

**MedTech Europe position
on
future EU cooperation
on Health Technology Assessment
(21 March 2017)**

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Executive Summary

The European Commission is conducting an impact assessment on ways to strengthen the use of and cooperation on Health Technology Assessments (HTAs) at European level. The aim is to explore their potential in keeping healthcare systems financially sustainable while ensuring timely access to innovation that benefits patients.

MedTech Europe, the European trade association representing the medical devices and *in vitro* diagnostics (IVD) manufacturers operating in Europe, fully supports the European Commission's intent. However, we urge the Commission to ensure that its ongoing analyses and future proposals examine and incorporate the specific conditions of the market access model for medical technologies. A dedicated cooperation on HTA for medical technology could then be one of many initiatives contributing to the Commission's objectives, including Europe's 'Better Regulation Agenda'. The proposal needs to recognise the clear differences between medical technologies and pharmaceuticals, as reflected in the specific CE marking regulations for the medical technology sector, which differ from pharmaceutical legislations.

For medical technology, any cooperation on HTA in Europe should be built on the following principles:

- The demand for assessments should come from national and regional decision-makers.
- Member States that share a common unmet need should collaborate on a voluntary, non-legislative basis.
- Avoid compromising the existing well-functioning, distinct market access model for medical technologies, which delivers timely access to innovation.
- Focus on those medical technologies that are truly transformative.
- Identify the optimal point in time for performing HTAs in order to capture the full value of the technology.

Overall, there needs to be a conceptual shift that makes HTA cooperation in medical technology a constructive component of a value-based market access model.

For these reasons, MedTech Europe proposes a modern 'fit-for-purpose' HTA cooperation in Europe, which is suitable for medical technology.

The need for healthcare reform

Europe is in a time of transition. Ageing populations lead to a rise in chronic conditions, which puts a strain on budgets. At the same time, citizens rightfully expect continuous access to high quality healthcare and beneficial innovations. Healthcare systems will have to respond to this mounting pressure. Key questions are how to eliminate inefficiencies in current healthcare delivery, how to drive outcomes that matter to patients, and how to obtain the best value for money.

Our medical technologies already play an important role in optimising treatments and thus the use of scarce healthcare resources. Beyond that, we want to contribute as an active and constructive partner in the public debate. We believe that a shift towards a value-based healthcare model is a key step in addressing the public needs.

The role that HTA can play in the needed healthcare reforms differs significantly between pharmaceuticals and medical technologies: while HTAs of innovative medicines typically inform decisions about pricing and reimbursement, the same is not true for medical technologies, where a strategic link between assessment and decision is missing in many Member States. Discounting this reality would lead to a flawed solution.

Whilst we support the intent of future EU cooperation on HTA, we urge the European Commission and Member States to take this reality into account.

Our industry recognises that there needs to be some way of defining and evaluating the value of innovation. However, this definition needs to embrace a holistic view of value whilst acknowledging the specificities of different sectors.

The following pages explain our concerns and put forward recommendations and solutions for future cooperation on HTA for medical technology in Europe.

The medical technology industry's concerns on future EU HTA cooperation

The Commission aims to strengthen EU cooperation on HTA in a way that will efficiently and effectively contribute to the sustainability of healthcare systems, and simultaneously facilitate timely access of innovation to the benefit patients. MedTech Europe is worried that for medical technologies, the options outlined in the Commission's 'Inception Impact Assessment' would be detrimental to both of these goals as the current proposals use the pharmaceutical market access model as a basis - a model that cannot be applied to our industry.

In the pharmaceutical sector, the information generated in HTAs informs pricing and reimbursement decisions. In addition, the benefit of cooperation that are foreseen arise through preventing duplication of assessments at national level, potentially reducing costs and delays for all Member States.

However, the reality for medical technology is different and thus the above assumptions do not apply for HTAs on medical technology: In those few countries and limited cases (1% of technologies) where HTA is performed, it aims to inform Member State's specific, decentralised decisions at differing times and for differing purposes. The circumstances where all Member States will seek identical information to inform decisions on a medical technology at the same time are not the reality, based upon the analysis of the last three years. This means a low probability of realising the predicted efficiency gains.

On the contrary, up to now HTA cooperation on medical technology has been challenging in terms of finding common ground between member state demands. Cooperation still needs to prove its value in genuinely improving access to innovation for patients or in effectively addressing sustainability.

