

Medical Device Industry Position on HTA

Contents

Introduction	2
The Purpose of HTA	3
Transparency & Stakeholder Involvement	3
MedTech Europe Perspective	4
Timing of HTA	4
Evidence Standards and Patient Access	5
Implementation of HTA Recommendations	5
HTA Impact on Innovation	6
Voluntary Harmonization of HTA	6
Summary	6

Introduction

Health Technology Assessment (HTA) is playing an increasing role in determining which medical technologies are available to patients throughout Europe. The International Network of Agencies for Health Technology Assessment (INAHTA) defines HTA as:

“The systematic evaluation of properties, effects, and/or impacts of healthcare technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in healthcare. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods¹.”

From a policy context, HTA is mainly applied by healthcare payers in decisions on the appropriate use, coverage or reimbursement of new technologies at different points of time of the medical device life cycle. Formal assessment of technologies usually occurs at a national level, although HTA is being increasingly applied at regional and local levels, for example within individual hospitals. HTA is also used to help inform best practice through the development of evidence based guidelines.

MedTech Europe is a European trade organisation representing the medical technology industries, from diagnosis to cure. HTA is influencing the degree to which technologies are adopted in practice. Whilst

¹ www.inahta.org

endorsing the value of HTA, Medtech Europe aims to ensure that it is applied in an appropriate manner. This position paper highlights the key tenets that MedTech Europe considers vital to the appropriate application of HTA.

The application of HTA to medical devices is challenging. HTA is a data driven process and many HTA agencies adopt a strict adherence to the hierarchy of evidence, demanding that technologies are supported by evidence from robust, randomised controlled trials. For many medical devices, such evidence is often limited or unavailable at the time of launch. Adopting a pharmaceutical paradigm, based on an expectation of multiple randomised controlled trials being available at the time of launch, may lead to restrictions on access to many new medical devices. A device specific assessment paradigm must be recognised.

The Purpose of HTA

HTA should be used to support patient access to innovative technologies by promoting the use of technologies that are clinically and cost effective. Conversely, HTA should be used as a mechanism to support disinvestment in current services and technologies which are cost ineffective, thus creating 'headroom' for new devices when they become available.

From a payer's perspective, HTA is used to inform decisions on the reimbursement, coverage, adoption and uptake of healthcare technologies. HTA should not be positioned as an additional barrier to regulatory approval. The focus of regulatory approval for CE marking (safety, quality and performance) and HTA (clinical and cost effectiveness) are fundamentally different and thus, require different data. Whilst the data required for regulatory approval are, to some extent, context free, data for HTA are largely context specific². That is, the applicability of the data will depend on local treatment practices, local funding levels and socio-cultural factors.

Transparency & Stakeholder Involvement

HTA process should be transparent and encourage the involvement of relevant stakeholders including healthcare practitioners, healthcare planners/payers, patients and manufacturers at all stages of the process.

The process including the selection of topics, appraisal criteria, process timelines, consideration of evidence, development of recommendations must be transparent and supported by a clear audit trail. Analyses should be independent of policy decision making and be conducted within a recognised process

² For a full discussion of context-free and context-specific evidence, see Dobrow M et al. Social Science & Medicine 58:1, 2004.

framework to ensure transparency, quality and stakeholder involvement. Conflicts of interest should be declared by all stakeholders including HTA assessors.

Where this process is not followed, or the recommendations are found to be perverse in light of the evidence considered, then there must be an opportunity for any of the stakeholders involved to appeal against the recommendations. Appeals should be considered by a body that is independent of the original assessment.

MedTech Europe Perspective

HTA should adopt a broad perspective, capturing the impact of new devices on patients, carers, the health service and society as a whole. We accept that healthcare decision makers are predominantly interested in the impact of new devices on healthcare budgets. However, HTA bodies should be encouraged to adopt a societal perspective considering the impact of devices on broader societal costs, such as productivity and social care costs.

Timing of HTA

From a healthcare decision maker's perspective, undertaking HTA early in the life-cycle of a device, prior to widespread dissemination is desirable. However, HTA bodies need to balance the demands for early assessment with the availability of data on new devices. Discussion between the manufacturer and HTA agency should seek to identify the optimal time to undertake HTA, taking into account the need to inform decisions on adoption with the availability of evidence. This is particularly important when considering devices intended for surgical use which are often associated with a 'learning curve' effect whereby their effectiveness can only be properly evaluated once healthcare professionals have adjusted their practice to incorporate the new device³. A process of HTA must be completed within a timeframe relevant to the pace of evolution of the device in question.

