Irish Medtech Association
Ibec

The Irish Medtech Association response to the proposed EU Commission Health Technology Assessment Regulation

Understanding barriers and identifying enablers for medtech HTA

[COM(2018) 51]

1. Executive summary

Health Technology Assessment (HTA) is defined as, an evidence-based process that assesses the added value (relative effectiveness) of a given health technology/ health intervention and compares it with other health technologies and/or the current standard of care, by the European Commission.

HTA has been used for the past 30 years to support budget allocation for health technologies with widespread adoption, particularly in Australia, Canada, EU countries and increasingly America as well as Asia. This practice has been driven by the pharmaceutical industries who led the development of the methodologies for HTA which were required to conduct formal economic evaluations to achieve market access.

Current practice in the European Union is for HTA to be conducted at a national level, eg by the Health Information and Quality Authority in Ireland, but there has been growing multinational collaboration since the foundation of the European Network for Health Technology Assessment (EUnetHTA) 20 years ago.

In 2018 the European Commission proposed a new regulation to 'promote convergence in tools, procedures, and methodologies and to facilitate a more efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability'.

However, as the development of HTA methodologies has been led by the pharmaceutical industry, this proposal would not support HTA best practice for the medtech industry which has a number of unique characteristics[1].

There are a number of key barriers of medtech HTA which we've identified are under these key four categories:

— Evidence factors: Constraints to the clinical study design like the inability to double-blind trials and availability of data
— Industry factors: Industry structure with 95% of companies in Europe being startups or SMEs, short-product cycle with iterative innovation and reusability of devices notably invitro diagnostics
— User factors: The individual learning curve affects device effectiveness, along with health system context and implementation strategy
— Market factors: Early market diffusion, the regulatory framework and dynamic pricing are key market drivers along with stakeholder support and clear decision making processes

To identify a forward to promote best practice in medtech HTA we surveyed experienced industry experts. The findings of this survey are presented in this publication and informed the development of the following recommendations for Irish and European policymakers in light of the proposed EU regulation on HTA. Medtech HTA should:

— Be conducted at the appropriate point in the medtech product lifecycle, post-market after regulatory approval, to effectively measure cost and clinical benefit by using a broad range of data such as real world evidence
— Move towards developing better understanding of the device-operator learning curve and consideration for ease of adoption factors for new medical technologies to ensure effective integration into healthcare systems
— Be transparent with clear decision making implication which must reflect local needs supported by clear methodologies which are in line with international best practice

If these three recommendations are implemented we can make great strides to supporting better decision making and HTA of medtech.

1 Drummond et al (2009)

2. Health Technology Assessment evolution and current practices

Healthcare costs and the evolution of economic evaluations

Economic evaluations are used to support health budget allocation by identifying, evaluating, and comparing costs and consequences of health technologies, including pharmaceuticals and medical technologies, being considered[1].

In Europe an average 10% of GDP is spent on healthcare. Of this 15.9% is spent on pharmaceuticals, with less than half as much spent on medical technologies at 7.2% (6.5% on medical devices, including imaging, and 0.7% spent on in vitro diagnosis)[2].

While economic evaluations can be applied to both pharmaceuticals and medtech, in the main formal requirements for assessment of cost-effectiveness have been applied to the former[3]. In the early nineties the Commonwealth of Australia began to require economic analyses as part of submissions to the Pharmaceutical Benefits Advisory Committee which advises the minister on publicly subsidised drugs. Subsequently this practice has become widespread in the European Union, Canada, and more recently it has been adopted by parts of America and Asia .

Economic evaluation has been widely applied to pharmaceuticals as there is usually a clear decision-making process for including drugs on national or local formularies, like in Australia with the Pharmaceuticals Benefits Schedule.

Conversely, reimbursement for medical devices is usually through a broader process of financing hospitals or compensating clinical professionals. Subsequently, where there has been an interest in conducting HTAs attempts have been made to introduce economic considerations through other routes such as the development of clinical guidelines.

In 2016, the European Commission began work to expand EU cooperation on Health Technology Assessment beyond 2020. Subsequently, a legislative proposal was adopted by the European Commission on 31 January 2018 for a new HTA Regulation.

While the proposed EU regulation on HTA aims to 'promote convergence in tools, procedures, and methodologies and to facilitate a more efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability'. Aligning the evaluation of medical technologies with that of pharmaceuticals is neither practical nor desirable, for a number of reasons as indicated below.

1 Kiristis and Redekop (2013)
2 MedTech Europe (2019)
3 Drummond et al (2015)

HTA survey of medtech industry

The survey results presented in this publication were developed in order to better understand medtech barriers, enablers, and best practice for HTA, a survey questionnaire was developed by Irish Medtech Association. The survey covered:

— Company information
— Health Technology Assessment
— Current practices
— Barriers and facilitators for conducting medtech HTA
— Market access and the proposed EU HTA Regulation
— Facilitating HTA activity for medtech

The survey was launched on the 10 April 2019 and closed on the 7 June 2019. It was targeted at medtech professionals with an understanding of Health Technology Assessment. By circulating it to members of the Irish Medtech Association, MedTech Europe and the US-based global trade association AdvaMed we were able to establish 12 indepth case studies.

