Joint Healthcare Industry Paper

The value of industry involvement in HTA

What is the aim of HTA?

According to the EUnetHTA definition[1], 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.eunethta.eu/Public/About_EUnetHTA/HTA/

1. Developing HTA policy and methodology

   a. *Industry is concerned with the assurance of efficiency and quality of HTA*
   Industry is concerned with managing scale, costs and predictability of the systems. It understands the need to balance the health system goals of affordability, access and incentives to innovate. An iterative dialogue and consultation between industry and the agency at key points in the evolution of an HTA system, as well as on an annual basis when the system is in place, will ensure that these goals are met. As existing HTA models are clearly not appropriate for all health technologies, specific industry segments may support the development of the right HTA models to evaluate technologies in the most appropriate manner.

   b. *Over time, industry has developed substantial in-house HTA-capacity*
   Through the involvement in different systems, industry gained experiences and understanding of HTA processes both locally and internationally. Trained specialist staff and multi-disciplinary topic groups have developed in-house knowledge and expertise of systems that can be valuable in the development of policies and methodologies. Continuous and consistent involvement of all the healthcare industry sectors (medical devices, diagnostics and pharmaceuticals) is essential to ensure that models for HTAs fully appreciate the specificities of these sectors and take account of sectors' specific characteristics e.g. the different evidence requirements or product life cycles.

   c. *Sharing the 'rules of the game' leads to better HTA outcomes*
   It is widely recognised that legitimacy of processes must be sought through transparent and open decision-making, providing opportunities for participation, consultation, explanation of decisions and appeal. As underlined, inter alia, by the International Group for HTA Advancement, "this is likely to result in technology assessments of higher quality that are more widely accepted and stand a greater chance of being implemented."

2. Providing expertise and experience on specific technologies

   a. *Manufacturers have expertise in HTA over time and across countries*
   By engaging in regulatory and reimbursement processes for their products in various markets, manufacturers gain a unique perspective on the assessment processes in different countries and over time. Industry can play an important role in sharing lessons learned from parallel processes (i.e. in different markets), which can save considerable time and effort in specific product assessments.

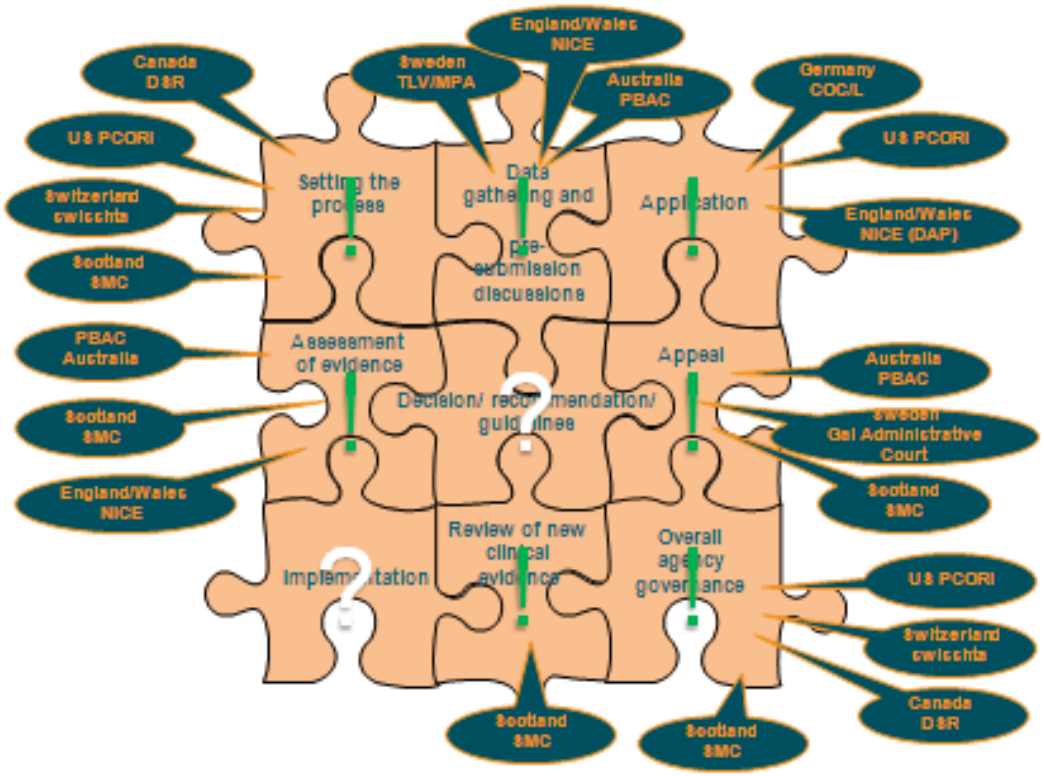
   b. *Manufacturers produce or sponsor the vast majority of evidence*
   Whilst developing new technologies, companies produce and interpret the vast majority of clinical evidence available for their products. Manufacturers therefore have a clear role in providing/submitting the medical, social, economic and ethical evidence on which any HTA exercise will be based. Furthermore, a balanced engagement of HTA bodies with manufacturers is likely to ensure that future data collection encompasses the different health sectors' specificities and that any change in evidence requirements is commensurate to the type of technology considered.