HTA is an iterative process and should be revisited at relevant time-points in the life-cycle of a device to take into account important new evidence. As the major providers of evidence, manufacturers should be consulted on the appropriate timing of a "lifecycle" HTA.

³ For a full discussion of the learning curve effect, see Ramsey et al, International Journal of Technology Assessment in Healthcare, 16:4, 2000.

Evidence Standards and Patient Access

HTA recommendations should be based on the best available evidence relevant to the question under consideration. Whilst randomised controlled trials are the most robust means of assessing comparative efficacy, they still represent an artificial setting and do not necessarily represent “real world” circumstances that are essential for analyses of cost-effectiveness. HTA bodies should be pragmatic in their consideration of other sources of evidence. Well-designed comparative and non-comparative observational studies inform clinical and cost-effectiveness assessments and should be considered, rather than being excluded on dogmatic grounds.

There may be ethical and practical limitations associated with the design of double-blinded randomised controlled trials, particularly in surgical indications. This is the case when the most appropriate comparator to determine a treatment effect would be a sham intervention. Furthermore, blinding may not be feasible. The extent of these issues will depend on both the device and the condition under consideration.

HTA should not restrict access to new devices that are proven to be safe and efficacious but have limited data on their effectiveness. Clinical and cost effectiveness (as differentiated from efficacy) data are frequently only available after a device has been in use for a period of time.

In order to support timely access to promising devices that have limited but positive effectiveness data to support their use at launch, alternative funding mechanisms may need to be explored, such as coverage with evidence development, which allows a technology to be covered for a period of time, during which effectiveness evidence is generated⁴. Such approaches are associated with both risks and benefits for manufacturers and payers and should be carefully considered prior to implementation.

Implementation of HTA Recommendations

HTA bodies, where relevant to remit, should put in place steps to support the implementation of HTA recommendations to ensure the funding follows positive decisions.

Implementation of both negative and positive HTA recommendations should be timely and effectively resourced and incentivised. Implementing positive HTA recommendations presents healthcare planners with challenges where this requires investments mid-way through the budgetary cycle; however this must be factored into implementation plans.

⁴ Hutton J, Trueman P, Henshall C. Coverage with Evidence Development: an examination of conceptual and policy issues. *International Journal of Technology Assessment in Healthcare* 23:4, 2007.

HTA Impact on Innovation

Policy makers should consider the implications of HTA on the environment needed to foster innovation of medical devices. If HTA introduces significant new challenges to market entry then there is a potential that this may impact on the rate of innovation of the device sector which already faces a number of challenges. Intellectual property associated with medical devices is less well protected than patents on new medical compounds. In addition to this, medical device development is characterised by iterative improvement of technologies resulting in a more rapid life-cycle and increased competition.

Voluntary Harmonization of HTA

There is considerable interest in the voluntary international harmonisation of HTA. Whilst there are potential efficiencies to be gained in reducing the duplication of HTA activities across countries and reducing the requirement for manufacturers to submit to multiple HTA bodies, the potential for harmonisation remains limited.

Harmonisation of approaches to HTA and evidence requirements is at least partially possible (systematic evidence review, alignment on key principles of process and methods) and there is already a significant degree of consensus between HTA bodies.

However, harmonisation of the application of HTA and the decision making processes remains a distant prospect. The decision outcomes and application of a HTA should remain at a national/regional level due to differences in levels of healthcare funding, healthcare priorities and treatment pathways.

Summary

Medical devices impact on all aspects of the operation of the health service and the availability of innovative devices is imperative to improving patient outcomes. MedTech Europe supports a transparent and voluntary collaborative partnership on the development of HTA processes and methodologies for medical devices. MedTech Europe is committed to working with HTA agencies throughout Europe to ensure that HTA is applied appropriately to medical devices. This fosters rapid patient access to effective, reliable and safe technologies. The principles presented above are intended to ensure that the application of HTA encourages the efficient allocation of healthcare resources whilst also acknowledging the value of medical devices innovation in Europe.