



**Irish Medtech**  
Association  
**ibec**

# Irish Medtech Association Budget Submission 2022

Unlocking a new formula for  
advantage, built upon collaboration,  
innovation and capability

September 2021

The Irish Medtech Association is the business association within Ibec representing the medical technology sector. We have more than 250 members, located throughout the island of Ireland. Our broad focus is to promote and support an environment that encourages the sustainable development and growth of our FDI multinational and SME member companies. The Irish Medtech Association is led by a Board of CEOs and Chief Representatives, it implements its strategy through working groups and taskforces.

# Ireland's global medtech hub

**Ireland is one of the top five global medtech hubs, competing with the likes of Massachusetts, Minnesota and California in the US and Israel and Germany.**

We manufacture:

- + 80% of global stents
- + 75% of global orthopaedic knee production
- + 50% of ventilators used in acute hospitals
- + 25% injectable devices for diabetics

Our success is over a century in the making. Johnson & Johnson have been in Ireland since 1935, Abbott since 1946, and Siemens since 1966, with more global players coming here along with a dynamic startup community attracting international attention. Ireland's medtech industry in numbers:

- + 9 of the world's top 10 medtech companies have a base here
- + 450 medtech companies
- + 60% of companies are homegrown
- + 4 out of 5 are startups or SMEs
- + €12.6 billion in exports and growing

Ireland is also one of the top 7 employers of medtech professionals in Europe as well as the greatest employer of medtech professionals, per capita, with more than 40,000 people working in the sector.

Medical technologies, invitro diagnostics and digital solutions are used for the prevention, diagnosis, monitoring, and treatment of disease and other conditions. The importance of this life changing industry has been highlighted by Covid-19 with Ireland standing out as one of the top 5 producers of Covid-related products.

The Covid-19 pandemic has accelerated change with the adoption of new technologies and new business models. While the rate of technology adoption across industries typically follows an S-curve, adoption is slower for medtech due to regulatory and evidence requirements. Under Covid-19 digital health solutions development and deployment into health systems has been fast-tracked.



**Dr Sinéad Keogh**  
**Director, Medtech**  
**& Engineering, Ibec**  
**Director, Irish Medtech**  
**Association, Ibec**

## Ireland's global medtech hub / continued

The OECD has noted that the Covid-19 pandemic has highlighted the importance of international trade and interdependencies. No one country can produce all the goods it needs. Subsequently, supply chain visibility, efficiency, and resilience has come to the fore with businesses looking to embrace analytics, reduce costs, and meet changing customer needs as part of their supply chain management.

There are a number of enabling technologies driving innovation in healthcare. Artificial intelligence is being advanced by companies as a revolutionary tool which can inform early diagnosis, as well as support more sophisticated advanced manufacturing. Nanotechnology offers the potential to support better drug delivery as well as reduce the quantity of drug needed and has the potential to play a role in advancement of wearable technologies. Robotics has already transformed manufacturing and robotics are also making great strides in advanced surgery. The 3D printed medical device market is expected to reach \$1.88 billion by 2022, with surgeons seeing a reduction in operating times for patients who had their surgery planned with a 3D model.

The Irish Medtech Association' vision is for Ireland to be a global leader in innovative patient-centred medical technology developments, products and solutions. We believe that with the right business supports and policies, not only can Ireland take a greater share of the global medtech market but also transform lives.

**Dr Sinéad Keogh**  
**Director, Medtech & Engineering, Ibec**  
**Director, Irish Medtech Association, Ibec**

# Policies for growth

**Ireland is a good place to start and grow a medtech business. Since the early 1990s, the number of medtech companies in Ireland has risen from 50 to more than 450 as we've evolved into a high-tech, global medtech hub. We have become established as a location of choice for business and a gateway to the world's second biggest medtech market, Europe, which is worth €120 billion, however competitor locations are powering ahead.**

The Irish Medtech Association have set out its vision to make Ireland a location 'Where Digital Health Thrives' with Ibec's first major cross-sectoral campaign, developed with Ibec's BioPharmaChem Ireland and Technology Ireland. There is a huge potential for Ireland to be a leading global destination for the development and commercialisation of convergent technologies. For mature economies, such as Ireland, innovation is the chief driver of sustainable economic growth. Looking across Europe and further afield, many competitor economies are synonymous with their innovation capability which helps prime their innovation ecosystems for the next wave of development and opportunity. France will mobilise €7bn to deliver an ambitious health care innovation strategy to 2030. This strategy brings all key industrial and relevant stakeholders together with the ambition to make France a global destination for the research and development of health care solutions. In parallel, through positive government policies, Israel has become a leading destination for medtech and digital health innovation, whilst Germany continues to be recognised as an Industry 5.0 powerhouse.

Ireland is well positioned to build on its success and achieve new heights by gaining a greater share of the global medtech market which is forecast to grow 4.4% (CAGR) annually with sales expected to reach over €508 billion by 2023. However, to reach our potential we need to maintain our competitiveness and ensure we have the right business environment, as well as foster collaboration between adjacent LifeSciences and technology industries.

