Brexit and the Irish medtech sector

Opportunities, risks and important negotiation recommendations
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The departure of the UK from the EU represents a profound change for Ireland and Irish businesses. Any change in the EU-UK relationship will likely affect Ireland more than any other EU 27 country due to our unique relationship.

Manufacturing is a major industry with more than 4,000 businesses employing more than 230,000 people. The sector had net sales value of €52.6 billion, excluding the pharma and food sectors, in 2015. Some manufacturing businesses are reliant on the UK market and supply chain with cheaper sterling driving competitive pressures. The largest manufacturing sector with goods exported to the UK was medical products at €1.5 billion. The medtech sector employs 38,000 people with a further 4,000 expected to be added by 2020.

During the recent recession, between 2008 and 2012, a lack of competitiveness meant domestic manufacturers struggled to compete with the number of companies and employment falling. The medtech sector and some other manufacturing industries responded to global economic changes by undertaking extensive measures to adopt lean practices and make Ireland more competitive. Now Ireland is the greatest recipient of Shingo Awards for operational excellence, per capita, in the world.

We must not lose these hard-won competitiveness gains, having the right business environment, infrastructure and skills will be essential. While we have seen a steady stream of international investment into Ireland with job growth right across the country the UK is taking steps to increase its attractiveness in the wake of Brexit. The UK is exploring new trade relationships and adopting polices to promote a more business friendly environment, underscored by greater competitiveness.
These changes could be compensated for with new opportunities as Ireland's position as the gateway to the European market with just over half a billion potential consumers.

The far reaching consequences of Brexit will not be limited to affecting businesses in Ireland and Europe. There are also serious implications for patients with access and safety being the primary concerns.

Medtech saves and improves lives. This is driven by continuous innovation by industry, with the sector arguably being the most innovative in Europe with more than 13,000 patents filed last year.

Globally there are more than 500,000 medtech product types on the market with new products designed on an ongoing basis to meet the growing demands for healthcare solutions in the face of limited resources and the rise of chronic disease.

Ireland is a leader in medtech with products manufactured here helping patients across the world, 80% of global stent production is here, 75% of orthopaedic knee production, and 25% of diabetes sufferers rely on injectables manufactured here. But to get them to the people that need them we need to ensure continued convergence of our world-class regulatory regime under the EU Medical Devices and IVD Regulation with well-equipped notified bodies certifying products to enter the market.

In Europe we have relied for over 25 years on the CE marking system, underpinned by the New Legislative Framework. This has allowed patients throughout Europe timely access to life saving and enhancing health technologies. One of the biggest concerns expressed by manufacturers, regulators and patient groups over Brexit is the uncertainty regarding the future regulatory framework in the UK.

This is further complicated by the fact that the current regulatory system is being updated and a new Medical Device Regulation (MDR) is currently being introduced, in stages, such that it will be fully implemented across the EU by May 2020, 14 months after Britain’s exit date. Any divergence in regulatory systems would affect the implementation of MDR and potentially leave manufacturers facing two regulatory systems. For many of the small, innovative companies exploring unmet clinical needs that typify our industry, this added burden is unsustainable. This will result in some medical devices no longer being widely available in Europe and risk others never being introduced or developed.
Opportunities, risks and important negotiation recommendations

Regulation

Opportunity: Ireland has a strong reputation for regulatory compliance and has worked to adapt to EU changes and increase the supply of regulatory talent to ensure continued success. There is an opportunity to attract more EMEA and global regulatory functions into Ireland.

Risk: Detrimental regulatory divergence may occur unless EU regulation is transposed into UK law. There is also a risk that Ireland loses a strategic partner in shaping the future direction of the EU Medical Device Regulation and IVD Medical Device Regulation. Any regulatory divergence would mean manufacturers facing a potential time delay in obtaining market authorisations before other EU27 Notified Bodies were able to pick up the capacity left by the UK leaving the European network. Additionally, manufacturers with drug-device combination products which use the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) may need to use an alternative competent authority post-Brexit.

Market access

Opportunity: As an English speaking, EU member, with a world-class talent pool Ireland is well located to give access to the European medtech market. This market is the second largest in the world with an average growth of 4.4% for nearly a decade and is worth €110 billion. There’s an opportunity for firms to relocate activities to Ireland to minimise the effects and non-tariff measures and regulatory compliance costs.

