OIREACHTAS COMMITTEE ON THE FUTURE OF HEALTHCARE

Submission by IMSTA

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Signed by

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Executive Summary

IMSTA is the representative body for medical technology manufacturers, distributors and service providers in Ireland.

The medtech industry is one of Ireland's greatest success stories with as many as 18 of the world's top 25 medtech companies developing next generation devices here. The sector employs over 27,000 highly skilled people and exports over €8.5 billion worth of health products annually. IMSTA believes the Irish health service can build on the intensive investment in medtech to deliver a better, sustainable healthcare system accessible by all the people of Ireland.

It is our shared view at IMSTA that numerous challenges for industry and healthcare providers lie ahead and will ultimately constrain the effectiveness of the healthcare system to achieve optimum outcomes for the patients it serves. These include:

- *Silo budgets preventing a more holistic approach being taken*
- *Lack of clinical engagement in procurement*
- *Commoditisation of health products*
- *Failure to evaluate medical technologies from the patient's perspective*
- *Lack of real world data on outcomes*

In addition, procurement currently remains a transactional process, with a focus on driving down the purchase price of individual items rather than capturing the capability of a medical technology to improve the value (outcomes set against cost) and quality (defined as clinical efficacy, patient experience and safety) of the overall healthcare intervention. Continuing on this path is a missed opportunity and one that has negative consequences for Irish patients and taxpayers alike.

We propose five key recommendations for further discussion with the Oireachtas Committee on the Future of Healthcare. These include:

1. **Government should adopt a 'value-based' procurement strategy** to harness innovation to deliver better patient and public outcomes through new medical technologies and treatments [1].
2. **The setting up of a single Health Technology Assessment agency** to align expertise and methods for the life science sector as a whole, to develop a value-based healthcare approach to the assessment of procedures, therapies and medical technologies.
3. That **1-2% of the health service non-pay procurement budget be provided annually**, primarily to SMEs, to fund the development of specific solutions for unmet health needs.
4. The Committee consider **the potential benefits of the Academic Health Science Network (AHSN) model** and use this to inform the development of equivalent structures in Ireland.
5. The **Committee invite IMSTA and other such stakeholders to develop the above proposals** for detailed consideration by the Committee.

We are strong proponents of the decision to consider a longer term view for health care and health policy in Ireland. IMSTA wishes to make a positive contribution to the debate, discussions and decisions that lie ahead. We look forward to discussing the content of this document in further detail in the near future.

1. Introduction to the Medtech Sector

IMSTA is the representative body for medical technology manufacturers, distributors and service providers in Ireland. We represent a sector that provides health products, services and information in the fields of prevention, diagnosis, chronic management, acute intervention, remote monitoring, rehabilitation and palliation.

Medical technology or 'Medtech' is a subset of Health Technology, defined by the World Health Organisation [2] as the "application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives."

Medtech offers the opportunity to revolutionise healthcare in the same way that other parts of our lives have benefited from the internet, smartphones and social media. It offers huge potential to improve the quality of healthcare delivered through earlier diagnosis, less invasive treatment options and reductions in hospital stays and rehabilitation times.

Medtech can facilitate the management and treatment of patients at the lowest level of complexity, leading to more self-care and self-management, more local diagnosis, treatment and management. Take as an example the case of Donal Burke a schoolboy suffering with Type-1 Diabetes (Appendix 2). When the HSE supplied him with an Insulin Pump his life was totally changed, as was the life of his family, and the burden on the health service was greatly reduced. This simple-to-use technology gave the boy back his life at minimal cost.

The Medtech industry is one of Ireland's greatest success stories with as many as 18 of the world's top 25 medtech companies developing next generation devices here. The sector employs over 27,000 highly skilled people and exports over €8.5 billion worth of health products annually. IMSTA believes the Irish health service can build on the intensive investment in medtech to deliver a better, sustainable healthcare system accessible by all the people of Ireland.