Personalised medical care is on the rise with greater adoption of digital health solutions. There is now an abundance of data, from clinical data, lifestyle data, real-time data, and more. Data has the potential to improve healthcare radically, but there are challenges to tapping into this valuable resource. Namely, data integration with technical and regulatory barriers, consumer attitude, and company cultures.



**Tom Clarke**  
**Senior Director, West**  
**Chair, Irish Medtech**  
**Association**

## Policies for growth / continued

However, policymakers must take measures to regain lost ground as Europe's medtech market has seen the gap with the US widen as it fosters better business predictability with a more agile regulatory environment that fosters transparency and innovation.

The EU has historically been a location of choice to develop, and launch life-changing medical technologies, however lack of predictability under the EU Medical Devices Regulation, which came into effect May 2021, and the Invitro Diagnostics regulations, which is expected to come into effect May 2022, has reduced its attractiveness. While these regulations were debated in the EU, the US has pursued the goal of being first among the world's regulatory agencies under the Medical Device Safety Action Plan and the US has advanced its lead as the biggest market at 43% compared to Europe's 27%. Over the course of the pandemic, the barriers to market entry were cut with the authorization of 250 emergency use authorizations (EUAs) since February 2020, in the US. This measure also ensured access to the latest cutting-edge technologies for US patients.

Moreover, while the sector is characterised by constant innovation to foster improved care, startups are the drivers of disruptive innovation. An incredible 95% of the European medtech industry are startups or SMEs. These small companies are increasingly adopting an America-first approach to launch new technologies and grow their businesses thanks to its improved policy environment.

While the Irish Government and state agencies have helped to foster an unparalleled era of medtech growth over the past 20 years, underscored by innovation and investment, our future looks uncertain unless policymakers take measures to maintain our position as a global leader.

In this document, the Irish Medtech Association sets out policy recommendations across four pillars, in key areas such as EU regulations, entrepreneurship supports, innovation incentives and skills development, to support the continued growth of Ireland's medtech community that's added investments and jobs across Ireland.

The Irish Medtech Association, our board, and working groups, have provided unique insights and we look forward to engaging with policymakers as well as stakeholders on these policy priorities.

**Tom Clarke**  
**Senior Director, West**  
**Chair, Irish Medtech Association**

# Pillar 1

## Enterprise and trade

**Ireland has become a medtech success story with FDI multinationals and start-ups developing innovative medical technologies while adding investment and creating jobs across the country. As we look to the future, we need the right environment to maintain our competitiveness and access to new technologies to support innovation and upskilling of our world-class talent pool.**

### **Advocate for tax policies that align profits with substance**

The global tax environment is changing. Proposals under the OECD/G20 Base Erosion and Profit Shifting (BEPS) initiative to drive greater alignment in international tax rules may impact on the future of our FDI-driven growth model, within which Ireland stands out as one of the top locations for medtech investment in Europe (Ireland is a second largest exporter of medical devices).

While our strategy might shift and adapt over the coming years, there are both challenges and opportunities. What Ireland will maintain, no matter what changes may come, are opportunities from our track-record of significant tax certainty and competitiveness in a world of greater tax uncertainty and higher rates. In this environment, we must provide certainty and innovative improvements to Ireland's current FDI tax offering, while making investments to help us compete in other key areas such as quality of life, infrastructure, and education. As part of Ibec, the Irish Medtech Association, supports engagement with the OECD to represent the voice of business by advocating that these international tax initiatives align profit with models of substance.

### **The Irish Medtech Association recommends:**

- + Respond to the challenges of BEPS by providing certainty that the corporate tax rate will be as competitive as possible, improving innovation supports and introducing accelerated capital allowances for investments in advanced manufacturing technology. Any future overruns in corporation tax revenues must be ringfenced for spending on non-tax elements of the business model such as infrastructure, innovation, education, and quality of life.

### **How Ireland will benefit**

Ireland has evolved from being an economic laggard to a country possessing one of the fastest growing economies in the developed world. Ireland is a model of substance as defined by the OECD's standards. The Irish business model is underpinned by six key characteristics namely: the evolution of our economic policies; global footprint serving global markets and attracting FDI investment; full business life cycle; world class globally competitive economy; global hub with the world's top companies having a base here; and clusters with diversity in the economy. As we plan for the future in the face of global change, smaller countries like Ireland must seek to ensure the global economy retains the open policies that benefit so many.

## Develop a national strategy for health industries for future competitive advantage

The need and benefit of undertaking a global outlook for health industries has been greatly emphasised by the COVID-19 pandemic. The far-reaching impact has seen national governments and international businesses respond at a pace and through collaborative means never seen before. Looking across Europe and further afield, many competitor economies are synonymous with their innovation capability which helps prime their innovation ecosystems for the next wave of development and opportunity. France will mobilise €7bn to deliver an ambitious healthtech innovation strategy to 2030. This strategy brings all key industrial and relevant stakeholders together with the ambition to make France a global destination for the research and development of health care solutions. In parallel, through positive government policies, Israel has become a leading destination for medtech and digital health innovation.

