: V.V. A.A. (2015): "European collaboration on relative effectiveness assessments: What is needed to be successful?"

Different scenarios for increasing cooperation

An increasing degree of cooperation on HTA in the frame among Member States could bring cumulative and increasing benefits outweighing modest increases in coordinating costs.

SCENARIO 1

Minimum variant. **Organisation and maintenance of an ICT platform for interaction**

SCENARIO 2

Development and application of generic guidelines for assessing different health technologies

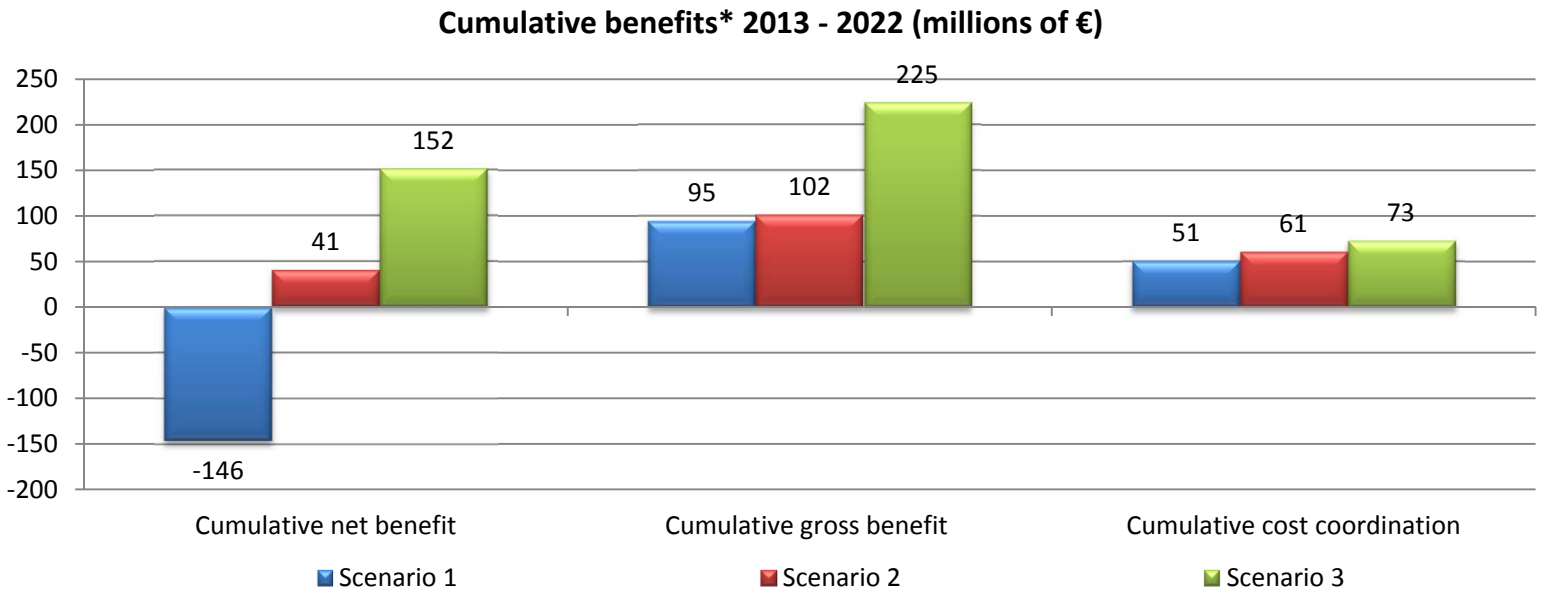
SCENARIO 3

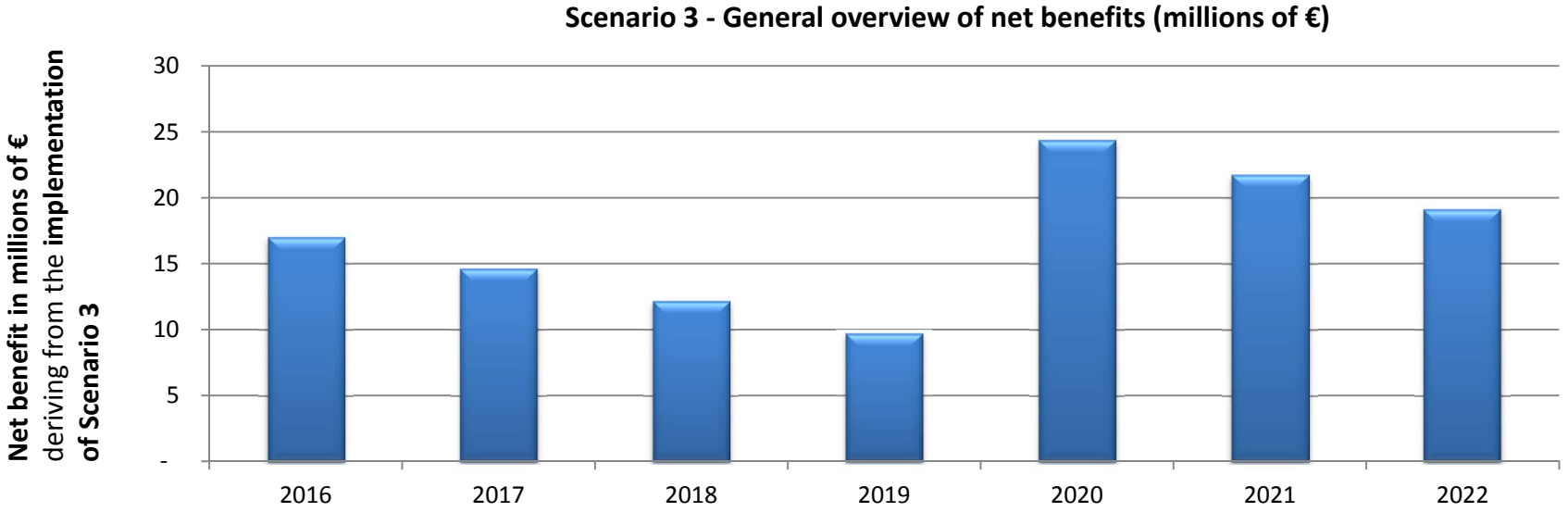
Coordination of joint assessments including both rapid assessments and full assessments for producing core HTA information

LEVEL OF WELFARE EFFECT

Source: Have A, Oortwijn W., Broos P., Nelissen E. (2013), "European Cooperation on Health Technology Assessment Economic and governance analysis of the establishment of a permanent secretariat", ECORYS for the Executive Agency for Health and Consumers, Final Report.

What is needed for success?





*Net benefits are defined as efficiency gains through cost savings minus outlays for coordination

Q&A inputs

- What do you think the harmonization process of HTA among Members States is going to be by the 2020?

- Which technologies do you think should be selected for assessment, who should identify them, and at present, what do you think are the main impediments to HTA production and use in Europe?

- Do you think Member States should have legislative requirements to consider the results of HTA in planning and budgeting decisions?

- In many countries, civil society (like patient associations) participates to the HTA assessment process. To what extent should this input influence the final decision? Is it worth to widespread this practice to all Member States? Why?

Source: V.V. A.A. (2015): "European collaboration on relative effectiveness assessments: What is needed to be successful?"

Q&A inputs

- Should Member States first focus on cooperation in Relative Effectiveness Assessment - REA, before addressing issues about health economic models harmonization?

- According to the Ecorys study (slide 15 and 16) reporting net benefits of increasing cooperation on HTA in the coming years, the major part of benefits would be gained by the industrial sector. To which extent do you think it is plausible? Which can be the direct and indirect effects of these results?

Source: V.V. A.A. (2015): "European collaboration on relative effectiveness assessments: What is needed to be successful?"

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