Medtech companies can also help the health system through productive partnerships and / or collaborations where the financial burden and risk is shared. Many other countries / healthcare systems utilise approaches such as Managed Equipment Service (MES) sourcing strategies, capital funding agreements, operational expertise, risk-sharing for outcomes, health economic analysis, and international benchmarking to deliver added value.

The benefits of medical technology are immense and their value to the health service should be considered in terms of outcomes rather than simply the front-end purchase price.

Patient / Health Benefits

- Medtech **can save peoples' lives.** This happens in emergency situations, i.e. heart failure or an inflamed appendix where surgery is needed

- Medtech also **saves lives by diagnosing** a health problem accurately and at an early stage or by preventing a disease through modern testing methods

- Patients can recover faster than ever through medtech: less invasive surgeries, more efficient technology and integrated processes **allow for significantly reduced hospital stay times**

- Technologies aimed at prevention **allow early and accurate diagnosis** and can thus deter diseases and ailments

- Medtech provides easy-to-use, personalised technologies and e-solutions, **allowing a high level of self-management,** especially for people living with chronic conditions

2. Issues with the Status Quo

Like many health and well-being systems throughout Europe, the existing acute sector-led arrangements in Ireland were not designed to address the challenges of a growing, older population with long term conditions.

A more holistic approach is required. Not only should the principal of local, least complex and least expensive care be at the core of the strategy – a primary care led service – but acute services should be rationalised to support a 'population health' approach with specialist services on an integrated basis.

Rationalisation of acute services will be necessary to support a primary care led integrated health and well-being system. It will be necessary to release investment to develop:

- *Primary care and community services – to meet 90-95 per cent of health and personal care needs* [3]
- *Secondary care based national clinical programmes – with the least complex care most local*
- *Specialist treatment and research centres*

Primary care should have dedicated resourcing for access to technologies, including diagnostics (imaging, laboratory tests, etc.). Access to such technologies will:

- *Enhance the quality (safety, efficacy and patient experience) of services*
- *Support increased 'out of hours' primary and community care services*
- *Facilitate less reliance on hospital based emergency services and a greater proportion of people's care needs closer to home.*

Research by the Irish College of General Practitioners/Irish Cancer Society [4] identified the need to improve access for GPs to diagnostics, with current structural problems causing unequal delayed access and barriers to healthcare provision for all socio-economic groups in Ireland, especially patients who utilise the public healthcare system. The report makes recommendations, inter alia, for greater access to diagnostics and improved information sharing and workforce planning. These actions – prompted by the technology - would impact substantially on the landscape of cancer services in Ireland.

There are also significant, currently unrealised, opportunities to apply novel technologies to improve outcomes and reduce unwarranted variations in clinical and cost effectiveness within the acute sector. Best practice hospital care is becoming increasingly more specialised and the application of national clinical programmes to ensure hospital groups provide the necessary standardised models of care on a national and regional basis should have regard for the use of medical technologies.

There are a number of challenges for industry and healthcare providers if the benefits of novel medical technologies are to be realised.

- *Silo budgets preventing a more holistic approach being taken*
- *Lack of clinical engagement in procurement*
- *Commoditisation of health products*
- *Failure to evaluate medical technologies from the patient's perspective*
- *Lack of real world data on outcomes*

Procurement currently remains a transactional process, with a focus on driving down the purchase price of individual items rather than capturing the capability of a medical technology to improve the value (outcomes set against cost) and quality (defined as clinical efficacy, patient experience and safety) of the overall healthcare intervention.

Greater savings are to be made through the innovative and transformational changes to services that novel technologies can enable rather than the reductions in price achieved in the current environment – especially given that technology usually accounts for a very small percentage of the overall patient pathway costs.

For example, the decision to procure wound pads centrally does not take into consideration the number of times wound pads will need to be changed by a community nurse. What is the cost to the HSE to send a community nurse to visit a patient in their home compared to the price of a wound pad, let alone the interruption to the patient's daily life (work, caring, study, etc.)? See 'A More Holistic Approach' in Appendix 3.