   c. *Manufacturers have a sophisticated understanding of their products*
   During the development process and across a technology's life-cycle, companies accumulate inside knowledge and expertise on the technology. Manufacturers understand the assumptions underlying particular pieces of clinical research, as well as the specificities of each disease and health technology that constrain the design of clinical trials. Once the technology is in use, companies continue collecting evidence on the technology's impact on health outcomes and feed this information back into further product development. Companies are hence well placed to facilitate the understanding of assumptions made, as well as features and interpretation of clinical evidence.

   d. *Manufacturers are a gateway to innovation*
   Understanding the "pathway to innovation" is a central pre-occupation of the industry. Innovative companies are responsible for taking forward these innovation efforts, and are therefore in a unique position to offer insight into the factors that should be taken into consideration when assessing the value embedded in an innovative technology.

At which stages of the HTA process can industry add value?

The following sections highlight some selected examples of industry involvement both in setting the HTA process and in specific assessments.



1. <u>Setting the process and overall agency governance</u>

   In collaboration with other stakeholders, industry can contribute to defining the role and objective of an HTA process, including the criteria to select those technologies that should undergo an assessment, and the methodologies used in light of current knowledge.

   Emerging systems have had the opportunity to involve industry representatives very early on in their reflection:

- In Switzerland, health insurers and the pharmaceutical industry started a joint reflection in 2010 to develop a Swiss consensus for the use of HTA. As a co-founder of the initiative, industry is an equal partner in the process.
- In the United States debate on Comparative Effectiveness Research, the Patient-Centered Outcomes Research Institute (PCORI) established in 2010 aims to carrying out research projects that provide evidence on the best way to manage diseases. The PCORI Board of Governors includes individuals representing manufacturers and developers of drugs, devices, and diagnostics along with other stakeholder representatives.

In other established systems, processes exist to ensure a regular communication between the HTA agency and the industry on issues of process, governance and methodologies:

- In the Drug Strategy Review of Ontario (Canada), the industry, represented by its association, was an equal stakeholder in the development of recommendations for government on the future of the drug plan.
- In Scotland, two representatives of the industry association ABPI are represented on the Scottish Medicines Consortium. Furthermore the SMC User Group Forum, including pharmaceutical industry representatives, aims to identify, address and resolve process issues relating to the work of the SMC.
- When the National Institute for Health and Clinical Excellence (NICE in England and Wales) developed the new evaluation pathway for medical devices and diagnostics, from the very start of the process industry was heavily involved, serving as formal co-chairs on the steering committee overseeing the development process and being consulted in detail on all elements of methods and processes. This dialogue between industry and NICE continues today a year after the Medical Technology Advisory Committee has been in operation, through routine quarterly meetings between the NICE Chief Executive and Evaluation Programme Director and the relevant device, diagnostic and imaging industry associations.

