Irish Medtech Association
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Invest in Innovation, Invest in People

Irish Medtech Association
Priorities for the next Government


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Who we are

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 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.

Ireland is one of the top five global medtech hubs, competing with the likes of Massachusetts, Minnesota and California in the USA. We manufacture:

80% of global stents

75% of global orthopaedic knee production

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

In the past year more than half a billion euro worth of investments by FDI multinationals and funding for startups has been publicly announced with many new jobs added benefiting the national and regional Irish economy with strong clusters in Galway, Limerick, Cork, Waterford, Sligo and Dublin attracting investments and adding jobs in the community.

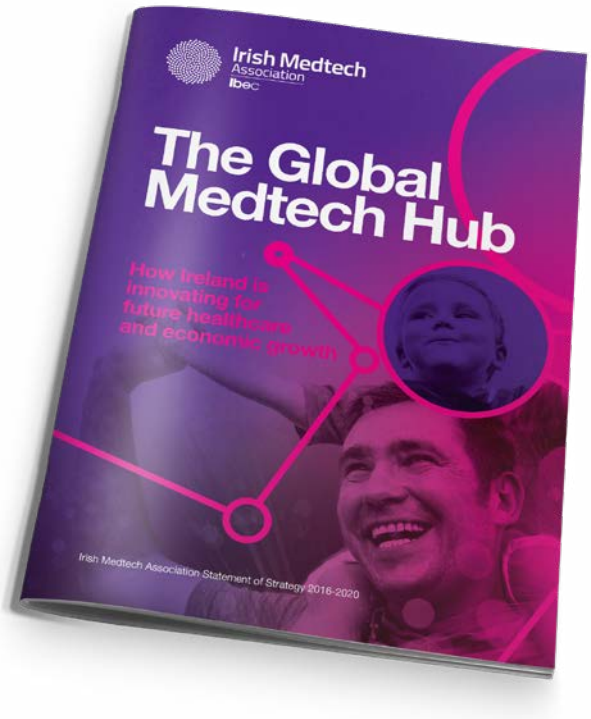
Ireland is also one of the top 7 employers of medtech professionals in Europe as well as the greatest employer of medtech professionals, per capita, with more than 40,000 people working in the sector.

What we do

Our vision is for Ireland to be a global leader in innovative patient-centred medical technology developments, products and solutions.

Irish Medtech Association has identified key priorities to ensure Ireland is innovating for future healthcare and economic growth in our strategy 'The Global Medtech Hub', namely:

- **Drive our future**
  Identify and influence key areas of focus such as trade barriers, skills needs, and changes to the business environment.
- **Achieve the potential of the cluster**
  Assist companies utilise the cluster to expand and achieve their potential developing new technologies from concept to market.
- **Use technological innovations to help patients**
  Facilitate cooperation between sectors such as pharmaceuticals, biotechnology and ICT and realise the potential for advanced, additive and cell manufacturing.
- **Nurture entrepreneurship**
  Develop policies and conditions to ensure entrepreneurship can thrive, such as facilitating new funding opportunities.



Welcome from the Irish Medtech Association Director

Ireland is a great 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 €115 billion.

Ireland is well positioned to build on this success and achieve new heights by gaining a greater share of the global medtech market which is forecast to grow 5.6% (CAGR) annually with sales expected to reach €530 billion by 2024. However, to reach our potential we need to maintain our competitiveness and ensure we've the right business environment.

The Government and state agencies have helped to foster an unparalleled era of medtech growth where medtech leaders innovated and thrived, but in the face of international economic and political change we need to ensure that Ireland remains a great place to do business.

In this document, the Irish Medtech Association sets out policy recommendations in key areas such as entrepreneurship, innovation, taxation, education and regulation 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.

Sinead Keogh,
Irish Medtech Association

Irish Medtech Association Priorities for the next Government

Pillar 1

Health and patient access

Medical technologies are used to prevent, diagnose and treat disease. 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) coming into effect May 2020, 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, well implemented and avoid regulatory divergence with the UK to ensure patient access to life changing technologies.