Risk: Possible customs delays into the UK will require companies to review their capabilities and that of third party vendors. Along with customs delays, other impositions, additional administrative work and risk to sales may lead to added costs. Government should minimise these risks and businesses will have to carefully consider and plan for all possible scenarios.

66% of medtech companies said disruption of transit through the UK to the rest of EU along with custom and certification barriers and procedures was a top three concern, with 25% saying regulatory divergence from the UK.

Ibec Research Unit survey
Commercial

Opportunity: Nearly two out of three medtech companies surveyed by the Irish Medtech Association have commercial capabilities here. Additionally, 30% of FDI medtech multinationals plan to either expand or introduce commercial operations in Ireland. Ireland’s attractiveness may increase in the wake of Brexit as it offers easier access to the European market. This is not only expected to drive increased sales, but also catalyse R&D growth, with companies looking to identify more opportunities for early stage product development and market gaps.

Risk: Many FDI multinationals treat the UK and Irish market as one, Brexit will likely impact not only market access as a result, but also product development, and decision making. The closer these markets, the better businesses can continue to coordinate their work across countries. The most alarming impact could be the systemic discontinuation of a number of medical technology products manufactured in the UK, sold in our healthcare system due to the impact of tariffs should the UK become a third country. In some cases, medical technology products are manufactured under extremely tight margins and additional costs associated with tariffs may impact decisions to actually commercialise technology. Patient access and safety should be prioritised in negotiations by ensuring the supply of, and access to, medical technologies for patients and healthcare providers not only in Ireland, but across Europe.

Manufacturing excellence

Opportunity: Ireland has a world-class reputation for manufacturing which already boasts more than 4,000 businesses, employs 230,000 and accounts for nearly a quarter of Ireland’s economic output. There’s an opportunity to leverage this by embracing advanced manufacturing, with collaboration between MNCs, and SMEs, with investment in new technologies and processes driven by empowered talent.

Risk: Ireland must invest ambitiously in a new discrete manufacturing centre of scale focusing on the higher Technology Readiness Levels or lose out to the UK for investment. Companies may choose to collaborate and innovate with centres in the UK such as the Catapults. These supports for innovation and growth are making the UK a more attractive location of choice for manufacturing.
R&D

Opportunity: The UK has seen a downward trend in indicators for Horizon 2020, the EU’s largest research and innovation funding programme to date, with an apparent reluctance of participants to take on projects with UK partners. Ireland, which has won €475 million from Horizon 2020 since 2014 and ranks 13th in the world for university industry collaboration in R&D, is well placed to take advantage of this chance to grow our research and innovation capabilities further.

Risk: Ireland has close R&D links with the UK and collaborates on EU-funded R&D projects. The reduction in funding to the UK may require Ireland to seek out new partners and potentially miss out on certain projects.

Supply chain

Opportunity: There is an opportunity for Irish sites to win more supply chain leadership and EMEA responsibility from Ireland. To be successful, the government needs to promote measures to enhance the ability of companies to diversify trade with non-UK markets. The government needs to enhance international trading, logistics and supply chain content in education and training provision.

Risk: Manufacturers, including SMEs, will need to liaise with their suppliers or contractors and divert considerable resources to undertake value-mapping exercises of their current supply chain whether they export to the UK or not. This is because many raw materials or component parts of their medical devices may transit through or originate in the UK. While businesses need to develop contingency plans, government must take measures to minimise uncertainty. Additionally, any manufacturer which provides medical devices for clinical investigations taking place in the UK will need to assess supply chain impact for these devices.
Investment

Opportunity: Ireland already leads in Europe for attracting medtech FDI investment. Companies wishing to expand or set-up operations in Europe may choose Ireland to tap into our collaborative medtech cluster and ensure greater stability.

Risk: The UK without EU constraints are expected to continue to introduce policy measures to make it more competitive and introduce new measures to improve their attractiveness.

Talent

Opportunity: The UK Office of National Statistics is already reporting both a rise in the number of people emigrating from the UK and a drop-in people immigrating to the UK. There’s now an opportunity for Ireland to attract talent here if the right supports and environment exist to ensure we’re a location of choice to live and work.