The medtech sector played a significant role in the global response to COVID. The combination of a changing location of health, a preventative focus, combined with a participatory and personalised expectation from patients is driving a need to innovate and collaborate across health industries. As the Irish sector looks ahead, a global outlook is needed to understand the future ecosystem in which it will play a key role. The wider 'Healthtech Ecosystem' focus must consider not only medtech, but also extend to biopharma and technology, as well as the wider ecosystem. We are calling on the government to develop a national industrial healthtech strategy. Led by the Department of Enterprise Trade and Employment, like Ireland's Industry 4.0 Strategy 2020-2025, and appoint an appropriate resource at the Department to oversee and implement same.

### The Irish Medtech Association recommends:

- + Develop a national industrial healthtech strategy, led by the Department of Enterprise Trade and Employment, similar to Ireland's Industry 4.0 Strategy 2020-2025. Appoint appropriate resources at the Department to oversee and implement same.

### How Ireland will benefit

Ireland is home to 9 of the world's top 10 medtech companies, 10 of the top 10 tech companies and 10 of the top 10 biopharma companies. Blurring of traditional industry lines continues, with many healthcare solutions now coming from convergence across these industries. In one segment, digital health, for example, we have already mapped out 200 companies in Ireland. Given this trend, national and/or cluster ecosystem strategies are becoming common place in countries known for healthtech and innovation. These regions have recognised the opportunity to develop a national collaborative approach for future competitive advantage. With sales of €15.7 billion forecast in digital health alone by 2024, and strong growth projections year on year, it's just one attractive area to drive competitive advantage for Ireland.



## Nurture entrepreneurship and support disruptive innovation

As many as four out of five medtech companies in Ireland are a start-up or SME. Medtech is the most innovative industry in Europe with nearly 14,000 patents filed with the EPO in 2018. The role of start-ups is different in the medtech community compared to other industries. The medtech innovation cycle is led by start-ups identifying an unmet clinical need and market opportunity. If the product is sufficiently innovative and differentiated from the competition, then following proof-of-concept and device development they can start to attract funding. There are several key milestones in the lifecycle of a medtech start-up with a funding injection needed at each stage to get to the next or risk the business failing. To ensure Ireland remains a location of choice for developing disruptive, life transforming medical technologies and help start-ups scale we need more funding and supports.

### The Irish Medtech Association recommends:

- + Increase in the threshold for the reduced rate of Capital Gains Tax from €1 million to €15 million to encourage risk taking and re-investment. Expand CGT entrepreneurs' relief to passive investors in high-potential and high-risk areas to increase the supply of equity for Irish companies. Losses on EIS investment should be allowed for CGT purposes and any capital gains on the sale of shares taxed as capital gains rather than as income, as is currently the case.
- + Reform of the Key Employee Engagement Programme (KEEP) to make it easier to engage in the programme and adopt it more rapidly, including an increase in the limit on market value of issue, but unexercised, shares under the scheme to €10 million to attract and retain talent.
- + Medtech founders experience of availing of the Employment Investment Incentive Scheme is mixed. Many have never used it, with some saying that the EIS limit and uncertainty caused by the current system are a disincentive to investing in medtech startups. We're calling on the Government to encourage investment in medtech startups by increasing the limit of the scheme to €2 million. The current level is severely restricting the flow of capital to firms.
- + Introduce a pro-forma R&D tax credit to help smaller firms overcome administrative costs and engage with the credit. The existing limit should be in line with UK's R&D tax relief for SMEs with more generous tax treatment, reduced additional recordkeeping requirements, cash repayments upfront, and 'advanced assurance' for the first three times you claim it. This would be in line with the OECD "Road Map for SME and Entrepreneurship Policy in Ireland". There should also be an increase in the science test limit to €100,000.

### How Ireland will benefit

There is currently a shortage of capital to support medtech companies in Ireland, therefore, the Government must look at all options available to support the growth and development of early stage medtech companies. Our research suggests that 7 out of 10 entrepreneurs rate Ireland's current policy on CGT as very poor. Competitor economies like the UK are seen as "way ahead" in terms of CGT according to a survey of Irish Medtech Association members. As many as 3 in 4 entrepreneurs rated Ireland's current policy on share options as poor or very poor. The UK, US along with Israel and Germany are seen as best in class for share options to attract and retain mobile talent. More than 7 out of 10 entrepreneurs said that Ireland's current Employment Investment Incentive Scheme (EIS) policy was average with many entrepreneurs considering relocating to the US, UK and Switzerland. With the right business environment and policies, we can make Ireland one of the top global start-up communities where the latest transformative medical technologies are developed.

## Inspiring girls and supporting female leaders

Most sectors of the Irish economy have shown improvements in female participation rates as well as management between 2001 and 2018 (Ibec Research Unit). But horizontal segregation in certain occupations, and vertical segregation in certain grades or levels remain significant challenges. The latest research by Ibec revealed that the number of women at Head of Function level for manufacturing dropped from 15% in 2001 to 3% in 2018 compared to other sectors which saw significant improvements like HR/personnel (72%), customer services (53%) and finance/accounting (39%). The manufacturing industry are working to reverse this trend, according to research conducted by the Ibec Research Unit, in association with the 30% club, and DCU, two out of five (41%) manufacturing businesses have a formal diversity and inclusion policy in place and two out of five (42%) manufacturing organisations felt that opportunities for women in their organisation had improved. To make Ireland a world leader for gender leadership, there are a number of key policy areas where the Government needs to match industry's ambition to drive meaningful change.