International research findings conclude that a singular focus on procurement price can result in a failure to reduce total healthcare costs [5].

Consider the comments of a successful indigenous SME on the marked impact current health system inefficiencies has on their ability to deliver their health products and services in the way that we do to other customers;

> ***"The HSE method of procurement greatly restricts the ability of clinicians to gain access to these cutting edge technologies. Clearly this has an impact on the clinicians who would use them and the companies who would provide them, but more importantly has an impact on the patients who would benefit from receiving them.***
>
> ***We have much to be proud of in our medical device industry but, at present, the body responsible for acquiring the products they yield, is sorely lacking in its ability to ensure our population benefit from the outputs generated.***
>
> ***Our experience with the HSE . . . should provide an insight into the complex and often challenging aspects faced by commercial entities attempting to deliver goods and services into this organisation. Despite an earnest desire and clear capacity of companies such as us to deliver high quality health products and services in an efficient and mutually beneficial way, the HSE, in its current position, does not possess the ethos to meet such offers in a meaningful or impactful way".***

A culture in the health service and in government generally needs to be developed that sees industry as a strategic partner rather than a transactional supplier of goods and services.

At present, in the absence of such a strategic partnership, there is no requirement on industry to demonstrate that products can realise population health benefits and address resource allocation challenges, within the context of a relevant patient/disease time period, as opposed to the current annual budget cycle. This is further compromised by a focus on price and 'easy' data such as percentage spend against GDP or bed-stays rather than more difficult but more useful 'real world' outcome measures.

3. The Opportunity that Exists

The true value of any health and well-being intervention or system are the outcomes achieved for any individual or population, set against the cost [6].

Many European countries have sought to measure healthcare value over the past decade but have focused on 'processes' rather than outcomes. This is reflected in the various initiatives to improve the efficiency of payment systems, although of late there is a trend for governments and health policymakers to introduce performance goals for providers as part of the process of reforming reimbursement systems.

A move from 'block payments' to 'episode-based' payments to one or more providers represents a more co-ordinated approach to treatment by rewarding a single pathway of care and making better use of more expensive services, such as hospitals [7]. Advocates of such payment systems say that they are especially efficient for the treatment of chronic conditions. The Netherlands introduced such a system in 2010 for the care of diabetes, chronic obstructive pulmonary disease (COPD) and for vascular risk management. German insurers have been able to negotiate integrated contracts with multiple health providers since 2000 [8].

The introduction of Activity-Based Funding (ABF) in the hospital sector in Ireland sees providers funded in line with the activity that they undertake. The absence of an effective activity-based system has meant an absence of transparency around costs and has undermined adoption of new innovations which could improve access to earlier diagnosis [9]. The ABF approach is a fairer and more transparent system of resource allocation that will establish a clear link between money and activity because hospitals will be funded based on the quantity and quality of services they deliver to patients.

However, ABF will have to be utilised system-wide instead of solely in the acute hospital environment if integrated care through the health service is to be measurable.

Community Healthcare Organisations (CHOs) and the Hospital Groups will have to be geographically re-aligned and a new governance structure developed to manage greater coordination of health care providers in order to provide care for a geographic group of patients. An Accountable Care Organisation (ACO) offers a good example of this in practice and is an organisation characterised by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients.

The challenge to both the medical technology industry and government is that medical technologies, whether:

- *high volume/low cost technologies or low volume/high cost*
- *technologies that are single use disposable or implantable, or*
- *assistive technologies including capital equipment which support the facilitation of a procedure or patient pathway*

are appropriately costed to ensure that no one hospital or provider is disadvantaged – such as using inferior technologies to 'balance the books'.

However, a key precursor to the costing of medical technologies (whether for ABF or as part of a procurement process) is the assessment of whether the medical technologies are of value to the health care system. This can be achieved in many ways, most notably in terms of clinical efficacy and cost effectiveness.

