



COCIR Position Paper

Measuring the value of Medical Technology, Devices and Healthcare IT The role of Health Technology Assessment (HTA)

The drive for sustainability of healthcare systems is an imperative in Europe, for reasons outlined in the strategic COCIR White Paper 'towards a sustainable healthcare model' published in November 2008 (http://www.cocir.org/uploads/documents/-34-cocir_wp_on_sustainable_hc_-_released_on_19_nov._2008.pdf). COCIR believes that the innovative solutions developed by the Medical Technology, Devices and IT industry sectors have a key role in addressing the increasing and unsustainable productivity, accessibility and affordability gaps. However at the same time, Public Authorities, which are understandably prudent in the administration of scarce healthcare resources while facing increasing cost pressures, often view innovative medical and information technology as a cost, rather than an opportunity to improve quality, efficacy and the efficiency of healthcare.

In an effort to better understand and reconcile these contradictory views it is essential that all stakeholders participate in developing appropriate processes to better evaluate the role Medical Technology, Devices and IT plays in the continuum of care.

COCIR argues that the timing is right for a European vision for the development of HTA in relation to Medical Technology, Devices and IT. Indeed, a 2010 Report of the Exploratory Process on the future of Medical Devices, chaired by the European Commission with representation of over 20 public and private health stakeholders, underlined the importance of "developing standardised, predictable and common criteria for HTA methods appropriately designed for medical technologies/devices."

However the Report also contained a number of collectively held stakeholder concerns that future HTA processes would need to consider when assessing medical technology, notably;

- the whole clinical pathway and the full life-time of a product
- the impact of the different and variable clinical applications of the same medical device
- non-monetary improvements linked to societal benefits (e.g. quality of life, reduced hospital stay for patients, social inclusion, etc.)
- the implications for the healthcare systems and organisations when introducing a new medical device (changes of practices, reorganisation of services; costs, terms and conditions of financing)

In this Position Paper, COCIR provides an industry perspective regarding Health Technology Assessment and sets out a list of expectations of future HTA processes:

- 1. Consistent and transparent**
- 2. Involves all relevant stakeholders**
- 3. Enables fast adoption of innovative medical technology**
- 4. Efficient and rapid evaluations**
- 5. Have a risk-based agenda – account for the risk of the procedure**
- 6. Uses comparisons with 'gold standards'**
- 7. Dissemination of findings to be completed in a timely manner**
- 8. Allows for early payment and reimbursement when justified based on clinical research**



EU Governance of HTA

Currently there is high degree of inconsistency within the field of HTA for medical technology. Partly driven by the fact that National HTAs are part of, not isolated from, healthcare delivery systems – therefore the inherent variability in health policy and budgetary decisions between Member States can result in an inconsistency of HTA processes, leading to inequalities between EU citizens of access to new and innovative healthcare technologies.

A unified EU approach to HTA that has standardized, predictable and transparent methodology and criteria upon which appraisals for new medical technology, processes or devices can be informed, may remove much of the inconsistency. This approach would not impact on Member State budgetary decisions which would still take place within the wider context of the economics of each country and their respective national healthcare system. But crucially, it could afford medical technology and IT companies, to develop innovative new technologies with more clarity, consistency and predictability of the EU 27's needs and technical requirements.

It is COCIR's intention, through the expertise of its membership to engage and work with EUnetHTA Joint Action to support the development of this new HTA focus.

HTA for Medical Technologies, Devices and IT... more complex than Pharmaceuticals

Healthcare systems can only hope to become sustainable by faster adoption of innovative technologies which promise better outcomes at lower costs, or deliver increased productivity and quality or preferably both.

The challenge for conducting HTA for Medical Technologies, Devices and IT, is to recognize, and account for, the impact of the variety of different clinical applications the same technology or device may have, and the indirect 'enhanced value' a technology, device or process provides within the continuum of care. From this perspective it is clear that the HTA processes currently applied to pharmaceuticals cannot be directly transferable to products from the medical technologies industry.

In addition the speed of development of Medical Technologies, Devices and IT is much faster (primarily in incremental steps) than pharmaceuticals, and they can be available to help patients more quickly. Many of these technologies have large upfront purchase costs, but over their life-time become cost-efficient. This raises critical questions as to when and how to perform an HTA.

HTA Criteria for Devices

Today safety and effectiveness are considered paramount for market approval of Medical Technologies and Devices, and in the future IT might also be impacted by market approval measures. When approved, the use of medical technology is often monitored and several provisions are aimed at ensuring promotion of appropriate use. In that respect, access to medical technology is increasingly considered as a means of assuring good quality care - for example, access to medical imaging for cancer patients is essential and critically time-sensitive. Access to medical technology is also a fundamental patient right. The availability of medical equipment can be influenced by the lack of investment, bureaucratic hurdles or other factors.

COCIR believes that HTA appraisals that are too device or process specific i.e., too narrow in scope, are unlikely to capture upstream or downstream benefits that arise from real-life working environments. The design of an HTA for any given medical technology, device or process will need to consider the interdependencies between



medical technology and the complex workflow and process at the point of care. Patient preferences and the practitioner's clinical expertise with the use of technology also need to be taken into account, next to clinical/economic data, in line with the paradigm of evidence-based medicine. International comparisons based on evidence-based gold standard practices should be mandatory.

COCIR believes that the HTA process and accompanying methodologies should allow for "Healthcare Process Assessment" to be conducted where appropriate, and because 'time-in-use' may play a key role in the evaluation of whether a technology is considered to be cost-effective, COCIR recommends that guidelines should be developed that outline when and how new technology should undergo assessment.

Conclusion

If used appropriately COCIR believes that health technology assessments (HTA), when transparently conducted, can be a useful evaluation tool for decision makers to better ensure the efficient use of, and access to, healthcare resources.

Innovation is one of the most important drivers for growth within Europe. Therefore it is essential that a future HTA process keeps pace with the highly innovative industries represented by COCIR. If well performed, perhaps as part of a "Healthcare Process Assessment", HTA may foster the diffusion of Medical Technology, Devices and IT and help introduce the proper incentives and regulation in order to accelerate the implementation of innovation.