### The Irish Medtech Association recommends:

- + Urgently prioritise the commitments outlined in the 'First 5' strategy in a much shorter timeframe: Current commitments would see a doubling of the investment in ELC and SAC from a 2018 figure of €485 million to €970 million by 2028. However, doubling the funding will not meet the OECD (0.8% of GDP) or UNICEF targets (1% of GDP). This incremental approach to funding in the sector is failing to achieve the desired outcomes of First 5 and failing parents and children, employees and providers. A greater ambition for the early learning and care sector is required by achieving the €970 million target by 2024. Following the report of the Expert Group on the First Five Funding Model a renewed strategy and ambition that delivers on a fit for purpose early learning and school age care model needs to be costed and a strategic commitment to achieving the aims reworked.
- + Make gender leadership a priority by tackling challenges such as occupational segregation, gender stereotyping, the division of caring responsibilities, and the gender imbalance in decision-making.
- + Support labour market participation by not disincentivising work with unfair tax treatment of second earners in married couples and investing in measures to address the lack of affordable childcare.
- + Don't cut-off girls from careers by expanding subject choices in secondary school as subjects like engineering are more likely to be offered in boys or mixed schools currently.

### How Ireland can benefit

Extensive research has identified a strong correlation between diversity in management, better organisational effectiveness, and higher financial results, as well as widen the talent pool businesses can tap into. A recent McKinsey study found strong correlation between the presence of women in company top management and better financial results with a difference in return on equity of 47% between the companies with the most women on their executive committees and those with none, and a 55% difference in operating results. Diverse teams outperform homogenous teams, whether they be all-male or all-female, and better reflect the customers they serve giving them a competitive edge with diverse perspectives. Better growth with more women in the workforce can have wider benefits as closing the gender gap could add €12 trillion to global GDP by 2025, according to McKinsey "Women Matters" report 2017. With 655 million fewer women economically active than men, women are one of the largest pools of untapped labour in the world.

# Pillar 2

## Innovation and collaboration

**Europe is an established leader in innovation (R&I), delivering major advances in health research, with investment in medtech R&D in Ireland growing. The annual European Innovation Scoreboard shows that amid increased innovation performance across the EU, Ireland remains a Strong Innovator and, in 10th place, remains one of the top ten most innovative Member States, performing above the EU average. Ireland must embrace a new approach to unlocking competitive advantage. With tax and regulation advantages under pressure, and increased competition for the required talent, new differentiators must be exploited. We must unlock a new formula for advantage, built upon collaboration, innovation and capability.**

### **Globally competitive innovation ecosystem and R&D supports**

The average medtech worldwide R&I investment rate (R&I spending as a percentage of sales) is estimated to be around 8% in the medtech sector. Products typically have a lifecycle of 18- 24 months before an improved product becomes available.

We are calling on the government to scale public investment for research and innovation by 60% to reach €1.25bn per annum, to address higher education institutions (HEI) core funding, agency specific programmes, infrastructure, and industry-led innovation. In 2019, nearly 14,000 medtech patent applications were filed, and 10,475 patents were granted by the European Patent Office (EPO). IP development is key to the production of new knowledge which drives economic growth for incumbent and frontier firms. Corporate IP-related activities, particularly in terms of patents, must be a key part of our national enterprise strategy. Expanding patenting activities by indigenous and multinational firms will have spill-over benefits to innovation and manufacturing performance. The new unified patent system (including the Unitary Patent and the Unified Patent Court) will create a simpler and more efficient mechanism for obtaining and enforcing patents in Europe.

### **The Irish Medtech Association recommends:**

- + Support R&D activity in the SME community by fostering collaboration and making funding mechanisms more accessible, such as the Disruptive Technologies Innovation Fund, and Horizon 2020.
- + Extend the eligibility criteria for medtech startups to avail of Enterprise Ireland HPSU support from 5 years from the date of registration to 8 years from the date of registration for to reflect the typically longer lifecycle for medtech startups because of new data, clinical and regulatory burdens.

## Pillar 2: Innovation and collaboration / continued

- + Remove barriers that prevent industry from engaging with academia (correct and clarify IP ownership to bring it in line with international norms)
- + Invest in measures to grow R&D capabilities in FDI multinationals by continuing the funding of the IDA Innovate Start Programme.
- + Create a network of innovation districts throughout Ireland, which build on the deep research capacity of the anchor institution and local enterprise to leverage synergies between business, academia, innovators and educators in Ireland.
- + Target competitive EU funding by delivering the Research Excellence Strategy and enhance the visibility of Ireland's research by participating in key programmes such as for Horizon Europe, European Innovation Council and European Research Council programmes.
- + Make the Irish health system a testbed for innovation and support the scaling of transformative technologies through initiatives such as Health Innovation Hub Ireland.
- + Conclude the ratification of the Unified Patent Court Agreement without delay; undertake preparations for the Local Division in Dublin and launch a promotional campaign for the new court; and actively campaign to secure London-seat of the Central Division.
- + Focus needs to remain on making progress on IP, licensing, and technology transfer through industry-academic collaboration. This includes ensuring the IP Protocol encourages IP-driven start-ups and scale-ups to engage, develop and access knowledge. Work is still needed on raising awareness of the value of IP across the spectrum, from the classroom to the boardroom, and with special focus on entrepreneurs, start-ups, and SMEs.

