



THE HEALTHCARE INDUSTRY VISION ON HTA NOW AND IN THE FUTURE



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THE HEALTHCARE INDUSTRY

- The healthcare industry comprises pharmaceuticals, medical devices and diagnostics manufacturers and wholesalers that work towards improving health outcomes of European populations and delivering the products to patients
- **AESGP:** The Association of the European Self-Medication Industry is the official representation of manufacturers of non-prescription medicines and food supplements in Europe.
- **COCIR:** The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry is the voice of the European Radiological, Electromedical and Healthcare IT Industry.
- **EDMA:** The European Diagnostic Manufacturers Association is the *trade association* that represents the *In Vitro* Diagnostic (IVD) industry active in Europe.
- **EFPIA:** The European Federation of Pharmaceutical Industries and Associations represents the research-based pharmaceutical industry operating in Europe.
- **EGA:** The European Generic Medicines Association is the official representative body of the European generic and biosimilar pharmaceutical industry.
- **Eucomed:** The European medical technology industry association represents the medical technology industry in Europe.
- **EuropaBio:** The European Association for Bioindustries provides a voice for the biotech industry at the EU level.
- **GIRP:** The European association of pharmaceutical full-line wholesalers is the umbrella organisation of pharmaceutical full-line wholesalers in Europe.

THE HEALTHCARE INDUSTRY CONTRIBUTION TO EUROPE

○ **The most R&D intensive sector**

- According to the 2011 EU Industrial R&D Investment Scoreboard, pharmaceuticals and biotechnology is the highest R&D intensive sector
- According to the European Commission, the medical device industry has a re-investment rate in R&D of 5-8%

○ **Employing high-skilled staff**

- According to EUROSTAT data, the pharmaceutical industry is the high technology sector with the highest value-added per person employed. Around 640,000 people were employed in the pharmaceutical industry in Europe in 2009, of which around 115,000 in R&D
- The generic pharmaceutical sector employs around 150,000 people, with over 1000 companies in 34 European countries (EGA data)
- Nearly 500,000 people are employed by MedTech in Europe, with around 22,500 trading companies (80-90% SMEs) (European Commission data)

○ **Whilst taking up relatively little healthcare resources**

- According to OECD data, pharmaceutical and other medical non-durables take up 17.1% of total health expenditure, of which 18% is spent on generic medicines which account for 50% of volumes dispensed (EGA data)
- The share for medical devices is 4,7% (World Bank, EDMA, Espicom and Eucomed calculations 2009)

EUNETHTA DEFINITION

- “Health technology assessment (HTA) is 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”
- Who produces information? / who assesses the information?
- “systematic, transparent, unbiased, robust manner” = valuable

AN INDUSTRY SHARED VISION ON HTA

- A **bridge** between scientific evidence, the judgment of health professionals, the views of patients and the general public, and the needs of policymakers
- Within a robust framework allowing for **transparency and public involvement**
- A tool to allocate resources **efficiently** and therefore free up resources for continued innovation
- Conducted by **independent** HTA agencies

ARE WE ON THE RIGHT TRACK?

1. At which stage of a HTA is the industry involvement of value: scoping? assessment of evidences? appraisal? implementation?
2. How will a systematic involvement of industry in HTA resolve controversies *upstream* in the process and reduce polarisation *downstream*?
3. Define the rules/principles that should guide between *who* produces information and *who* assesses the information

A common goal...

A systematic and transparent involvement of the industry in HTA to improve patients access performances and overall system efficiency