Moreover, there is a risk of further unintended consequences, if the specificities of the market access model for medical technology is not taken into account:

- **Significant delays in access** to medical technology innovation valuable to patients and health systems. This would have a particularly negative impact on countries that already struggle with unsustainable healthcare systems.
- **Added bureaucracy and costs**, running counter to the Commission's principles of better regulation. Especially the sizeable SME proportion of the medical technology

industry (around 95%) could be severely affected, with a risk of losing jobs and innovation potential in Europe.

- **Investment into medical technology and clinical research could shift out of Europe**, which would have a negative effect both on inward investment, and the development of technologies specific to European needs.

Moreover, using HTA inappropriately in access pathways may actually further **increase healthcare costs** by reducing **competitiveness**. It will thus lead to fewer choices available for personalised care and optimised care pathways.

There are other approaches and initiatives that may better serve the Commission and Member State objectives. One example is the value-based purchasing of medical technologies, in line with the EU Public Procurement Directive, which includes a comprehensive assessment of the value that medical technologies, services and solutions bring.

The industry recommendations for: “Modern ‘fit-for-purpose’ HTA cooperation in Europe for MedTech”

We call for the Commission, Member States, EU Institutions and stakeholders to ensure that the ongoing analyses and future proposals take into account the reality of the medical technology market access model. Any cooperation on HTA in Europe should recognise the clear differences between medical technology and pharmaceuticals in the same way as they do for regulatory approvals.

Any future proposal needs to recognise that the current market access model for medical technology is well-functioning and goes far beyond HTA. HTA is only performed in a limited number of countries for a limited amount of technologies (i.e. 1% of new technologies per year). For the vast majority, well established procurement systems at hospital, local, regional or national level determine the uptake and price. HTA cooperation should add value within this medtech reality.

For HTA cooperation to add value in this environment, **we recommend a fit-for-purpose fully separate modern HTA cooperation for medical technologies**, corresponding to the elements outlined below.

From a governance perspective:

HTA cooperation in Europe in medical technology should:

- Be structured as **voluntary collaboration**, that does not require new EU legislation,

- Operate in **collaborative groups of Member States**, smaller and more flexible than EU28, that can respond to shared unmet needs of specific countries at specific times, supporting effective, decentralised decision-making,
- Be **coordinated by a dedicated body within the European Commission** that understands the specificities of medical technology,
- Be primarily **funded by the EU** to support Member States and to reach the objectives of the European Commission.

From an implementation perspective:

HTA cooperation in Europe in medical technology should:

- Be **driven by demands of Member State decision-makers**, to allow the HTA cooperation to meet the specific needs of those who are responsible for the introduction, coverage, funding, adoption, and/or use of medical technologies.
- Use clear and predictable criteria for the **choice of technologies** undergoing an evaluation. We suggest focusing on 'transformative technologies', which address a high unmet need and involves a structural or organizational reform, leading to sustainable solutions in healthcare delivery.
- Identify, in collaboration with stakeholders, the **best time for conducting HTAs**. For medical technologies, this will not be at market entry since the true effectiveness and full value can only be assessed with the aid of real world evidence, by taking contextual factors into consideration, understanding the differing care pathways and diagnostic information, and the learning curve of professionals or patients using the new technology.
- Retain the focus of the HTA cooperation on further developing the concept and acceptance of **post-launch evidence generation** to capture the full value of technologies.
- Use **consistent methods, data requirements and outcome measures** that are able to capture the broader value that medical technology offers.
- Ensure close collaboration between HTA agencies, decision makers and stakeholders at all stages of the EU HTA cooperation.
- Feed into **a value-based access model for medical technologies**, where the **HTA genuinely informs decisions such as reimbursement**, funding and use in clinical practice **for transformative technologies**.

As a last but important note CE marking and HTA assessments must be maintained as separate processes with distinctly different purposes and should not be confused:

- The regulations of medical technologies (called CE marking) address the demonstration of the **safety, quality and performance** of a technology throughout its whole lifecycle.
- The concept of HTA aims to **inform** decision makers on questions such as the **use of technology in clinical practice, coverage, and funding**. It thereby often uses comparative, context-specific data and the information need to be fit-for-purpose for decision making.