### How Ireland will benefit

As the global trading environment becomes more competitive, the ability to innovate will help business to build resilience to such challenges. Boosting Ireland's overall capacity for innovation must remain a national priority. The high level of ambition of a robust, stable and future-orientated innovation system should be to focus on knowledge and technology creation and diffusion and building human capital.

A well-run Local Division (Unified Patent Court) has the potential to complement and expand corporate IP activities. It will build on our growing reputation for IP enforcement and position Ireland for global legal services. Enhancing Ireland's position as an IP hub would benefit SMEs, as well as securing further inward investment. The future location of the London-seat of the Central Division is critical to the Medtech sector. Its future location has yet to be decided, and it will be a political decision. It is clear we can put forward a compelling case.

## Ensure competitiveness through sustainable advanced manufacturing

Ireland is already a world leader in manufacturing and boasts more than 4,000 businesses which employ more than 260,000 and accounts for nearly a quarter of Ireland's economic output. Manufacturing in Ireland contributes 35.5% of the total economic output (value-added) which is significantly above the EU average of 14.1%. In fact, Ireland was the only country in Europe where manufactured exports grew in 2020, despite the Covid crisis. However, the business survey of the manufacturing industries which we published in 2019 worryingly revealed that, only 55% of companies have a partial digitalisation of manufacturing strategy, with only 17%, having a full digitalisation strategy.

Globally the manufacturing industry is experiencing a major shift to Industry 4.0 – with the digitisation and advancement of manufacturing processes and the ecosystem around them to create more adaptable, effective, and sustainable production lines. In December 2019, the Government published Ireland's Industry 4.0 strategy 2020 – 2025. The implementation of this strategy is paramount and the engagement and representation in delivery of this strategy is key.

We are calling on the Government to lead and enable digital opportunities by providing €5M for accelerated capital allowances for advanced manufacturing and €1 M towards mechanisms to help implement national strategies on digital, AI and Industry 4.0 and unlock further funding (from NDP, public and private spending) on digital and EU funding on digital, including leveraging the €85M provided for in the agreed NRRP (National Recovery and Resilience Plan) to drive further digital transformation across enterprise through the introduction of a new grants scheme for businesses and the establishment of European Digital Innovation Hubs (EDIHs). Post-establishment, Government should ensure that the EDIHs and the new Advanced Manufacturing Centre continue to have adequate resources to support shared ambitions to keep Ireland at the forefront of a digital future.

### The Irish Medtech Association recommends:

- + Immediate commencement of the development and Implementation of the National Digital Strategy.
- + Representation from the Irish Medtech Association and Ibec's Manufacturing Sectors representative bodies on Government's Industry 4.0 Stakeholder Forum to oversee implementation of Strategy and report on an annual basis to the Minister for Enterprise, Trade and Employment.
- + Incentivise manufacturing enterprises to embark on their digitisation journey, through step change programmes that positively impact on ROI. These government supports should be made available to help industry identify gaps in their digitalisation maturity and be collaboratively developed, such as; accelerated capital allowances for several areas of advanced manufacturing including computerised/computer aided machinery and robotic machines are also needed.

## Pillar 2: Innovation and collaboration / continued

The Government should also incorporate a 'step change initiative' to help companies make progress in their digital transformation journey. This can be achieved by working together with industry to identify trigger points for companies to receive an injection of supports, such as funding, grants, consultancy, and/or training. A benchmarking system coupled with a digital accelerator fund, which applies at certain stages of the digital maturity journey is recommended. This could be a hybrid model of Enterprise Ireland's company supports by 'stages of development' and their 'Lean Start, Lean Plus and Lean Transform' initiative.

- + Provide incentivised upskilling programmes to ensure employees have a greater knowledge of new methods for analysing and adapting processes and to drive a digital implementation strategy. The Skillnet Networks are very well placed to provide direct benchmarking and self-assessment diagnostic supports to firms. For example; The Irish Medtech Skillnet has funded the development a number of framework models including; the Medtech and Engineering Competency Framework and Operational Excellence Benchmark Model – which is currently being upgraded to the MÓRTM Transformation Model. This incorporates Enterprise Excellence and a Digital Maturity diagnostic, along with a skills competency framework.
- + Government to assist firms in applying for European Funding for Industry 4.0 through the Next Generation Recovery Plan. 20% has been assigned towards digital.
- + Maximise the use of Government funded research centres such as the new AMC, iForm, IMR, and accredited Institutes of Education for the off the job training for manufacturing engineering and the polymer technology apprentices.
- + Government must enable the relevant physical infrastructure to support advanced manufacturing by enabling further investment in high-speed broadband, 5G and fibre.

