Irish Medtech Association
Ibec

Irish Medtech Association position on the European Commission Proposal for a Regulation on Health Technology Assessment (HTA)

June 2018

A. Executive Summary

Sustaining a world class capability and reputation for medtech in Ireland requires a best in class HTA system which should be guided by the unique composition and business environment of the medtech industry and its product and services. To reiterate findings of the Commission's Impact Assessment, the current HTA proposal would have a negative impact particularly on SMEs, which account for 60% of the medical technology industry in Ireland. In its current formulation, the European Commission HTA proposal could lead to unintended consequences, namely delays in access, drop in investments in new technologies and reduced choices and treatment options available to patients in Europe. The Irish Medtech Association calls on the European Parliament and the Council to take the suggested proposals into account to ensure that a new Proposal on HTA cooperation will accelerate the timely access and use of valuable innovative technologies for patients and can support the financial sustainability of healthcare systems both in Ireland and in Europe.

B. Background

The Irish Medtech Association is the Ibec association which represents over 250 medical technology companies in Ireland shares the European Commission's goal of making valuable innovative technologies accessible to patients and healthcare systems in a timely manner.

On 31 January, the Commission published its Proposal for a Regulation on Health Technology Assessments, establishing a support framework and procedures for cooperation on HTA at EU level.

The medical technology industry **is generally supportive of assessing the value of medical technologies with the aim to foster timely access to innovation beneficial to patients and citizens and to ensure financially sustainable healthcare systems.**

The assessment of medical technologies should take place through **tools that are appropriate to the nature of the sector and its innovation model.** HTA can be one of these tools if it meets the following criteria: (i) it focuses on transformative technologies, (ii) it is conducted with the appropriate methodology, (iii) it aims to inform the specific demands of members states' decision makers, and (iv) it ultimately impacts funding or use.

The Irish Medtech Association therefore calls on the legislators to amend the Commission Proposal in a way that it delivers on these elements.

The Irish Medtech Association welcomes that the Commission Proposal acknowledges the **different access pathways for pharmaceuticals and medical devices**. There are certain provisions in the proposal that reflect these specificities. Those elements should be further strengthened.

The environment in which the medical technology sector operates has certain characteristics that differ significantly from the pharmaceutical sector. They consist of the sector's continuous innovation with cycles of 12 to 36 months, the learning curve of the users and an open competitive market with many, mainly small and medium sized, medical technology players. This environment allows healthcare systems in having a vibrant medical technology market and a high number of technologies and solutions available. For 70% to 80% of all medical technologies available on the market, their access happens through procurement procedures of hospitals.

Currently, approximately 1% of medical technologies are subject to an HTA and only in a certain number of member states. Over the last years, less than five medical technologies were assessed in more than three countries within the same year. Furthermore, these HTAs inform on different questions, such as clinical guidelines, the use or the funding of a technology. This demonstrates that for medical technologies the **window of opportunity for a cooperation of all 28-member states on a clinical assessment with an agreed set of conditions** (question to be answered, timing, patient population, desired evidence etc.) **is very limited.** Imposing an EU-wide cooperation through a Regulation without having a common demand creates the risk of an additional regulatory burden with no proof of positively impacting the access to valuable technologies. As also seen in the Commission's Impact Assessment, this would have a negative impact particularly on SMEs, which account for 95% of the medical technology industry in Europe. In its current formulation, the European Commission Proposal could lead to **unintended consequences**, namely delays in access, drop in investments in new technologies and reduced choices and treatment options available to patients in Europe.

C. Proposals to amend the European Commission Text

For HTA to become a meaningful tool to assess the value of and to support timely access to valuable medical technologies, we ask European legislators to consider **amending the European Commission Proposal in three key areas:**

- **The governance of the HTA collaboration**: a) letting those Member State representatives, that have decision making power on the funding and use of medical technologies, define the questions of a joint assessment, and b) letting those member states with a similar need (less than 28) collaborate on a voluntary basis;
- **The appropriate rules and methodologies** for assessing medical technologies;
- **The clear separation** of the regulatory approval (CE marking) and the HTA assessment processes, since they serve two different purposes.

In detail, we propose these three areas to be addressed in the following way:

Chapter I. General Provisions

- **(Art.3) – The Member State Coordination Group on HTA**

HTA requests should be defined by member state representatives involved in the decision-making for the funding, coverage, reimbursement or use of health technologies at national/regional level. This would ensure that the clinical assessments will be taken up at national level. Therefore, **these decision makers in member states should be part of the** newly established **Coordination Group.**

Chapter II. Joint Work on HTA at Union Level

Section 1. Joint Clinical Assessments

- **(Art.5) – Scope of Joint Clinical Assessments**

Evidence shows that the **window of opportunity for a cooperation of all 28-member states on a clinical assessment with an agreed set of conditions** (point in time, question to be answered, patient population, desired evidence etc.) **is very limited.**

The regulation should not force all 28-member states to conduct joint clinical assessments. To facilitate agreeable and meaningful clinical assessments, they should be conducted instead by a group of member states that share the same needs. These would also facilitate the uptake of the reports at national level.