A heath technology assessment (HTA) is a complex appraisal which should assess considerations of safety, efficacy (or better, 'real-world' effectiveness), innovation and ideally incremental cost-effectiveness, as well as social, ethical and legal factors. Whilst the assessment of medical technologies is within the remit of the Health Information and Quality Authority (HIQA), the National Centre for Pharmacoeconomics (NCPE) has traditionally had responsibility for carrying out HTAs - exclusively for pharmaceuticals and not medical technologies. It is worth reminding that one of HIQAs functions is to carry out HTAs to inform safe and effective health policies that are patient focussed and achieve best value.

IMSTA contends that the health system in Ireland is inadequately resourced to undertake a methodical approach to the selection of innovative medical technologies or to provide an independent, timely and transparent assessment process. As a consequence, medical technologies are considered in cost terms alone. This leads to stifled adoptions and/or irrational price-lead procurement and undermines the contribution of medical technology to the development of ABF and a value-based approach to the improvement of the health and well-being of the nation [10].

The failure to appreciate the value – and processes to ensure the practical application of a value-based approach to procurement and reimbursement - of a medical technology, could for example lead to unwarranted variation across the public and private sectors (or between Ireland and other jurisdictions in the UK and mainland Europe) in the provision of:

- *Molecular tests to patients thereby denying clinicians detailed knowledge of a patient's cancer and therefore the best treatment options for them. (Early diagnosis often means a cancer is more likely to be treated successfully, intervention will be less complicated, and chances of survival may be higher, however, the ability to pay, cited by 88.5% of GPs surveyed, either 'always' or 'usually' affects access to referral services – ICGP/Irish Cancer Society 2016).*
- *Self-monitoring technology for conditions such as diabetes or for patients taking warfarin – reducing or negating the need to use hospital out-patient services. See Case Study in Appendix 4.*

One of the challenges for Governments and the medtech industry is gathering 'real world' data, especially with regard to outcomes, to inform development, as well as investment and procurement decisions. Whilst Ireland is already one of the most successful global medtech hubs – as mentioned above – it can continue to grow and consolidate. The opportunity exists to boost innovation and increase employment potential within the SME sector, as well support the production of 'real world' data.

Complementing the capacity and resources within the acute sector, Government should seek to utilise and develop the Small Business Innovation Research (SBIR) mechanism, a tried and tested government programme (widely used in UK and Europe, more recently in Ireland). It is intended primarily to help SMEs conduct research and development (R&D) but is not restricted to SMEs only.

Drawing upon a small, ring-fenced element of the health service non-pay procurement budget to find solutions for identified healthcare problems - the funding would be provided, primarily to SMEs, to fund the development of specific solutions for unmet health needs. In return, the Government would receive access to the innovative solutions developed. In addition to healthcare system savings and improvements in patient care, the multiplier effect would prompt other economic benefits, such as job creation [11].

As part of this approach, Government should seek to develop strong, sustainable, cross-boundary networks between industry, healthcare providers, academia and others, to support the development and spread of high-impact, designated innovative technologies to address the specified healthcare problems. Consideration should be given to the adoption of a model similar to the Academic Health Science Networks (AHSNs) in England.

IMSTA RECOMMENDS

1. **Government should adopt a 'value-based' procurement strategy** to harness innovation to deliver better patient and public outcomes through new medical technologies and treatments (IMSTA 2015).

2. **The setting up of a single Health Technology Assessment agency** to align expertise and methods for the life science sector as whole, to develop a value-based healthcare approach to the assessment of procedures, therapies and medical technologies.

3. That **1-2% of the health service non-pay procurement budget be provided annually**, primarily to SMEs, to fund the development of specific solutions for unmet health needs.

4. The Committee consider the **potential benefits of the Academic Health Science Network (AHSN) model** and use this to inform the development of equivalent structures in Ireland.

5. The Committee **invite IMSTA and other such stakeholders to develop the above proposals** for detailed consideration by the Committee.