Survey responded were asked to answer 32 unique questions on their understanding of HTA, information on their current practices, along with selecting and/or ranking what they believed to be the greatest barriers and enablers to medtech HTA.

HTA current practices in Ireland and how the proposed EU regulation will change this

HTA is currently conducted at a national level (eg Health Information and Quality Authority in Ireland) with limited joint clinical assessments, where relevant, being conducted at European level.

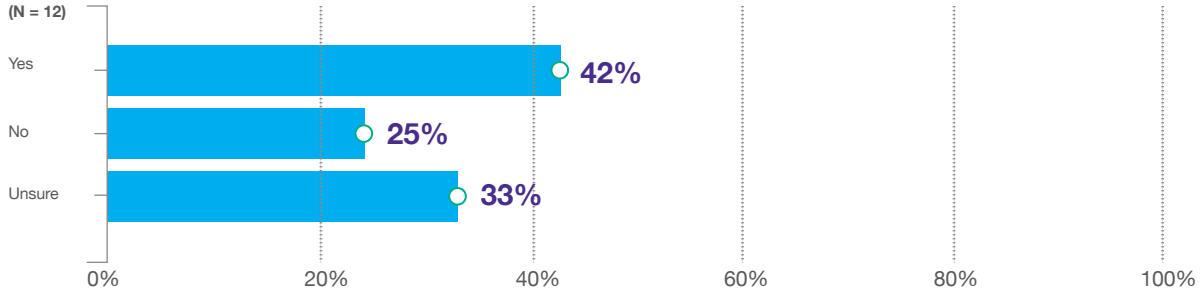
According to MedTech Europe, currently only 1% of medtech products are reviewed under HTA, mainly in France, the UK and Sweden (Repertorio and Synergus). As many as 100,000 products are renewed a year in Europe with 20,000 new products Class III (highest risk, eg pacemakers), Class IIb (high risk, eg anaesthesia machines) each year.

Further afield, a survey of the activities for medical devices across 36 non-EU HTA agencies was conducted[1]. Although 27 (75%) of the agencies surveyed had adopted HTA-specific approaches for devices, these were largely organizational (eg staff assigned to medical devices assessment) or procedural (eg organising committees to appraise device evidence and offer policy advice) in nature. Moreover, only one agency, the Department of Science and Technology in Brazil, had developed methodological guidelines specific to medical devices.

The 12 case studies in this report, generated by circulating a targeted survey of medtech professionals with an understanding of HTA, revealed that 5 out of 12 had a dedicated HTA resource and 4 out of 12 respondents said they'd plans to expand the level of their HTA activity. Of these companies 9 out of 12 said their organisation currently engage in HTA, with 9 out of 12 saying they have 'Heard of it and I have experience conducting it' and 3 have 'Heard of it and think I know what it covers'.

1 Ciani et al (2005)

Graph 1: The European Commission has described Health Technology Assessment as a: procedure for assessing the added value of new medicines and medical devices. Do you agree with the statement: A technology represents value if its additional health benefits are expected to exceed the health foregone from curtailing other activities to accommodate the technology's costs?



Note: Multiple answers per participant possible. Percentages added may exceed 100 since a participant may select more than one answer for this question.

The European Union's journey towards pan-European Health Technology Assessment

The European Commission proposed a regulation on HTA [COM(2018) 51] aims to 'promote convergence in tools, procedures, and methodologies and to facilitate a more efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability', 31 January 2018.

Most medtech companies disagreed with the EU's definition of HTA, finding that it was too restrictive to define it as an opportunity cost between the existing comparator technology and the cost of foregoing it to introduce new technologies.

When asked about the EU's proposed regulation 3 out of 12 expect it to have a positive affect on their organisation, while 2 out of 12 expect it to have a negative effect. The harmonization for methodologies and proposed timing of HTA, pre-market, were identified as the factors most likely to affect respondents. Those who responded 'Yes' that EU's proposal would affect their organisation expected the proposed timing of HTA and harmonization of methodologies for clinical assessment as the elements most likely to affect their organisation.

The proposal by the EU builds on previous European-wide collaboration over the past 20 years (see appendix), however, few respondents had an experience of engaging with the European Network for Health Technology Assessment (EUnetHTA) which was established in 2009 to create a sustainable HTA network. One in three survey respondents said that they had experience engaging with EUnetHTA.

While the move towards EU HTA regulations is intended to increase cooperation and decrease HTA workloads through collaboration only 2 out of 12 respondents thought that it would decrease their workload and 5 out of 12 said no it would not decrease their workload.