2. Specific technology assessments

a. *Data gathering and pre-submission discussion*

Communication and discussion between the applicant and the HTA agencies pre-submission provide the opportunity to complement and/or clarify methodological guidance to ensure high quality submissions. Such discussion can, for example, clarify outstanding questions on e.g. evidentiary and analytical standards. HTA agencies such as the Dental and Pharmaceuticals Benefit Agency (TLV) in Sweden provide a clear framework for such early discussions with manufacturers, where joint scientific advice meetings with the Medical Products Agency (MPA) have been introduced since 1 January 2011.

b. Decision to assess a given technology and application

Based on its knowledge of the product, the manufacturer can provide a rationale for the selection of a given technology for assessment, in addition to selection criteria embodied in guidelines. Many processes are based on manufacturer notifications and applications, for example:

- With the establishment of a new fast-track HTA procedure for laboratory tests in Germany in 2010 conducted by the K(B)V-Kompetenzzentrum Labor (COC/L), the national in-vitro diagnostic industry association has been given the possibility to propose technologies to the assessment working group.
- Similarly in England and Wales the Centre for Health Technology Evaluation of NICE set up the Medical Technology Evaluation Programme (MTEP) in 2009. Within this programme manufacturers can notify NICE of new technologies they believe are suitable for a national evaluation. The Medical Technology Advisory Committee (MTAC) will determine if the technology is appropriate and will route technologies to specific evaluation processes. For medical devices there is an evaluation process through the MTAC and for diagnostics an evaluation is conducted within the specific Diagnostic Assessment Guidance. The Committees involved in both evaluations include industry representatives to provide their expertise in the technology/ies under review.

c. *Assessment of evidence and production of recommendations*

Providing the opportunity for manufacturers to discuss their HTA submissions with agencies will enhance the overall quality of specific assessments by giving further opportunities to discuss upfront study designs as well as the models underpinning the assessment. In line with available methodological guidelines, discussion can for example address the choice of comparator or endpoints, the sources of evidence used and the methods developed to overcome evidence gaps. This will also be the opportunity to clarify any outstanding question from the assessors on the contents of submissions. For example in Australia, there is a formal exchange of evaluation reports and responses. The sponsor company is permitted a time-limited appearance in front of the committee and there is an opportunity for the sponsor to meet with the Chair in case of rejection of an application.

Industry can also contribute more effectively to the assessment of evidence when the legal framework allows for an open, transparent, direct interaction with the evaluation committees.

- In England and Wales, NICE's Technology Appraisal Committees are composed of members from the NHS, patient and carer organisations, academia and pharmaceutical and medical devices industries.
- In Australia, the pharmaceutical industry association Medicines Australia is represented on key PBAC subcommittees, such as the Economic Subcommittee and the Drug Utilization Subcommittee.

d. *Review of new clinical evidence*

A technology's relative impact on patient health and the health care system may change over time in light of patterns of usage and further product developments. Furthermore, the knowledge and evidence base of a technology usually grows throughout a product's lifecycle as manufacturers continue to follow the impact of their products once in use. A range of data sources could be available after launch, such as post-marketing interventional trials, follow-up systems, registries, and observational studies, many of which will be managed by the manufacturer himself. An agreed periodical assessment of these new data which is based on

the characteristics of the technologies and of the patient population, will improve the overall assessment of technologies. For example in Scotland, the SMC provides the opportunity to request re-assessment at any point in time.

Conclusion: industry is a trustworthy partner respecting the remit of agencies

The healthcare industry recognizes that HTA agencies must retain their independence in providing advice to decision-makers. The final recommendation or decision which will be issued by an HTA agency to support healthcare decision-making, whilst taking into account all the aspects reviewed during the assessment as outlined above, must remain independent from stakeholders' interests. In cases of disagreement however, it is good practice to ensure that an independent appeal process exists, as is the case today in several countries across Europe.

As the aim of HTA is to provide a bridge between scientific evidence, the judgment of health professionals, the views of patients and the general public, and the needs of policymakers, transparency and public involvement are essential to increase society's ability to ensure access to innovation in a responsible and timely manner.

The healthcare industry calls for a robust and transparent framework in which HTA, by allowing healthcare planners to manage resources effectively and to appropriately fund healthcare would be a tool to encourage development of new and innovative technologies for the benefit of patients and society.