4. Concluding Remarks

IMSTA believes that the five recommendations outlined in the previous section are fundamental to the reform and future successful enhancement and delivery of public healthcare services in Ireland.

To repeat, we are strong proponents of the decision to consider a longer term view for health care and health policy in Ireland. The recommendations proposed at this point by IMSTA should be considered in the context of an overall reform programme. IMSTA wishes to make a positive contribution to the debate, discussions and decisions that lie ahead.

The medtech sector in Ireland has grown considerably in recent years. It is now estimated that 27,000 people are employed across 400 companies in this state alone [12]. In addition, directly exporting to over 100 countries worldwide, Ireland's medtech sector is now the highest employer in Europe per capita.

A continuous focus on innovation is key to all sectors, healthcare and medtech are no different in this regard. For IMSTA and all member organisations it remains a critical ingredient to the future success of the sector as a whole. It is our view that fostering an environment where innovation can flourish is central to achieving better patient outcomes and a sustainable healthcare system.

The medtech sector in general has considerable value to offer to the global health economy. We at IMSTA want to engage with you to ensure that Ireland optimises the opportunities that lie ahead, and that ultimately this supports patients in all healthcare settings across Ireland.

We welcome the opportunity to engage further and directly with you on this journey to a better and more sustainable healthcare system.

Appendix 1: About IMSTA

IMSTA is the representative body for the Medical Technology supply industry in Ireland.

IMSTA provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs and is a member of GMTA, the Global Medical Technology Alliance, whose members are national or regional medical technology associations which represent innovative companies that currently develop and manufacture 85 percent of the world's medical devices, diagnostics and equipment.

IMSTA member companies in Ireland include the full spectrum of medical technology supply and service companies from SMEs to MNCs, many of whom have R&D and/or manufacturing facilities in Ireland.

IMSTA member companies provide highly trained clinical professionals, biomedical / clinical engineers and medical scientists to support the medical technology in use in the Irish health service. They provide training for clinicians, nurses, biomedical and clinical engineering and other health care professionals in the application and the use of innovative medical technologies.

"Members of IMSTA provide safe, effective and innovative medical technologies that save and enhance lives, benefiting people and society".

Previous publications include:

2015 Health Policy Paper – proposing SBIR mechanism

2015 NEW APPROACHES for procuring Effective Healthcare Solutions

2014 'Should Ireland have a framework for evaluating new medical technologies?' (Discussion paper)

2012 A Review of Current Procurement Practices in Ireland (with DCU and Enterprise Ireland)

2011 Investing in Medical Technology: Good for patients and good for the economy

2009 Working together to improve patient outcomes: A partnership approach to Medical Device Procurement

Appendix 2: Case Study A
Freedom at last, thanks to medical technology

The first speaker at the IMSTA annual conference was a seventeen year old Dubliner, **Donal Burke**.

A Leaving Certificate student at Castleknock Community College, he is a keen sportsman and musician. He plays hurling and Gaelic football as well as the guitar. However this tall, confident and good looking lad has had to live with a disease that affects thousands of Irish people every year. Since Donal Burke was three years of age, he has managed Diabetes, type 1. However this has not been without inconvenience and difficulties.

“All my life I have had to make sure that sugar levels were properly controlled. That meant that I had to eat three meals at the same times, every day, even if I was away on holidays and the time zone was different.

“I also had to make sure that I had access to my insulin injections. So when I was going to school, heading off on holidays or even going out to play football with my mates, I had to be careful. I usually ended up with a case for my clothes and another one with the syringes and medication,” he explained.

Five years ago Donal swapped the needles and injection for a special diabetes pump, which monitors his condition and allows him to pump the correct dosage of insulin when required.

His mother, Jacinta, was reluctant to move to the pump, but Donal and the local nurse convinced her to let him try it. “It was not that I did not like the pump, but Donal had been great managing his diabetes and had been taking his injections. I was afraid of change rather than fearful of a pump. But they convinced me to let him try the pump. And to be honest, after a month or so, if anyone tried to take it off him, I’d have kicked up murder,” Jacinta explained.