3. Drivers or medtech health technology assessment

Table 2. Comparing Europe's medtech and pharma industries

Medical Technology Industry in Europe	Pharmaceutical Industry in Europe
13,795 patents filed	7,441 patents filed
27,000 companies	~40 companies (EFPIA members and affiliates)
95% of companies are SMEs	unknown
7.2% of healthcare expenditure	15.9% of healthcare expenditure
Second largest market in the world (27%)	Second largest market in the world (22%)

Challenges with applying pharma style HTA to medtech

A medical device is defined as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination… to be used for human beings for the purpose of diagnosis, prevention, treatment, monitoring or alleviation of disease" according to the EU Directive (2007) 2007/47/EC, amending Council Directive 93/42 EEC.

The European medtech and pharmaceutical industries reflect different structures and innovation processes.

The medtech industry and the technology it develops is characterised by fast paced, iterative, innovation, as well as a broad spectrum of devices (500,000 thousand product types are on the market), and a significant representation of startups and SMEs (80-90%) which drive disruptive innovation.

Factors which act as barriers and enablers of HTA

Health technology assessment is a "relatively young science" and uptake is "too recent to be fully understood"[1], better matching of HTA and user needs can help to strengthen it. This would include the medtech perspective, notably, manufacturers including both multinational companies and startups.

This report explores drivers of medtech HTA and the way forward. A "driver" is defined as a factor that could potentially have an impact on the development or use of HTA, if it is positive it is a facilitator and if it is negative it is a barrier[2, 3, 4]. Below are a list of the drivers identified in the research.

1 Cheung et al (2017)
2 Castro Jaramillo et al (2016)
3 Cheung et al (2017)
4 Kirisits et al (2013)

Table 3. HTA Drivers, barriers and facilitators

HTA Drivers	Descriptions
Evidence factors	— Inherent constraints to clinical study design, such as the inability to double-blind trials, ethics of placebo control and blinding of patients and difficulties recruiting patients Availability and quality of data
Industry factors	— The reusability of devices, notably in vitro diagnostics which are intended for repeated use across different target indications and exhibit different clinical effectiveness, this is associated with difficulties estimating lifetime use and use capacity — Industry structure, dynamic startups and SMEs make up the majority of the industry, they have limited product portfolios, serving small markets which may not be able to conduct large RCTs — Short-product lifecycle, diminishes the relevance of clinical studies, makes it harder to identify optimal time for assessment, and the next generation of device may outpace the time needed for evaluation
User factors	— The dynamics of outcome and procedural integration of medical devices, with individual, institutional learning curves which means effectiveness varies with level of experience of the health care professional using the technology — Health system context affects HTA — Implementation strategy, the need for well-planned HTA strategy
Market factors	— Regulatory framework, the limited availability of RCT data leads to different pre-market clinical evaluation compared to pharma — Early market diffusion, given the regulatory prerequisites and early adopters looking for new ways to treat patients means that conducting economic evaluations prior to its use is not the optimal time for medical devices — Dynamic pricing stemming from procurement strategies and market entry of competing technologies — Local capacity, the existence of human technical capacity, infrastructure, tools, resources and academic institutions — Cultural aspects which relate to specific conduct or behaviours that impact HTA — Globalisation and social trend to engage in HTA to inform decision making — Stakeholder pressure, including patient associations, insurers, manufacturers, academics and government bodies, to either use or prevent the use of HTA — Lack of support within the organization and/or amongst politicians for the use of HTA — Financial support to promote the development of new and ongoing HTA — No explicit framework for decision-making process, usefulness perception and limited generalisability

In the survey of medtech drivers, medtech business rated their experience of drivers across the five categories identified in the research.

Table 4

What evidence factors do you regard as the barriers (where 1 represents the greatest barrier) to conducting health technology assessment of medical technologies in your organization?	Overall Rank
Inherent constraints to study design, ethics and RCTs	1
Use of real world evidence and observational studies	2
Risk based evidence base	3
Other	4
Total Responses	**11**

Table 5

What industry factors do you regard as the barriers (where 1 represents the greatest barrier) to conducting health technology assessment of medical technologies in your organization?	Overall Rank
Short product life cycles	1
The incremental nature of innovation (13,090 patents filed with European Patent Office)	2
Broad spectrum of devices (200,000+ product types on the market)	3
Prevalence of SMEs (80-90% of the medtech industry)	4
Other	5
Reusability of medical devices and lifetime capacity (notably IVDs)	6
Total Responses	**11**

Table 6

What user factors do you regard as the barriers (where 1 represents the greatest barrier) to conducting health technology assessment of medical technologies in your organization?	Overall Rank
Device-operator learning curves affective measures of outcomes	1
Broader organizational impact in terms of training and infrastructure	2
Other	3
Total Responses	**11**

Table 7

What market actors do you regards as the barriers to conducting health technology assessment of medical technologies in your organization?	Overall Rank
Early market diffusion	1
Regulatory framework	1
Dynamic pricing	2
Other	3
Total Responses	**9**

Table 8

In your opinion which of these factors act as the greatest barrier (where 1 represents the greatest barrier) to conducting medtech HTA?	Overall Rank
User factors and outcomes	1
Evidence Factors	2
Industry factors	3
Market factors	4
Other	5
Total Responses	**11**

Implications of medical technology characteristics for HTA

The value of a technology, in terms of cost effectiveness, is based on the balance of evidence currently available[1]. However, uncertainty is present when a technology is:

- Evaluated too early in its lifecycle when the evidence base is in its infancy
- Establishing a treatment effect and approximate the counterfactual
- Disentangling effectiveness from user experience
- Establishing a causal relationship for outcomes
- Combining multiple sources of evidence on the same outcome, missing information
- Transferring study findings to a population or setting of interest.