Therefore, medical devices and *in vitro* diagnostics should be deleted from the scope of the mandatory EU28 Joint Clinical Assessments and instead be put under the voluntary cooperation scheme in article 19, including the criteria for selection of medical devices and diagnostics (see below).

Section 2. Joint Scientific Consultations

- **(Art.13.5) - Preparation of Joint Scientific Consultation Reports**

The paragraph establishes an unlimited suspension clause if the assessors deem the desired evidence as insufficient. This measure risks to trigger additional and recurrent evidence demands, whilst withholding the option for member states to run their own assessment during the ongoing suspension time. This means that the technology in question would be trapped in the procedure. Consequently, this would jeopardise both the timely access for patients to beneficial innovative solutions as well as the Commission's goal of enhancing predictability for the industry.
Instead of requesting additional evidence, the assessors should develop a summary report of the existing available evidence for use of the member states.

Section 3. Emerging Health Technologies

- **(Art.18) – Identification of Emerging Health Technologies**

A horizon scanning mechanism specific for medical technologies should be established to identify 'transformative' technologies relevant for a joint clinical assessment.

Section 4. Voluntary Cooperation on Health Technology Assessment

- **(Art. 19) – Voluntary Cooperation**

Firstly, to facilitate meaningful cooperation on clinical assessments for medical devices and *in vitro* diagnostics, the assessments should be conducted voluntarily by a group of member states that share the same needs. **In that way, an agreement on the various parameters necessary to decide upon for an assessment is more likely.**

Secondly, for those Member States that decide to collaborate on a clinical assessment for a medical technology, it should be representatives that have decision making power on the funding and use of medical technologies, who will define the questions that the assessment should answer.

This would facilitate the actual use of the assessment report in the decision-making process at national level.

Thirdly, the scope of technologies eligible for voluntary cooperation should be prioritised. Focus should lie on technologies that qualify as 'transformative'. These technologies have the potential to induce better outcomes and significant cost-efficiencies for member states through, for example, structural and organizational changes of care pathways. However, these technologies have currently a limited use, despite their high value for patients and health systems. This prioritisation would support the investment in high-value innovation as well as the disinvestment of lower value care.

Thus, for selecting medical technologies eligible for a collaborate clinical assessment, the five criteria originally foreseen for a mandatory assessment should be kept (from article 5) and be extended by a criterion on 'transformative innovation'.

Chapter III. Rules for clinical assessments

- **(Art.22) - Common Procedural Rules and Methodology**

The appropriate time to conduct a clinical assessment for medical technologies is after the CE marking approval, when effectiveness data are available to demonstrate the full value of the technology. This allows taking the learning curve of the user of a technology into account while acknowledging the use of real-life evidence in the assessment. Recognizing the learning curve plays an important role for medical technologies since the outcome of a product and procedure does not only depend on the product itself but also on the context in which it is used. The article should reflect these critical methodological elements.

Recognition of the distinct roles of CE marking and HTA in the access pathway

- **(Art.11(f) and Art.16(f))**

  To obtain a CE marking approval, every single medical technology must demonstrate safety and performance, including a clinical benefit. Furthermore, the technology is monitored throughout the full product life-cycle. These obligations are regulated by the EU Regulations on in vitro diagnostics and medical devices that have been adopted in 2017.

  It is important that the different roles of this CE marking approval (which allows to place a technology on the EU market) and an HTA assessment (which informs on the relative (cost)-effectiveness compared to a current practice) are clearly distinguished and the respective Regulations remain detangled.

  Interlinking a future HTA Regulation with these CE marking Regulations, as proposed in articles 11(f) or article 16(f), would risk creating duplication and disproportionate complexity in both procedures, and should be deleted.

D. The economic contribution of Ireland's medtech sector is of increasing importance.

Ireland is well positioned to capitalise on global medtech market which is forecast to grow €435 billion by 2022, it's:

- A global medtech hub with 9 of the world's top 10 medtech companies having a base here
- The number one location for medtech foreign direct investment in Europe
- Spans 450 medtech companies, including leading contract manufacturers, designers and service providers
- As many as 60% of businesses are homegrown and 80% are either start-ups or SMEs
- Ireland is the second largest exporter of medtech products in Europe with €12.6 billion in exports
- The highest employer of medtech professionals in Europe, per capita, with many as 38,000 already working in the sector and 4,000 jobs to be added by 2020
- Ireland has the most Shingo Prizes for operational excellence of any country, per capita, in the world
- A whopping 68% companies do R&D and spend €181 million on R&D annually
- Nearly two out of three medtech companies have commercial capabilities here and a third of FDI multinationals plan to expand or introduce new commercial operations

E. About the Irish Medtech Association

The Irish Medtech Association is the business association within Ibec representing the medtech sector. The Irish Medtech Association has more than 250 members, located throughout the island of Ireland. The Irish Medtech Association's broad focus is to promote and support an environment that ensures the sustainable development and profitable growth of our multinational and small to medium size medtech companies. Irish Medtech Association is led by a Board of Industry CEOs and Executive Leaders. Strategy implementation is coordinated through working groups and taskforces.