Moving to rewarding value in the area of funding & reimbursement of medical technologies

Reflection paper

MedTech Europe
from diagnosis to cure

Introduction

The current paper presents reflections of MedTech Europe, and aims at facilitating the dialogue between industry and funding, and reimbursement decision makers (collectively referred to as "payers"; please see Annex for definition), in order to create an innovation-friendly environment for healthcare in Europe. A desired outcome of the paper would be that reimbursement authorities and the broader payers' community would reflect on the initial conclusions and recommendations and engage in a **dialogue with the Medical Technology Industry in Europe**.

Key Principles – Funding & Reimbursement

MedTech Europe issued a Position Paper about the *'Six Key Principles for Efficient and Sustainable Funding & Reimbursement of Medical Technologies'*[1], which was updated in 2017. This paper identified that the funding and reimbursement of medical technologies in Europe is provided independently by each Member State, and that every Member State has its own system resulting from its own political, administrative and constitutional structure. The principles are proposed to minimise inefficiencies in healthcare systems and uncertainty for manufacturers, and thus to prevent:

- Unnecessary delays in access to innovative technologies;
- Slow adoption of new and effective technologies;
- Inequalities in guaranteeing that patients receive the most effective and efficient treatment;
- A negative impact on investment in Europe with the latest technologies being made available in other countries first.

The six key principles identified in 2017 are as follows:

1. Transparency of funding & reimbursement policies
2. Predictability & consistency in decision-making processes
3. Stakeholders' involvement in funding & reimbursement processes
4. Enabled patient access to care
5. Support and reward of innovation
6. Seamless care creation

Utilizing these principles would put a basis for the dialogue between payers and the medical technology industry.

[1] http://www.medtecheurope.org/index.php/node/1098

An Initial Assessment – Payer & Evidence Survey

MedTech Europe has undertaken an ambitious exercise in collaboration with Deloitte in 2017 to get a baseline understanding of the perceptions of medical technologies from a payer's perspective. The intention of this qualitative investigation was to gain a better understanding on how payers in several European countries perceive the value of medical technologies, the evidence requirements to underline the value of such technologies, their current/future expectations on the assessment, and their decision-making on funding. Apart from broader healthcare trends, there are other tendencies, too, to be discussed in a dialogue with all healthcare stakeholders.

Determined by a sample size of 20 interviews with payers, some themes emerged, most notably:

1. Differing perceptions between payers and industry stakeholders
2. Improvement of the collaboration between payers and industry needed in terms of clarity, consistency and regularity
3. A consistent need to know about emerging technologies entering healthcare (horizon scanning)
4. A desire to understand how to more effectively allocate scarce resources, and disinvest from low-value technologies
5. Willingness to engage in small-scale, local pilots based on real-world evidence generation

Other interesting insights included the general recognition that healthcare systems in Europe are having to deal with significant budgetary difficulties, facing rising demand for health services disproportionate to public spending on health care.

Some more specific answers regarding payers' interest in collaborating with the industry are summarised below (names and organisations have been withheld for confidentiality reasons)**:**

- A German representative indicated that "an early dialogue approach between medical device industry and payers should be developed to define how to assess innovative medical device technologies".
- An English representative expressed the need for establishing "a national or European non-governmental organization advising companies".
- A Dutch representative proposed "to increase the transparency on the use of criteria for decision-making, such as cost-benefit, or of criteria for measuring efficacy and health outcomes".

Utilizing this initial assessment would be a basis for the dialogue between payers and the medical technology industry.

Slowly Emerging Trend: Managed Entry

One of the clearly emerging trends in the collaboration with payers is the need to ensure transparency, early dialogue and consistency of decision-making. However, the medical technology industry recognises that this comes with potential challenges. One of the key challenges is the asymmetry or incompleteness of information at the time of decision-making on funding and reimbursement.

Therefore, performance-based risk sharing agreements, coverage with evidence development schemes, or patient access agreements have begun to emerge to mitigate the asymmetry of information and align stakeholders around driving better patient outcomes.[2] In 2017, the European Med Tech and IVD Reimbursement Consulting Ltd. (MTRC) used its in-house expertise to identify and provide an overview of the innovative payment schemes for medical devices and in-vitro diagnostic tests in 13 European countries. This research (link) was supported by an unrestricted grant from MedTech Europe and is a first of its kind, identifying and trying to understand the European landscape of innovative payment schemes for medical technologies and IVDs.