The price also plays a role in determine the value of the technology and affects the level of uncertainty by changing the likelihood of an incorrect decision as well as the value of future research. Therefore, new or incremental innovation will change the value of a technology and the value of research.

Decision makers have two options when reimbursing or implementing a new medical device[2]:

- Make a decision based on available evidence, or
- Delay the decision until the evidence gaps are filled

Furthermore, there are two risks associated with making a decision:

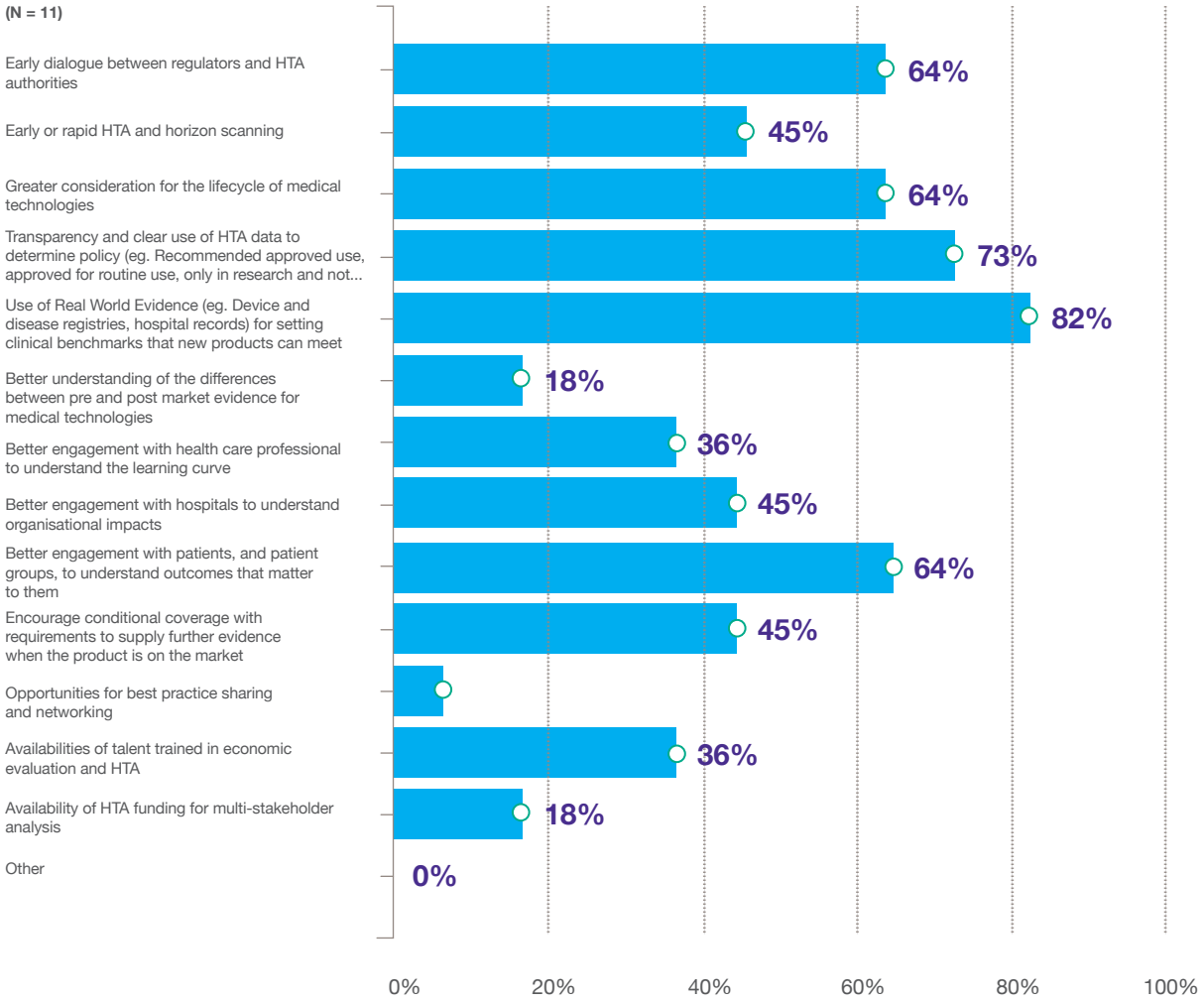
- Making an incorrect decision to reimburse a device, or
- Making an incorrect decision to reject a device

Increasingly another path is seen to be attractive, conditional coverage is being adopted to manage risk sharing agreements, outcomes-based reimbursement schemes, and volume or target population restrictions.