Risk: Brexit has implications for talent within larger corporates, which may use the UK as a market for talent rotation. This may become harder to facilitate as immigration policy may change.
Important considerations for medical technologies during Brexit negotiations

Legally enshrine Brexit transition period

Implement a formal agreement to ensure the transition period officially runs up until 31 December 2020, at least, which takes into consideration the challenge of ensuring adequate notified bodies for re-certification under the new Medical Device and IVD Medical Device Regulations.

Promote regulation convergence

Close cooperation in any new EU-UK regulatory cooperation framework will be required to minimise regulatory divergence post-Brexit. This should include a convergence of the regulatory framework in key areas, notably, the implementation of the new Medical Device and IVD Medical Device Regulations to promote market access. Any new EU-UK FTA must include comprehensive, legally enforceable commitments to fair competition.
Important considerations for Medical Technologies during Brexit negotiations / continued

Ensure mutual recognition of CE marking certificates

UK Notified Bodies are used for a very large amount of CE marking activity, and the loss of this capacity could not be easily or quickly replaced. In a survey conducted by the Irish Medtech Association, 43% of its members said that they currently use UK designated Notified Bodies for their conformity assessment requirements, which is in line with the MedTech Europe estimate that 30%-40% of all medical technologies approved in Europe are reviewed by UK designated Notified Bodies. Irish existing and valid CE marking certificates issued by UK Notified Bodies should continue to be recognised until their expiration date. It is vital that UK Notified Bodies remain within the existing European network and oversight mechanisms and continue to be designated to assess devices for the EU27 and UK markets. UK Notified Bodies should maintain their Notified Body identification number independently of the future contractual arrangements, for manufacturers to avoid re-labelling challenges and related costs. 70% of non-EU based manufacturers use UK notified body services as springboard into the EU, further compounding the crucial role UK Notified Bodies play in supporting technologies to market.

Ensure cross-border medical device data flow via Eudamed

Eudamed is the European Databank on Medical Devices. Its purpose is to strengthen market surveillance and transparency in the field of medical devices, by providing national competent authorities with fast access to information. It also contributes to a uniform application of the current medical device directives and critically will play a greatly enhanced role in the application of the new regulations thus contributing to greater patient safety. Continued access to the EU27 Eudamed for the UK, and vice versa, should be ensured, without which there is a risk of information delay and lack of information concerning products on the market. Risks of information delay is also envisaged for clinical studies and data, reported adverse events and market surveillance, all of which might undermine patient safety. Additional concerns are in relation to clinical investigations, the departure of the UK severely compromises the patient population where medical technologies can be trailed under the EU Medical Devices Regulation.
Advocate for the UK to remain in the EU customs union

Advocate for the UK to remain in the EU customs union, support close cooperation and simplified custom procedures if they exit. An agreement on trade, customs and regulatory alignment on the island of Ireland should be framed in the first phase of talks. The UK and EU should also agree a common transit system early in the negotiations. In Europe, an average 10% of GDP is spent on healthcare. A trade agreement to prevent trade barriers that would decrease investment and delay patient access to care should be prioritised.

Promote customs cooperation

Close cooperation between EU and UK customs authorities is vital, with new pre-clearance procedures and mutual recognition. Businesses will need significant support to train staff in new customs procedures and upgrade IT systems, while customs authorities will need additional resources to address Brexit pressures.

Ensure common travel area and all island economy

Maintain the Ireland-UK Common Travel Area and support measures to preserve the Northern Ireland Peace Process. The future development of the all island economy must be an explicit shared EU-UK objective, matched with ongoing funding for key all island projects.

Alleviation measures

Adopt a temporary EU state aid framework to support companies through any adjustment period and the European Globalisation Adjustment Fund should be reformed to ensure it can address the economic fallout of Brexit. Funds amounting to 5% of the value of current annual indigenous export sales to the UK will be needed annually from domestic and EU sources to help Irish companies innovate, diversify into new markets, train staff and invest for the future.
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. This country is:

- 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 staggering 68% of 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
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 and represents over 80% of the employment in the sector. 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.

www.irishmedtechassoc.ie