INDUSTRY'S CONTRIBUTION

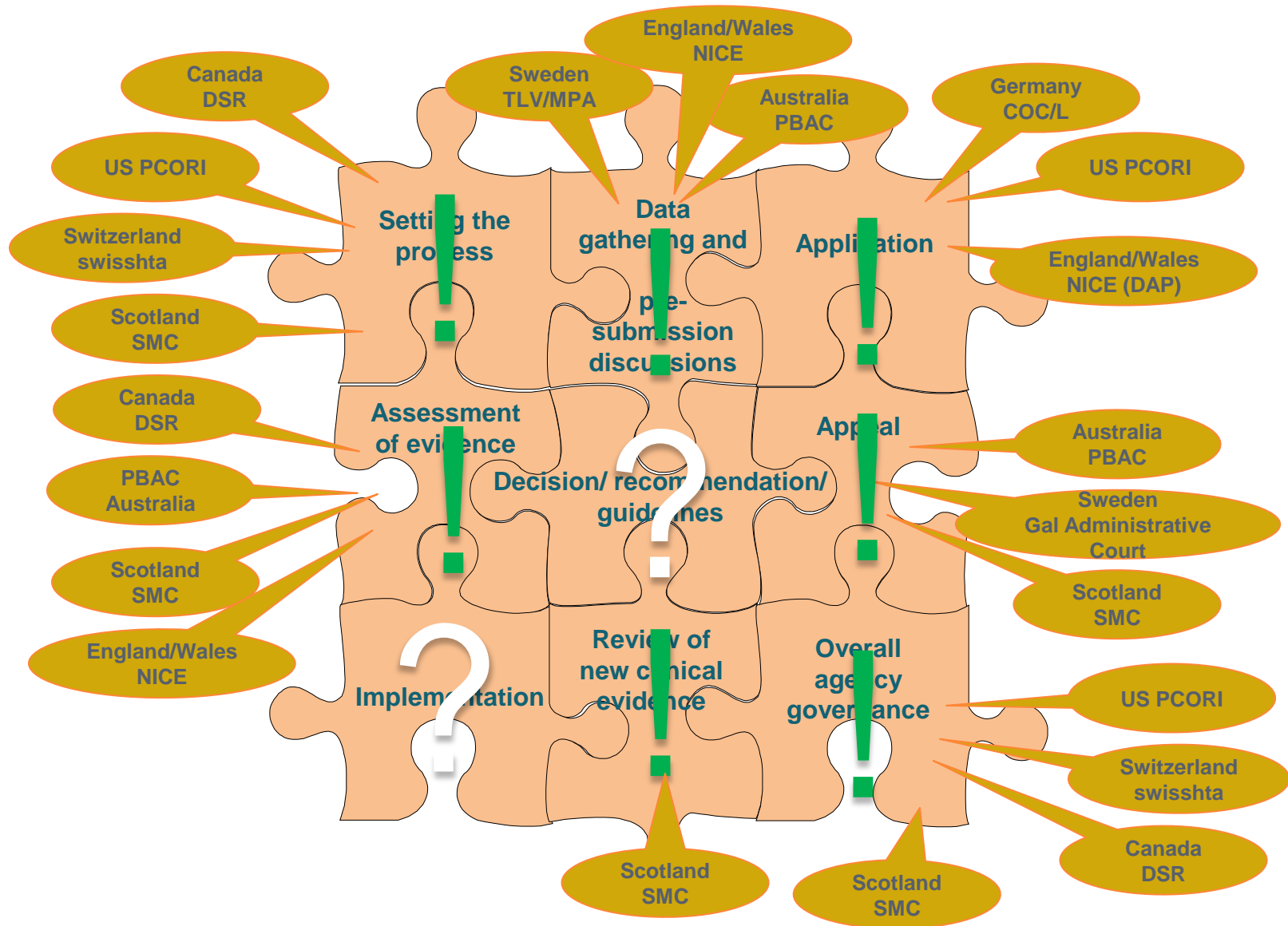
Industry's knowledge

- Extensive experience of HTA systems
- Professional know-how as provider or sponsor of clinical data
- Unique knowledge about technologies
- Commitment to improve healthcare standards

Realising the knowledge

- Scoping
- Assessment
- Appraisal
- Implementation

INTERNATIONAL EXAMPLES



CONTROVERSIES IN INNOVATION

« Controversies appear when the **distribution of expertise during the innovation process does not take into account** some potentially interested actors.

The controversies begin when some actors who claim **the right to participate to the definition of risks, cost and benefit** are not included in the management of innovation ».

Source: Senker, J et al (1999) - EC Targeted Socio-Economic Research (TSER) Project for the period 1998 – 2000 European Biotechnology Innovation System (EBIS)

OVERCOMING CONTROVERSIES

“In order for the necessary dialogue to occur there must be greater transparency (including international exchange of evaluations) and a cessation of “emotive” statements that do little more than polarise attitudes rather than develop partnerships”.

Lloyd Sansom – Chair of PBAC Australia – July 2006

EUNETHTA ACHIEVEMENTS

Achievements	Pending issues
Setting up of Stakeholder Advisory Groups	Limited role of stakeholders Unfitting governance for 2 nd JA - pilots
Sharing of information on activities of Work Packages	'Cultural barriers' lowering to the minimum common denominators
Availability of Work Package leaders	Process management – (timing / lack of hearings and other F2F interactions)

MOVING FORWARD:

- All the 8 industry associations are ready to get engaged in EUnetHTA JA 2 both in:
 - **Governance:** “fit for purpose” approach, and
 - in **pilots** of collaborative assessments and early dialogue
- Industry welcomes a joint discussion on
 - Criteria to select pilots
 - Evidence and methodologies used in pilots
 - Impact of pilots on decision-making
- Industry offers its HTA expertise to support the EUnetHTA JA 2 activities on capacity building



JOINT INDUSTRY PAPER

Joint Healthcare Industry Paper The value of industry involvement in HTA

What is the aim of HTA?

According to the EUnetHTA definition¹, health technology assessment (HTA) is 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.

Sound and transparent HTA, with proper involvement of patients, health care professionals and industry can support: i) efficient decision-making, ii) efficient allocation of resources, and iii) informed uptake and diffusion of health technology.

Whenever required, HTA complements the information available on the performance of the technology as specified in its label (assessed by regulatory agencies) by providing insight in the value of the technology for healthcare and society, considering multiple aspects, in the context of a specific healthcare system.

If correctly carried out, HTA is also a useful tool to encourage and reward innovation with the greatest value to patients and society.

Why involve the healthcare industry in HTA?

The healthcare industry believes it can be a valuable partner in the overall HTA process, acknowledging agencies must retain their independence in providing advice to payers and governments.

Most systems have evolved over time and strive to increase industry engagement, both at the policy level with representative associations and in specific technology assessment processes with manufacturers. This evolution is crucial as it will lead to system and methods improvements.

¹ http://www.eunetha.eu/Public/About_EUnetHTA/HTA/

- Published on all associations' website
- To be published in ISPOR connection