# Interview: Sinead Keogh â?? Director, Irish Medical Devices Association (IMDA)

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*Already the fifth-largest MedTech manufacturing hub in the world, Ireland is fast growing as an innovative center for the global industry, with several multinational R&D facilities in the country and a vibrant startup scene. IMDA Director Sinead Keogh discusses the changing regulatory and policy environment, how this is impacting the MedTech industry, and the steps that IMDA and its members are taking to achieve success.*

**Could you please provide an overview of the MedTech industryâ??s importance within Ireland today, and the role that Irish MedTech plays at the global level?**

Ireland is one of the top five MedTech manufacturing hubs in the world, employing more than 29,000 people across 450+ companies. It is a very large and regionalized industry in Ireland, and the second greatest employer per capita in Europe of MedTech professionals. In gross terms, this means that Ireland produces roughly 80 percent of the worldâ??s supply of coronary stents, 75 percent of prosthetic knees, over 40 percent of the worldâ??s contact lenses, and 25 percent of injectable diabetes products.

Our country is also a major hub for R&D as well as manufacturing. Firstly, the Irish MedTech sector has been a major recipient of foreign direct investment (FDI) in the past, and over the past five years, we have seen strong growth in job announcements for R&D-related positions coming from the FDI segment of the sector. Some of the multinationals behind this trend include Stryker, which has recently set-up an innovation center in Cork; Cook Medical with an R&D facility in Limerick; and Medtronic, which has an innovation center in Galway. Much of this investment can be attributed to the availability of talent and the financial incentives Ireland offers, including the most recently announced â??patent boxâ?•, as well as the robust business ecosystem here in Ireland.

Secondly, Ireland has also fostered a lot of indigenous growth and innovation with over 60 percent of the 450 MedTech companies operating here being Irish. This is testament to our strong ecosystem. Similar to the wider global MedTech industry, roughly 80 percent of the global MedTech industry consists of SMEs; this is partly a consequence of the relatively short two-to three year innovation lifecycle, and the â??relativelyâ?? lower investment required to bring a medtech product to market, compared to pharma, for example.

There are some particularly exciting developments happening in the startup scene, notably the convergence of the MedTech and ICT sector. New devices which are focused on information technology in connected health and big data are an important and growing market. The medtech sector is known for its ability to innovate. Irelandâ??s strength in IT means we are uniquely placed to develop new products. Connected health will define a new approach to promoting patient health and empowerment, as well as drive economic success.

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**What is the greatest challenge your members are currently facing?**

At an international level, and across Europe, some members are coming under pressure as hospitals and payers try to balance costs with increased demand for services. All stakeholders involved are currently working to find new ways to evaluate the value new technologies can bring to patients as well as payers. The MedTech industry is seeking new, more effective ways to promote better value to patients and improve awareness of the role which medtech can play in tacking healthcare costs through constant innovation.

This value can be quite substantial, for example, telemedicine solutions â?? particularly those which monitor predictive factors of acute health events â?? can significantly reduce the frequency of patient visits, reduce the number of hospital days, and decrease the number of sick days. These products may seem expensive relative to the traditional care pathway in terms of short-term cost but they offer the potential to generate very significant savings in the longer term and better for patient care.

However, as it stands, many markets are still very price-oriented, and it remains a critical challenge for the MedTech industry which is now looking to play a stronger role in promoting procurement decisions made on with a focus on value-based healthcare outcomes.

**The European Commission has recently introduced new legislation with the goal of promoting value-based procurement decisions; what effect do you see this having on the industry?**

Certainly, there has been a number of welcomed policy changes influencing the way that procurement decisions are being made. The new public procurement directive, Directive 2014/24/EU, encouraged public entities to consider full life-cycle costs and the price-to-quality ratio rather than just the upfront purchase price when making procurement decisions. It also introduced a new procurement procedure called â??innovation partnershipsâ??, which allows public purchasers to enter into structured partnerships with innovators during development, and the subsequent purchase of the final product. EU countries have been implementing laws and policies to this effect over the past two years.

While this is certainly a step in the right direction, the challenge is that while hospitals and payers may now have more freedom to make decisions based on non-price factors at present, more work can be done to further develop procurement models and the processes by which new technologies and their potential overall budgetary impact are assessed. As such, there is currently a lot of variation in how procurement decisions are being made across countries, regions, or even hospitals. New economic models will be required that can evaluate the impact of new technology on the longer term outcome and total cost of a patientâ??s illness will need to be considered, as opposed to models that are based on cost alone.

**What steps have you and your members taken to encourage purchasers to develop more consistent approaches to assessing the value of innovative technologies?**

IMDA is involved, through MedTech Europe, at an EU level in the development of a new model that incorporates different criteria to help analyse the value of innovative products, in order to aid healthcare professionals and administrators in making better procurement choices. The model is essentially a software package that takes into account information regarding upfront costs, healthcare outcomes, sustainability, disposal costs, and many other factors.