### How Ireland will benefit

Boosting the uptake of digital technologies along value chains and promoting business growth is deemed key to Europe's competitiveness. Ireland needs to enhance and grow our overall adoption of industrial digitalisation to ensure that we are staying abreast of new innovations, skills and technologies in order to remain competitive in manufacturing. The number one prohibitor to enabling digitalisation are capital supports and education – addressing these two key issues will be essential to improve our attractiveness as a place to do business for manufacturers by increasing jobs, our competitiveness and add significant value to our economy.

# Pillar 3

## Education and skills

**Ireland is one of the top employers of medtech professionals in Europe thanks to our rich talent pool of third level graduates and dynamic supports for upskilling. As a competitive knowledge economy, we need to build on our success by doing more to embrace lifelong learning to help people achieve their potential by embracing disruptive technologies and new careers opportunities in the face of ongoing social change.**

### **Support lifelong learning for a world-class knowledge economy**

Globalisation, rapid digitalisation, changing lifestyles and new consumer preferences mean jobs and careers are being transformed. As Ibec has outlined in its 'Smarter World, Smarter Work' campaign, the archetypal worker used to be a person on a production line or a salaried employee in an office. The needs of businesses and individuals are shifting, and so too are career paths. How organisations, government, and individuals respond to these trends will fundamentally affect the quality of our jobs and our lives in the future. To address this, public policy must focus on investing in an individual's employability and lifelong approach to skills development. At present, Ireland's lifelong learning rate is less than half the benchmark set by the EU and significantly below what is required by a knowledge-based economy.

Underinvestment in higher education is threatening the quality of Ireland's education system, widening the gap between Irish universities and their international counterparts and damaging Ireland's international reputation including our ability to attract research and business investment. The financial impact of the COVID crisis has further highlighted the difficult and uncertain funding environment facing higher education. A significantly higher level of sustained investment is essential for maintaining Ireland's competitive advantage and supporting national ambitions to be a global education and innovation leader

#### **The Irish Medtech Association recommends:**

- + Implement a sustainable long-term funding model for higher education. There must be a sustainable model across core, capital and recurrent funding to preserve the success and quality of Ireland's education offering: An additional €100m in core funding will ensure Ireland's HE system remains high quality, delivering programmes that enhance the graduate pipeline for Irish industry and support an engaging student experience.
- + Support enterprise-led skills development and greater educational attainment through the National Training Fund. Provide additional funding to Skillnets, which are a crucial part of the countries training infrastructure, linking employees and employers.
- + Ensure adequate resourcing of visa and work permit applications: Resourcing of work permit applications must be restored to at least pre-covid levels. Delays or impediments to bringing in key skilled staff from abroad must be eliminated. It is essential that there is no delay in processing permits and visas especially for trusted partner companies.

## Pillar 3: Education and skills / continued

### How Ireland will benefit

Ireland has one of the largest shares of tertiary education with 47% of 25- 64-year-olds having third level degrees, with 85% of tertiary educated adults employed and enjoying greater earnings according to the OECD. However, the OECD suggests that for skills to remain relevant, the domains of employment and education must work together to ensure education and learning is of high quality and has a long-term perspective. Lifelong learning through programmes like Skillnet and Springboard can help ensure upskilling and reskilling of the Irish workforce. The Irish Medtech Skillnet in 2019 trained over 1,950 employees and delivered over 14,000 training days for 195 companies with a budget of €1.7million. While the Connected Health Skillnet trained over 240 employed trainees and delivered over 1,000 training days for 60+ companies with a budget of €280k. Additionally, the Irish Medtech Springboard trained 60 professionals with a budget of €353k. We need to build on this success as we prepare for the future.

### Ensure the sustainability of the new apprenticeship programmes

The Irish Medtech Association and Polymer Technology Ireland launched three new apprenticeships as part of the Department of Education and Skills wider national strategy in 2017. The Manufacturing Technician (level 6), Manufacturing Engineer (level 7), and Polymer Processing Technologist (level 7) provide fundamental building blocks to future proof the medtech and polymer sectors in Ireland as well as meeting the skill needs of the broader manufacturing industry and creating world class talent. Companies have to pay a salary and subsistence for 15 weeks while the apprentice is off the job in college. Smaller companies are not engaging with the new apprenticeship programmes in Manufacturing Engineering or Polymer Technology fundamentally because of cost. Covid-19 had an impact on the numbers participating in the apprenticeships in 2020, however, we have seen a recovery in 2021, in part due to the €3k incentive and the positive press coverage for Apprenticeships. Despite this positive work, the overall participation of SMEs in the programme continues to be very low due to financial restrictions.

#### The Irish Medtech Association recommends:

- + Increase the incentive scheme to €7,000 per year to cover off the job expenses and reduce the financial burden for industry associated with taking on apprentices. This will bring the modern apprenticeships in line with the craft apprenticeship programmes.

### How Ireland will benefit

A sustainable funding model for these programmes can help the Government achieve its ambition to deliver a target of 10,000 new apprentice registrations per annum by 2025 as laid out in the Apprenticeship Action Plan 2021-2025. The medtech and polymer sectors are drivers of regional growth and investment. These apprenticeships can meet the demands of these growing industries and help them reach their potential by addressing skills shortages for technicians, engineers, and technologists as well as support staff retention through upskilling.