1 Rothery et al (2017)

2 Kirisits et al (2013)

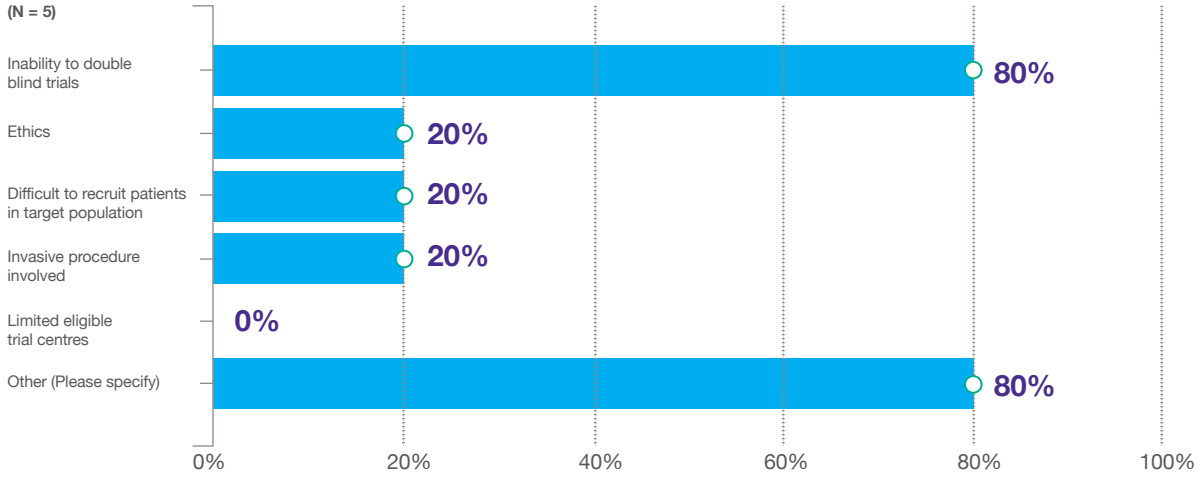
Graph 2: What factors would facilitate and enable you (where 1 represents the greatest facilitator/enabler) to conduct health technology assessment?



Note: Multiple answers per participant possible. Percentages added may exceed 100 since a participant may select more than one answer for this question.

4. Demonstrating clinical effectiveness and the value of medical technologies

Graph 3: If your organization does not use RCTs to demonstrate clinical effectiveness? (please select all relevant responses below)



Note: Multiple answers per participant possible. Percentages added may exceed 100 since a participant may select more than one answer for this question.

Assessing and demonstrating the clinical effectiveness of health technologies

The new EU HTA regulations seeks to strengthen the requirements for clinical studies and RCTs conducted in the in the pre-market phase1[1] but this may be "difficult or impossible" for medtech due to practical and ethical limitations.

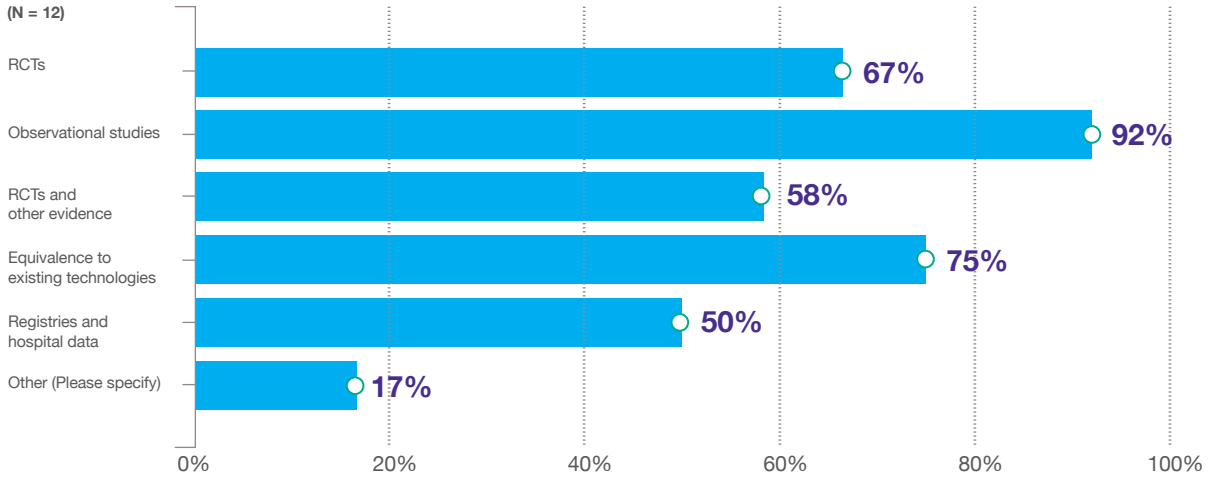
Including empirical data on the clinical effectiveness from observational studies (OS) can complement evidence from RCTs. Device and disease specific registries have been established to provide long-term data on the effectiveness and safety of medtech in routine clinical practice, Shenll-Inderst et al (2017).