In conclusion

The European medical technology industry supports the European Commission's objectives of assisting member states in making their healthcare systems sustainable and providing access to innovation for the benefit of patients. Cooperation on HTA for medical technologies may prove beneficial provided it fully recognises our reality of a well-functioning access model, with decentralised, localised decision-making, and is designed and implemented accordingly, and in response to decision-makers' common needs.

A fit-for-purpose, modern HTA cooperation needs to be seen in the context of a value-based market access model for medical technologies, where uptake and price for the vast majority of medical technologies is determined by well-established procurement processes at hospital, local, regional or national level. Otherwise, it will hinder rather than help achieving the stated objectives of the European Commission, and furthermore undermine Europe's dynamic, innovative, SME-driven, competitive medical technology sector.

We believe that the benefits of cooperation will only be fully realised if they take into account the specificities of the sector. This implies recognising and rewarding value with a focus on transformative technologies and solutions. This will be most effectively done by voluntary groups of collaborating Member States with a common need; and a 'fit for purpose' role for the HTA cooperation in informing their decisions. Such modern, 'fit-for-purpose' HTA cooperation will also make the most effective contribution to realising the European Commission's ambitions, ensuring timely access to innovation for the benefit of patient and support Member States to keep healthcare systems financially sustainable.

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Annex

Detailed Proposals on the Governance of HTA cooperation for MedTech in Europe:

Voluntary collaboration

- Any demand for HTA in medical technology will reflect specific situations in specific countries at specific times; plans for cooperation should reflect this reality. Such cooperation should not require new EU legislation.

Operating in collaborative groups

- Rather than seeking broad alignment between all EU Member States in spite of their very different needs and circumstances, several collaborative groups of Member States should identify shared needs and then collaborate on a voluntary basis, supporting national decision-making.
- These collaborative groups should be based on memoranda of understanding, mutual recognition agreements or similar, signed by participating Member States and those that will be informed by an HTA. This will foster national use of the cooperation outputs while supporting the subsidiarity principle.

Organisation and coordination

- A body, ideally within the European Commission, with dedicated expertise in medical technology should coordinate the voluntary collaborative groups of Member States.

Funding

- HTA cooperation in Europe should primarily be funded by the EU, helping to support EU and Member States in achieving their objectives of sustainable healthcare and supporting innovation.
- In case stakeholders such as industry want to ask participating bodies to perform a specific activity - like scientific advice - it is reasonable to expect a fee in return for such services. For SMEs, specific funding mechanisms should be considered, such as fee waivers.

Detailed Proposals on implementation of HTA Cooperation for Medtech in Europe:

Demand-driven

- The relevant decision-makers from collaborating Member States should determine the information they require, based on their shared needs. This will allow outputs relevant for informing the decisions at stake and contributing to a value-based access model.

- HTA cooperation in Europe should focus on generating post-launch evidence for evaluating the full value of medical technologies, services and solutions, taking the contextual factors into consideration.

Focusing on 'transformative medical technologies'

- Cooperating Member States need to agree on predictable criteria to identify medical technologies, services or solutions for common assessments.
- These criteria should guide the cooperating HTA agencies in selecting only the most relevant technologies for common assessments. Selecting products based on their value rather than risk directs resources to where they will make the biggest difference.
- The suggested criteria would be to focus on 'transformative' medical technologies. These are determined by:
 1. Their ability to address high unmet patients and/or healthcare needs (common to several Member States); and
 2. Imply a significant structural or organisational reform of healthcare delivery.

Existing horizon scanning initiatives and industry can help identify these transformative medical technologies.

- The HTA Network of Member States and relevant stakeholders, including industry, should collaborate in the prioritisation process from the outset.

Capturing the full contribution of medical technology

- Decision-makers and HTA agencies need to agree on common and proportional evidence requirements that consider agreed standards of care, contextual factors, acceptance of data, evidence, and studies to demonstrate benefit and outcome measures.
- These criteria should be decided in advance, and used consistently within the collaborative groups.

Conducting HTAs at the right time

- Identifying the best time for performing an HTA on a medical technology is critical to assess its full value. Patients, decision-makers, healthcare professionals and industry need to be involved in this.
- Evaluating genuine value is a dynamic process, which needs to account for 'real life' conditions of use. These include continuous product modifications, the 'learning curve' of professionals using a new technology and differing care pathways depending on the diagnostic information.
 - Conducting assessments too soon in the life cycle of a technology risks failing to capture its full benefits. These include the genuine effectiveness, the socio-economic value, and outcomes that matter to patients