# Pillar 4

## Health and patient access

**There are more than 500,000 different types of medical technologies on the market ranging from glasses and wheelchairs to pacemakers and MRI scanners. To get to market a high bar is set for demonstrating safety, efficacy, and clinical benefit. With the EU Medical Device Regulation (MDR) which came into effect during May 2021, the IVD Regulation deadline approaching in May 2022, and the proposal for a new EU Health Technology Assessment Regulation, we must ensure that these regulations are fit-for-purpose and well implemented in full.**

### **Implementation of the new EU Medical Device and IVDR Regulations**

#### *Implementation of the new EU Medical Device Regulations*

Manufacturers must demonstrate that medical technologies meet EU safety, health and environmental protection requirements before they go onto the market. The new EU Medical Device Regulations represent the greatest change for the regulatory system in over 20 years. Although the transition period for MDR ended on 26 May 2021, the new regulatory system is not yet totally ready to support the transition of tens of thousands of life-transforming technologies from the old regulatory regime to the new. As the Irish Medtech Association has stressed over a number of years, this represents a critical situation for patients, healthcare systems and early stage medtech companies, especially the SMEs which represent 80% of the sector here. There are several significant challenges today that prevent manufacturers and their devices from being (re-) certified against the new rules of the MDR among these the lack of Notified Body capacity. As of July 2021, there are 22 notifications under the MDR (out of a pool of 55).

IMA conducted a member survey in March 2021 to gather information to help build a picture of the level of Virtual Audit activity nationally of 26-member company responses, 25 had undergone a virtual audit with a Notified Body. Members report that 75% of audits are a review of records which are for the most part in electronic format. Post Covid-19, all respondents would support using virtual audits as an auditing mechanism by Regulators/ Notified Bodies as it means that it's easier to schedule which prevents backlog situations for both manufacturer and regulator and less costly as no travel costs are incurred. The experience to date has shown that the efficiency and effectiveness of the audit is not compromised so industry would certainly be supportive of virtual audits continuing as part of a blended risk-based audit approach on a longer-term basis.

#### Pillar 4: Health and patient access / continued

##### The Irish Medtech Association recommends:

- + That Notified Body designation progress is progressed with urgency
- + Rapidly establish expert panels, so that devices depending on these panels can start going through MDR certification as soon as possible.
- + Ensure the rapid publication of Commission guidance documents to support industries implementation of MDR.
- + Avoidance of a fragmented Member State approach to the utilisation of remote/virtual audits during the ongoing Covid-19 pandemic and post pandemic environment.
- + That remote/virtual audit should form part of a bended approach to certifying manufacturing sites into the future. Remote audits and the associated rapid development of IT tools has also allowed the Notified Bodies to reduce their carbon footprint, meet UN Sustainable Development Goals, increase diversity and inclusivity, and increased transparency to the authorities.

##### *Amend transitional provisions to extend the grace period for EU IVD Regulation to ensure successful implementation*

The Covid-19 outbreak has highlighted how critical in vitro diagnostic medical tests (IVDs) are to our health systems. Medical tests are essential both for combatting the current pandemic and for diagnosing, measuring, predicting, screening, and monitoring other medical conditions in our health system including cancer, infectious diseases, and blood screening. For these tests to remain available to patients and healthcare systems, they must be certified under the new EU IVD Regulation 2017/746. Today there are around 40,000 medical tests on the EU market, of which approximately 35,000 need certification by no later than 26 May 2022.

Recent industry surveys show that at least 78% of manufacturers are encountering real-life problems in successfully certifying medical tests under the new IVD Regulation as, a significant number of manufactures do not yet have a notified body as there are only five designated notified bodies available which are already at capacity, limiting their ability to take on new clients (July 2021). To prevent shortages of IVD medical tests, the transition to the new IVDR system urgently needs to be given more time. Many healthcare stakeholders, including groups representing hospitals, Notified Bodies, laboratories, and healthcare professionals, have publicly shared their concerns as well.

## Pillar 4: Health and patient access / continued

### The Irish Medtech Association recommends:

- + Amend the transitional provisions to extend the grace period for the In Vitro Diagnostic Regulation, this is needed to prevent shortages of IVD medical tests, particularly for diagnostic devices that need to be up classified (use a NB for the first time). The regulatory system and infrastructure that is needed to comply with the new IVDR is not adequate at this time.
- + That Notified Body designation progress is progressed with urgency, particularly in relation to those Notified Bodies which support IVD devices.
- + Ensure the rapid publication of Commission guidance documents to support industries implementation of IVDR.
- + Avoidance of a fragmented Member State approach to the utilisation of remote/virtual audits during the current Covid-19 pandemic and post pandemic environment.

### How Ireland will benefit

The EU has historically been a location of choice for the launch of new medical technologies and Ireland has benefited from this with investments. However, a lack of predictability relating to MDR/IVDR coupled with an increasingly predictable regulatory environment in other markets, such the US under the FDA, means that the EU is no longer seen as the most attractive location to develop and launch new medical technologies.