In our survey 9 out of 12 respondents said that they had experience conducting RCTs, which reflects the fact that large manufacturers undertake clinical studies, when appropriate, as part of their work to demonstrate clinical effectiveness and gather evidence on clinical benefit and safety.

Medical technology manufacturers in the EU must already provide clinical evidence to a high standard to receive a Conformité Européenne (CE) mark to get their products to market by demonstrating safety, reliability and performance but not cost-effectiveness. However, the full clinical and cost effectiveness cannot be accurately measured pre-market due to factors such as the user learning curve associated with adopting new technologies, organizational impact, dynamic pricing and iterative innovation.

1 Drummond et al. (2016)

Graph 4: What type of evidence do you use to demonstrate clinical safety, benefit and efficacy, as defined by requirements for EU CE marking to get products to market? (please select all relevant responses below)



Note: Multiple answers per participant possible. Percentages added may exceed 100 since a participant may select more than one answer for this question.

In the European Union new Medical Devices and Invitro Diagnostic Regulations are already being transitioned in to strengthen the EU legislation and bring it into line with technical advances, changes in medical science, and create a robust, transparent and sustainable regulatory framework.

Post-market effectiveness research may be more important for medtech than pharmaceuticals as the performance of device often depends on the interaction with the user (the so-called learning curve) which if not taken into account could bias the results1[1]. In our survey, one in three respondents said pre-market HTAs would affect product development and innovation in their organisation negatively, and one in four were unsure.

While, Drummond et al. (2016) remark that there's "no simple solution" it would be "too simplistic" to treat medical devices and addressing the clinical evidence gap the same way as pharmaceuticals. And we need to understand the differences between measuring safety under the CE mark and clinical effectiveness as understood by HTA.

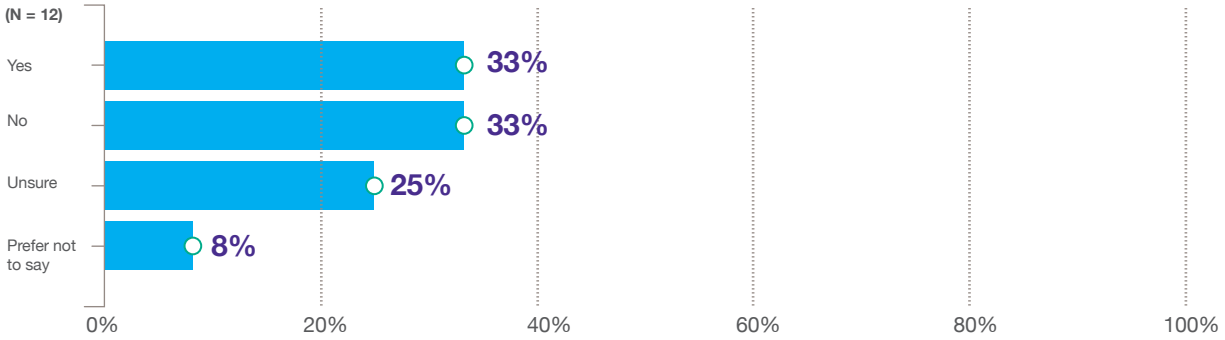
The value of medtech and local factors

HTA is an emerging field, and is not a requirement for medtech market access which differs from the pharmaceutical industry. To gain market access, medical technology companies have negotiated prices with hospitals and other payers, with diagnostic related group payments or fee-for-service.

However, there has been a concentrated effort within the medtech industry to move to value-based healthcare. To do this companies both independently and through organisations such as MedTech Europe are working to create a transparent framework that measures outcomes that matter to patients and the cost of delivering them, namely value-based healthcare.

1 Drummond et al. (2016)

Graph 5: Does the procurement process you engage in include criteria for promoting value-based care* (ie with a focus on identifying and delivering outcomes that matter to patients, rather than a focus on price alone) *Value = Health outcomes that matter to patients



Note: Multiple answers per participant possible. Percentages added may exceed 100 since a participant may select more than one answer for this question.

An overwhelming 11 out of 12 survey respondents said localised, national, decision making an important factor for HTA of medtech. Additionally, coverage decisions will always remain local1[1], but the need for high level evidence review to manage the total cost of care is increasing for payers and producers. Medtech manufacturers increasingly need to demonstrate product value, but the application of value-based approaches are not as straightforward as they are for drugs.

More than 5 out of 12 said they had conducted HTAs for the same product in more than one country, and this involved some duplication of work. Those who had conducted HTAs in multiple countries were asked to list the countries, Germany, France and the UK were named 3 times, followed by Belgium twice. While smaller countries, like Ireland, indicated early support for the proposed regulation, France and Germany, which have a greater level of HTA activity are leading efforts to block the proposed EU HTA regulation. Additionally, the UK voted to leave the European Union in 2016 and is preparing to exit this year, 2019, which means their expertise may be lost in any European-level collaboration.