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Testing of this model began two and a half years ago, and now it is being piloted in 10 different European jurisdictions. In fact, we are currently engaged in discussions with an Irish hospital to test it. As the model becomes more refined and widely adopted, the idea is that it will provide a much more effective framework for assessing products.

IMDA also has a very active regulatory steering committee, with many of its members holding international responsibility. These individuals have been active in inputting into the new Medical Device Regulations (MDR) and in vitro diagnostics (IVDR) which was reached a political agreement this summer. The two regulations include measures which will have a significant impact on patients, regulators and industry. The MedTech industry recognises the importance of these updated regulations and the implementation will require substantial resources from all stakeholders. It is critical to keep the overarching goals of patient safety and innovation in mind during the translation into implementable rules and it is critical that the large volume of secondary legislation transfers this complex framework into feasible and implementable rules, whilst avoiding unnecessary bureaucracy for all involved parties. The industry will continue to work together with legislators and other stakeholders to achieve this objective.

**How do you see these policy changes affecting the way your members operate and carry out innovation here in Ireland?**

The MDR will bring a lot of changes to our industry from an operational and financial perspective as well as affect other key business functions. To ensure that our members are adequately prepared, IMDA has organized several workshops on the implications of these changes. We also launched a two year Regulatory Affairs Masters last year, funded by Skillnets, to support the development of regulatory talent and we are currently working on a number of shorter programmes.

From an innovation standpoint, there are a couple of key trends that must be explicitly recognized. The first is that drive towards disruptive innovation; on the whole, payers are now much more scrupulous towards paying for innovation; they are no longer willing to pay for incremental innovations with limited patient impact. Secondly, we are also a seeing a lot of â??proceduralâ?? innovation where companies are working with physicians to streamline and make procedures more efficient.

Taken together, these trends will push innovators into a more radical space. Startups will still likely be the source of the majority of innovative technologies. That said, with increasing development and compliance costs, startups will require more investment to bring them to a stage where they can hope to be acquired, if that is the path they have chosen.

**What are some of the initiatives the IMDA is currently leading to help foster innovation here in Ireland?**

One of our four key focus areas from our 2020 strategy to make Ireland a global MedTech hub is to promote collaboration between MedTech and other strategic industries, including biopharma and ICT industries. Ireland is an ideal location for innovation through convergence, with 18 of the worldâ??s top 25 MedTech companies in the world operating here alongside nine of the top 10 biopharma

manufacturers and all of the top 10 ICT businesses. And as a relatively small country, it is an easy place to build networks and relationships within and across industries.

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To support innovation in this space we set-up a formal group between the IMDA and ICT Ireland, which is the Ibec group which represents the technology sector in Ireland. We also appointed a number of connected health companies onto the IMDA board, who are helping to help drive our strategic direction in this area. Within the context of this group, we have had in-depth discussions about how to make Ireland an optimal location for these cross-industry projects to take place. Now, we are working on a strategy to improve Irelandâ??s capabilities in this area and promote its application.

One of our major initiatives is the undertaking of a global foresight study on skills that will explore the future needs of industry to help us build that capability. This will be needed by industry to ensure theyâ??ve the talent to develop connected health technologies in the coming years, and understand the regulatory requirements, specifically in the area of cybersecurity. Of course the greatest challenge remains the business model for these technologies and their commercialisation. There are many existing examples of pilot programmes across many jurisdictions; however, examples of full scale integration of connected technologies throughout entire healthcare systems are limited.

Another area where we see potential to improve the ecosystem is by leveraging the significant investment to date in our clinical research infrastructure. Steady progress has been made in recent years; however, the level of medtech clinical investigations taking place in Ireland is currently low considering the number of medtech companies here. We now have seven clinical research facilities in Ireland and have recently launched a new agency, the Clinical Research Coordination Ireland, funded by the Health Research Board, which is a one-stop-shop to guide companies who want to engage in clinical research here.

This year, the National Healthcare Innovation Hub will be launched in Ireland, itâ??s a welcomed initiative which will support companies by facilitating the trialing and evaluation of products in clinical settings (primary care, hospitals, pharmacies and community health centres). It will connect them with clinical teams, patients and management teams as well as the research expertise needed.

BioInnovate Ireland, which is now in its fourth year is starting to make its mark on the startup scene in Ireland. Itâ??s a national medtech training programme that aims to act as a neutral territory in which academia, clinicians and industry can collaborate to develop novel medical technologies. The programme involves a strong partnership between multiple universities as well as hospitals all over the country. To date the programme has delivered many spin-outs and entrepreneurial talent. IMDA supports the programme and currently run a startup network in collaboration with BioInnovate called Medtech Brew.

Whilst there are excellent examples of leadership within Irelandâ??s healthcare settings, hospitals and primary care centres, we are working towards further developing our R&D capability and the promotion of early adoption of new technologies in healthcare settings. Ultimately, we are very optimistic about the future trajectory of the Irish MedTech landscape and we are committed to being one of the key drivers of this industry.

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