This issue risks being further compounded by investors choosing not to invest in early-stage companies with plans to launch new products in the EU given the lack of business predictability thereby limiting patient's access to transformative technologies. Irish Medtech Association members advise that businesses here are continuing to win new product development projects and that product innovation is continuing to take place in Ireland, Irish based medtech companies are continuing to deliver life changing technologies to the global marketplace. However, the slow progress of MDR/IVDR implementation is creating an innovation backlog and some companies are adopting a 'US-first' launch strategy. This alarming trend will ultimately adversely impact Irish and EU patient access to new medical technologies if steps are not taken now to turn the tide.

## Make sure any Health Technology Assessment regulations are fit-for-purpose

Health Technology Assessment (HTA) is an evidence-based process that assesses the added value of a given health technology and compares it with the current standard of care. Current practice in the European Union is for HTA to be conducted at a national level. 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 spanning evidence factors, industry factors, user factors, and market factors.

### The Irish Medtech Association recommends:

- + Predictable joint clinical assessments for selected medical technologies (with transparent selection criteria, a predictable timeframe, use Real World Evidence, use fit-for-purpose methodologies, and involve technology developer in final assessment)
- + No interference of the HTA framework with regulatory assessments on medical technologies under MDR/IVDR
- + Secure a pre-defined and clear purpose on how clinical assessment reports will be used

### How Ireland will benefit

Healthcare spending continues to rise with a projected increase from €6.9 trillion to €9 trillion, 2017-2019, Deloitte (2019). This is ‘shining a light on health systems’ need to reduce costs and increase efficiency”. Within the medtech industry “investors talk about the 4 Ps: patient, physician, provider (i.e., hospital system) and payer”, now there’s greater scrutiny from payer to demonstrate value, EY (2018). 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. If these three recommendations are implemented, we can make great strides to supporting better decision making and HTA of medtech.

## Make Ireland a location of choice to develop, launch and adopt transformative digital health

Healthcare spending has been increased due to rising demands driven by ageing populations and the rise of chronic diseases. Many medtech companies are now future proofing their research and development (R&D) departments towards complete care solutions, looking at how digital technology can not only improve outcomes, but also improve the patient experience and deliver value. Our vision is to enable Ireland to become a recognised global hub for digital health, where companies can develop and commercialise products, as well as attract projects and investments.

### The Irish Medtech Association recommends:

- + Make Ireland a location of choice to develop, launch and adopt transformative digital health solutions with the right financing for businesses to ensure competitiveness (by reforming CGT, KEEP, EIS, and making the R&D tax credit more accessible, as outlined earlier), along with reimbursement policies that reflect international best practice.
- + Encourage health system transition by setting targets for investing in digital health solutions of 8% healthcare expenditure by 2030 like Germany, facilitate regular engagement between policymakers, business, and clinicians, as well as identify the right infrastructure and governance structures needed to integrate digital health solutions into the healthcare system.
- + Create a clear framework for data use, integration and sharing by reducing barriers to effectively using data by advancing the European Health Data Space, establishing a harmonised approach for data use, make Ireland a leader in cybersecurity.
- + Establish a regulatory pathway for digital solutions and services that is clear, agile and fit-for-purpose to optimise patient access to life changing innovations.
- + Attract and develop mobile talent by upskilling and reskilling people through the Connected Health Skillnet, as well as revising university curriculums.

### How Ireland will benefit

Ireland is uniquely placed to become a leader in this field with 9 of the world's top 10 medtech companies, 10 of the top 10 tech companies and 10 of the top 10 biopharma companies all having a base here. We have mapped nearly 200 companies, who are already delivering digital health solutions here in Ireland in a range of areas including, telehealth, data, analytics and cyber security, health information technology, connected medtech, mobile health and more. Moreover, with sales of €15.7 billion forecast in digital health by 2024, and strong growth projections year on year, it is an attractive area to drive growth, innovation and transform healthcare. "Health spending before Covid-19 was an average 8.8% of GDP in the OECD. Management of health spending has had to adapt to face the challenge of the pandemic, this is unsustainable, but Covid-19 has increased the adoption of digital health solutions in the health system.

# About the Irish Medtech Association

The Irish Medtech Association is the business association within Ibec representing the medical technology sector. The Irish Medtech Association has more than 250 members, located throughout the island of Ireland. The group's broad focus is to promote and support an environment that encourages the sustainable development and profitable growth of our FDI multinational and SME member companies. The Irish Medtech Association is led by a Board of CEOs and Chief Representatives, it implements its strategy through working groups and taskforces.

We also deliver training and upskilling for the MedTech and engineering businesses in Ireland through our apprenticeship and springboard programmes and our Skillnets Networks.

# About Ibec

Ibec is Ireland's largest lobby and business representative group. Our purpose is to help build a better, sustainable future by influencing, supporting and delivering for business success. With over 230 employees, Ibec engages with key stakeholders in Ireland and internationally through our six regional offices and our Brussels office, along with an extensive international network in the UK and US.

Ibec positions are shaped by our diverse membership, which range from small to large, domestic to multinational and our 38 trade associations cover a wide range of industry sectors. Ibec members employ over 70% of the private sector workforce in Ireland.

As well as lobbying, Ibec provides a wide range of professional services and management training to members on all aspects of human resource management, occupational health and safety, employee relations and employment law.

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