These countries represent the top three markets for medical devices, Germany (27.4%), France (15%) and the UK (11%) according to the MedTech Europe “The European Medical Technology Industry in Figures – 2019”. Germany is also the largest market for IVDs in Europe (20.3%), France is third (13.4%), while the UK is fifth (8.7%). Despite ongoing debate on the proposed HTA regulation, EU Health Commissioner-designate Stella Kyriakides has indicated that this will be one of her top priorities in the new role.

Other countries cited where HTA was conducted by survey respondents are Australia, Austria, Chile, Italy, Mexico, Netherlands, Norway, Peru, Spain and Sweden.

1 Onwudiwe et al. (2017)

5. The EU HTA regulations and the way forward for medtech

Fifteen years ago, the European Commission and Council of Ministers identified HTA as a "political priority" citing "an urgent need for establishing a sustainable European network on HTA". Last year, the Commission proposed a new regulation to promote cooperation of HTA as an evidence-based process that assesses the added value of health technologies compared to the standard of care.

While in principle most stakeholders, including the medtech industry, support EU level cooperation on HTA to inform decision making with an evidenced-based approach, it's vital that the methods used are fit-for-purpose and voluntary. The proposed policy by the EU to 'promote convergence in tools, procedures, and methodologies and to facilitate a more efficient use of resources and strengthen the quality of HTA across the EU and improve business predictability' cannot achieve its aim if it ignores key differences between the medtech and pharmaceutical industries or how this applies to HTA.

The evidence herein captured by the survey of the medtech industry suggests both practical impediments to the implementing the proposed EU regulation and a way forward to support best practice for medtech HTA. We can break down the key findings of the survey and relate them back to the EU's stated aim to understand this matter further

Convergence in tools, procedures and methodologies

While the HTA regulation calls for Joint Clinical Assessments and most the companies surveyed have some experience conducting RCTs, there are barriers to adopting pharma-style RCTs such as the inability to double blind trials, and clinical evidence differs across countries with different populations, health needs and health systems as well as funding structures.

Additionally, post-market the device learning curve for healthcare professionals, or patients, means that effectiveness can improve with skill and experience using a technology over time and organizational impact of adopting new technologies play an import role in the effectiveness of medical technologies, as such full HTAs should not be conducted pre-market as is done in the pharmaceutical industry.

Therefore, it should not be tied to the EU Medical Devices and Invitro Diagnostic Regulations for two reasons, clinical effectiveness can only be measured post-market not premarket when the regulations are applied and secondly there remains uncertain surrounding the clinical guidance under the new regulations which are being transitioned in currently and will not come into full force until May 2020 and 2022.

Efficient use of resources

There is support amongst industry for European level cooperation, but this should be voluntary and foster the adoption of best practice. To date, HTA has largely been conducted in a small number of countries such as the UK, France and Germany which represent the largest markets for the sector in Europe. With our relationship with the UK changing under Brexit, and opposition from Germany and France to the regulations on the basis that it infringes on national responsibilities, it would be recommended to put a greater emphasis on establishing best practice to support the adoption of HTA before mandating cross-country collaboration.

Companies are already proactively working towards an evidence-based and transparent approach to value-based health care to reflect the sense of responsibility which the industry has to improve lives with recognition of health system cost pressures.

Table 9. Benefits of Real World Evidence

Factor	Benefits
Evidence	— Can be used in settings where clinical trials cannot be conducted — As a substitute for technologies that are already on the market — To fill evidentiary gaps — Can help inform research
Patient representation	— May be more generalisable for wider populations — Can help identify outcomes that matter to patients and caregivers — More inclusive of patient populations and ensure better representation of minority as well as other groups — Relevant to local considerations such as diseases prevalence and demographic changes
Outcomes	— Offers insight into outcomes for patients in real world setting — Shows use in clinical and care setting which can support better use as well as quality improvements
Reporting	— Provides evidence to support safety and effectiveness claims — Can be used for post-market reporting requirements
Time	— Supports rapid evidence development — Aims to deliver regulatory ready evidence, while protecting IP
Cost	— Low cost evidence that can compliment or act as substitute for costly alternatives

Quality of HTA

The proposed regulation places the emphasis on clinical assessments and increasing the level RCTs. The industry survey both highlights problems with this approach and offers a way forward.

HTA for medtech could be adopted as a two-step process, with the final HTA being conducted post-market following regulatory approval.

There are two key reasons for this, firstly to reflect the importance of post-market evidence. As well as to ensure effective measurement of clinical and/or cost effectiveness the EU should embrace the use of Real World Evidence which compliments other evidence currently used such as RCTs and observational studies. Secondly, there is a broad spectrum of medical devices which include implantable medical devices and reusable devices, such as MRI scanners or robotic surgery, it is hard to estimate the benefit, lifetime use and capacity for reusable devices as it varies across patients and over time[1].

HTA's role in supporting decision making

Beyond the convergence in tools, a more efficient use of resources and strengthening the quality of HTA, the survey suggests frustration amongst the role of HTA in decision making. While positive HTAs may not necessarily lead to the adoption of new technologies, negative HTA can block products from entering the market.