The following information was provided in relation to every innovative payment scheme: title, objective, overview, inclusion criteria, applicant, administrator and evaluator, clinical and economic requirements for the scheme, and statistics about the scheme. Out of 13 studied countries, seven (Austria, Belgium, England, France, Germany, the Netherlands and Switzerland) had innovative payment schemes in place. On average, there were two innovative payment schemes per country. The largest number was available in France (n=4) and England (n=3); Austria, Belgium and Switzerland each had one program in place.

Limitations of the existing innovative funding schemes can be summarized as follows:

- Dedicated funding schemes to reward innovation have only been implemented in a few countries, often in the form of coverage with evidence development programs;
- These schemes can be inconsistent, non-transparent, not rewarding the value delivered, unpredictable and limited in scope and time;
- There is often no link to permanent funding and reimbursement decisions causing uncertainty for payers, healthcare providers and industry alike.

Utilizing managed entry trends would be a basis for the dialogue between payers and the medical technology industry.

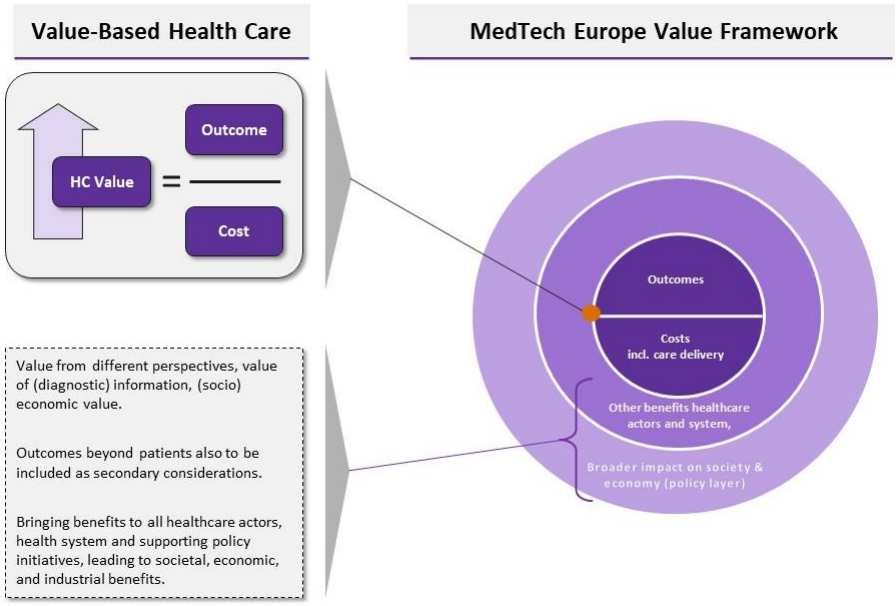
[2] Walker, Sculpher, Claxton, Palmer. Coverage with Evidence Development, Only in Research, risk sharing or patient access scheme? A Framework for Coverage Decisions. Value in Health, 2012.

Emerging Trend: Full Value Appreciation

In Europe there is a perceivable trend towards a value-based paradigm to support the long-term sustainability of healthcare systems. Consequently, there are additional challenges emerging, like how to demonstrate and evaluate the value.

To ensure patients access to medical technologies and fair awarding of value creation, the fundamental shift to value-based health care (VBHC) needs to continue. In simple terms, the objective of Michael Porter's VBHC is to improve the value of healthcare, whereby 'value' is defined as *outcomes that matter to patients relative to the total costs of providing healthcare*.[3,4] In the European context, MedTech Europe has identified that the theory of VBHC needs to be applied in a way that is consistent with the provision and financing of healthcare in Europe and can be operationalised, especially in view of the payer landscape. Therefore, MedTech Europe's Value-Based Framework (refer to Figure 1) builds on Porter's theory to ensure its operability within the European health landscape, and suggests considering value from various relevant perspectives.

Figure 1: **Value Framework for Medical Technologies proposed by MedTech Europe**



Therefore, to establish appropriate levels of funding and reimbursement, it is now demonstrated that the value of certain medical technologies and their impact on patient-relevant outcomes must be considered with different, more relevant criteria, dependent on the stakeholder, such as a provider or a healthcare professional. Moreover, value assessments need to be flexible enough to consider national or even regional distinctions in terms of funding and reimbursement pathways, including the role of payers and the diversity and nature of medical technologies (e.g. nuances of evidence generation that are more conducive to real-world evidence and effectiveness, shorter product life-cycles, user skills and learning curves). If these elements are not considered, there is a risk of underappreciating value, purchasing low-value care and economically less advantageous medical technologies. This would materialise in a disconnection between value on the one hand, and funding and reimbursement on the other.