“The pump allows Donal to lead a normal life. He is now 17 years of age and six foot one. So I can’t really baby him anymore! However the fact that he has grown so tall so fast has brought its own problems. The amount of insulin required varies so we have to be extra careful”.

Night time is the worst as this is when the insulin levels are at their lowest. Maturity has resulted in Donal’s condition fluctuating. Indeed he has had two or three diabetic comas before he got the pump.

Eighteen months ago, the medical team who look after Donal identified a new pump with advanced facilities to help him take better control of the condition. This new pump, not only alerts you if your insulin levels are low, it also administers the correct amount for you. Donal was the first patient in Ireland to get this new device and it effectively gives him the peace of mind and great quality of life.

He explained that for the first time he now can live a normal live and both he and his parents have the confidence to let him do so. “It’s the first time since I was three that my mother does not know my blood levels and while that suits me, she finds it hard to let go. But I can now play GAA and go on holidays knowing that I am not restricted to eating at the same time every day, or leaving my friends to check my bloods and inject myself,” he explained.

Appendix 3: Case Study B
A more holistic approach

In 2012, the **Stockholm County Council** (SCC), which runs most of the city's hospitals, offered an innovative tender for wound care products.

Instead of looking solely at product price, the invited bids included three hypothetical patient cases and asked bidders to calculate the total cost of treatment for each.

As part of the tendering process, suppliers needed to determine the total cost of the wound care element using a calculation model that the SCC provided: the calculation included the unit cost of the wound care dressings, the number of dressing changes, staff costs for time spent changing dressings (hourly rates for nursing were provided), as well as transportation costs to and from patients' homes. The tender also considered the expected level and frequency of complications caused – or avoided – by using the suppliers' wound care dressings. It is notable that the winning bid came from the bidder with the highest-priced products: the company was able to show a lower total cost of care over time and could document its claims with clinical evidence.

Best practice: Requiring that bidders calculate the total cost of care – including costs related to complications – for a variety of patients helped SCC move beyond purchase price to consider costs on a more holistic level.

Appendix 4: Case Study C
Self-management in the home

An example of the use of technology and education to transform care for patients is the warfarin monitoring service in Durham and Darlington, England.

An estimated 1 million people in the UK take warfarin; the medication is the most commonly prescribed anticoagulant, slowing the rate at which blood clots. In so doing, it reduces the risk of potentially seriously conditions such as deep vein thrombosis, pulmonary embolism, heart attack and stroke. However, its use involves careful monitoring, which has traditionally involved seeing a healthcare professional for a blood test to measure how quickly the blood is clotting. The test will indicate whether the warfarin dose needs adjusting or not.

These tests usually require attending a clinic, at least monthly and sometimes as frequently as weekly. There is significant disruption to a person's life; the challenge of securing time away from work or other responsibilities etc. Too often the impact on the warfarin patient means losing money and time – and overall quality of life with it. Patients cared for by County Durham and Darlington Foundation Trust now have the option to use a digital self-testing service.

They are trained to take a finger prick blood sample, put it onto a test strip, and then place the test strip in a monitor with which they are provided. The monitor gives a reading of the person's international normalised ratio (INR), a measure of how quickly blood clots, which he or she can then share with clinic staff via an automated phone call.

Software automatically shares the figure with clinical staff, who check it, and the patient receives an automated call back letting them know whether they need to adjust the dosage.

No need to attend a clinic. The patient can choose the time of day at which they submit their reading and at which they receive the call back with their dose.

It has also helped improve the patients' outcomes. Before the project began, these people were only in therapeutic range around 60 per cent of the time. By the end of the trial, time in therapeutic range had increased to around 75 per cent [13].

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IMSTA is an independent representative body for med tech suppliers in Ireland

Members of IMSTA provide **safe, effective** and **innovative medical technologies** that save andenhance lives, benefiting people and society