This means that not only is there no incentive to conduct HTAs, there's a clear disincentive. However, with transparency and clear use of HTA data to determine policy, supported by a medtech-appropriate approach to HTA the industry surveyed appears to be willing and open to build on the growing number of medtech companies investing in HTA.

1 Kiristis et al (2013)

Recommendations

Healthcare spending is continuing to rise with a projected increase from €6.9 trillion to €9 trillion, 2017-2019[1]. This is "shinning a light on health systems' need to reduce costs and increase efficiency". Within the medtech industry "investors talk about the 4 Ps: patient, physician, provide (i.e. hospital system) and payer"[2], now there's greater scrutiny from payer to demonstrate value. Additionally, budgetary pressures are exacerbated by ageing populations and the rise of chronic diseases.

This is likely to ensure that the trend towards greater adoption of HTA will continue with the proposed EU regulations bringing the second largest medtech market in the world more in line with experienced leaders in the field such as Canada, Australia and the UK. In light of the medtech input presented in this study we would like to make three recommendations to support HTA for medtech, it should:

— Be conducted at the appropriate point in the medtech product lifecycle, post-market after regulatory approval, to effectively measure cost and clinical benefit by using a broad range of data such as real world evidence
— Move towards developing better understanding of the device-operator learning curve and consideration for ease of adoption factors for new medical technologies to ensure effective integration into healthcare systems
— Be transparent with clear decision making implication which must reflect local needs supported by clear methodologies which are in line with international best practice

If these three recommendations are implemented we can make great strides to supporting better decision making and HTA of medtech.

1 Deloitte (2019)
2 EY (2018)

Ciara Finlay joined the Ibec Medtech and Engineering team in May 2015 to represent businesses from some of Ireland's worldclass manufacturing sectors which are members of the Irish Medtech Association, the Polymer Technology Ireland and Ibec Engineering Network. She manages a number of working groups and forums in strategic areas such as public relations, gender leadership development, entrepreneurship, health technology assessment, as well as digital health.

She also sits on a number national and international committees, namely, the Health Information and Quality Authority Scientific Advisory Group, MedTech Europe Most Economically Advantageous Tender Committee, MedTech Europe HTA Advocacy Team, and MedTech Europe Communications Committee.

Ciara has worked in Ibec, one of Europe's top three lobby groups, since 2012, and previously held roles in Ibec as a Corporate Affairs and Communications Executive, and on the EU Presidency Planning Team. She earned a BA in Sociology and Social Policy from Trinity College Dublin, an MSc in International Political Science from Trinity College Dublin, and an MSc in Health Economics from NUI Galway.

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7. Appendix

Table 1. The EU's journey towards pan-European Health Technology Assessment (2009-2019)

Who	What	When
European Network for Health Technology Assessment (EUnetHTA)	— EUnetHTA was established to create an effective and sustainable network for HTA across Europe to develop reliable, timely, transparent and transferable information to contribute to HTA's in European countries	2009
Tarricone et al. (2017) European Union FP7 funded research programme	— Align regulatory and HTA processes for devices with respect to data requirements — Harmonize the HTA evaluative framework for devices across international HTA agencies — Recognize that assessment of expected cost-effectiveness is not sufficient: conditional coverage and evidence development decisions should be assessed — Consider the implications of the learning curve on policy decisions — Consider the likely prospects of research and who should pay for it	2017
European Commissioner for Health and Food Safety Vytenis Andriukaitis	— Strong support for EU cooperation beyond 2020 — 92% pharma industry and their trade organizations — 85% medtech industry and their trade organizations — Both industries said they need joint tools, guidelines and early dialogues, but medtech businesses were less likely to say joint clinical assessments (JCA) responded to their needs	2017
European Commission	— The EU proposed a regulation on the Health Technology Assessment. The legislative proposal sets out four pillars of joint work at EU level: — Joint clinical assessments — Joint scientific consultations — Horizon scanning — Voluntary cooperation	2018
Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)	— Policy debate on proposed HTA regulation	2018
European Parliament	— MEPs voted on amendments to the proposal. The amended text stipulated that HTA shall be used to promote innovations that produce the best results for patients and society in general. Therefore, joint clinical assessments should aim to identify the added therapeutic value of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials.	2018
Austrian Presidency of the Council of the EU	— Working Party on Pharmaceuticals and Medical Devices met the subsequent revised text proposed — to provide for complementary national clinical assessments and the possibility to adapt the JCA to the needs of the national decision making process (Article 8) — in "special circumstances" give Member States the possibility to carry out their own clinical assessments when needed — it limited the number of health technologies which undergo JCA	2018
Romanian Presidency the Council of the European Union	— Working Party on Pharmaceuticals and Medical Devices met and the two main areas of interest were (Articles 12 to 18) — the joint scientific consultations with redrafting to clarify their aim and nature — the identification of emerging health technologies, it stressed non-duplication with other initiatives and extending the time horizon	2019

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