Utilizing the "Value" framework would be a basis for the dialogue between payers and the medical technology industry.

[3] What Is Value in Health Care? Michael E. Porter, Ph.D. New England Journal Medicine 363;26 nejm.org December 23, 2010
[4] HTAi Policy Forum, International Journal of Technology Assessment in Health Care, 00:0 (2013), 1–7.

Initial Recommendations

The Medical Technology industry has the ability and readiness to deliver on its stated purpose of providing patients, healthcare systems and societies with a timely access to beneficial technologies through value-based health care. We would like to invite the payer community in Europe to reflect upon the presented recommendations and to engage in a constructive dialogue with the medical technology industry.

Based on the data collected through the qualitative interviews with payers, Deloitte offers the following recommendations both for payers and industry:

For Payers	For the Medical Technology Industry
1. Articulate needs and engage in an open dialogue with stakeholder representatives; if necessary, sign memorandums of understanding to set up clear rules and boundaries of such a dialogue. 2. Recognise the value of medical technologies and the role they can play in safeguarding the sustainability of healthcare systems. 3. Reward proven value creation through transparent and consistent decision-making.	1. Acknowledge the need for a change in the dialogue with payers. 2. Demonstrate the value of medical technologies, which improves patient outcomes and contain cost, and indicate benefits to the stakeholders involved in healthcare (patient, provider, HCPs). 3. Build and engage in stakeholder dialogue platforms to collectively establish the opportunity and value of medical technologies.

Based on the research by MTRC, MedTech Europe offers the following recommendations:

1. **Budgets** need to be allocated to support and reward value-based innovation as a bridge to permanent funding and reimbursement decisions. Healthcare systems need to encourage the introduction and development of innovative technologies as also the European Commission considers innovation as one of the major instruments for improving patient outcomes and guaranteeing value for money in healthcare. Even more, there is empirical evidence that political support and availability of dedicated funding and resources may increase the likelihood of implementing innovations in healthcare.[5]

2. **Processes need to be transparent and predictable**, with manufacturers and payers partnering in an inclusive and trustful manner.

Conclusion

The medical technology industry is fully supportive of the shift towards value-based health care. Therefore, we aim at enhancing the communication with the payers' community, as one of the most prominent stakeholders for the funding and reimbursement dialogue. The industry would welcome any constructive feedback on how to accomplish this. A constructive dialogue would lead towards designing and implementing the state of the art methods for an appropriate assessment of medical technologies, using the most relevant data to achieve a system that incentivises healthcare innovation and which truly delivers value for the main beneficiaries of improved healthcare outcomes, the patients.

[5] *Mylotte et al; Journal of the American College of Cardiology, 2013

About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are multinational companies and national medical technology associations operating in Europe and worldwide.

There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors.

Our sector employs more than 675,000 people. There are more than 27,000 medical technology companies in Europe, of which 95% are SMEs.

Annex

Definition of "Payers"

The definition is often varied, nuanced and in general, unclear for many stakeholders. One of the reasons is the variety of stakeholders involved in the decision-making process on funding and reimbursement. It is also jurisdiction dependent, and sometimes product/service dependent. Therefore, defining a 'payer' is of crucial importance.

For the purposes of this paper, the following definition of a "payer" has been adopted: *An institutional organisation that holds budget, and has direct decision-making role on the reimbursement and funding of medical technologies. Therefore, conventional HTA bodies are out of scope; given that hospitals often receive funding either partially or in full from 'payers', hospitals are also out of the scope. For consistency, private hospitals, who can act as a quasi-payer, are also out of the scope. Lastly, procurement authorities, given that they are determining whether to grant access or not and not the amount of budget to allocate, are also out of the scope. Therefore, the remaining organisations would include, but are not limited to:*

- *Statutory 'sickness funds' or 'Krankenkassen' in Germany*
- *Regional health authorities in Italy, Spain, or Sweden*
- *Regional CCG's (or their iterative structures) and NHS England in England*
- *Health funds in the Netherlands*
- *Ministry of Health in France*