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 Medical Devices Regulations represent the greatest change in over 20 years. Although the transition period is nearly over, the new regulatory system is not yet ready to support the transition of tens of thousands of lifesaving and life-transforming technologies from the old regulatory regime to the new. As the Irish Medtech Association has stressed throughout the past two 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 very severe lack of Notified Body capacity. Most of today's 55 Notified Bodies are still awaiting their MDR designation, and thus may not yet start certifying devices to the new Regulation.

This is not expected to change for several more months. There is also a lack of expert panels, needed Delegated and Implementing Acts and much needed EU Guidance. Although the legal framework of EU 2017/745 establishes ways in which a manufacturer can temporarily keep a given medical device available to patients after May 2020 these approaches pose challenges and are insufficient in the long-term.

The Irish Medtech Association recommends:

- Progress with urgency the proposal to conduct a comprehensive "readiness check" with all key MDR implementation partners at EU level, to identify and prioritise the main implementation challenges for the medtech sector ahead of the date of application of 26 May 2020.
- Call for faster designation of Notified Bodies to the MDR and enable them to certify manufacturers' quality systems in as timely a manner as possible.
- Rapidly establish expert panels, so that devices depending on these panels can start going through MDR certification as soon as possible.
- Ensure the publication the most needed Delegated and Implementing Acts as soon as possible, including common specifications. As well as provide good-quality guidance in the most urgent areas eg, clinical evidence requirements for existing devices, to make MDR certification faster and more workable for as many devices as possible.

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 coupled with an increasingly favourable 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 people's access to transformative technologies. In addition to the lack of expert panels required by the new Regulations, newly MDR-designated Notified Bodies (9 organisations to date from a pool of 55) have no spare capacity to evaluate files for new/innovative products, neither under the MDR nor via the MDR Grace Period. While the Irish Medtech Association member survey reveals that businesses here are continuing to win new product development projects and that product innovation is continuing to take place in Ireland MDR implementation is creating an innovation backlog and some companies adopting a 'US-first' launch strategy. This alarming trend will ultimately adversely impact Irish patient access to new medical technologies if steps are not taken now to turn the tide. Being prepared for the new Medical Devices Regulations will mitigate against these negative outcomes.

Promote regulatory convergence after Brexit and the recognition of CE marks

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. Medical technologies need to be certified by a notified body, under EU legislation. UK notified bodies currently play a central role in this certification, covering between 30-40% of medical devices used in the EU and 43% of Irish Medtech members rely on UK Notified Bodies to gain certification. However, in key fields such as emergency and routine care, the role of UK notified bodies is even more important as they cover over two thirds of all devices used in the EU. Without a valid certification it would no longer be legal to place these products on the EU market, potentially leading to shortages and disruptions for healthcare delivery and more specifically, blood supply. Moreover, the ongoing Brexit negotiations also risks splitting the EU regulatory system and the world's second largest medtech market in two.

The Irish Medtech Association recommends:

- Work with the European Union to intervene and ensure the continued supply of medical devices to the EU-27 and consider contingency measure to maintain access to devices required for essential therapies.

How Ireland will benefit

The withdrawal of the United Kingdom from the European Union will impact the ability of healthcare systems to ensure patient care. 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. 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. Policymakers must work with manufacturers to maintain the care continuum for patients in Ireland and across Europe. Regulatory convergence ensures our medtech sector will not unnecessarily face the burden of two regulatory systems.

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:

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

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 (ie 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.

Pillar 2

Enterprise and innovation

Ireland has become a medtech success story with FDI multinationals and startups 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 worldclass talent pool.

Embrace new technologies with advanced manufacturing

Manufacturing is a vital part of the Irish economy with more than 4,000 businesses employing in excess of 250,000 people. The Irish Medtech Association have called on the Government to invest ambitiously in a discrete manufacturing centre of scale to help companies take new technologies from proof of concept to commercialisation. This has been a major gap in the Irish innovation ecosystem. Centres like Tyndall (ICT), NIBRT (biopharma), and Teagasc (agri-food), have already paid dividends for other sectors. The Advanced Manufacturing Centre will help companies' de-risk the commercialisation and ensure our manufacturing talent have access to the latest technologies to upskill and compete. Manufacturing accounts for nearly a third of Irish GDP, to realise the sector's potential we need the right business environment or Ireland risks losing out to competitor economies that are already investing ambitiously.

The Irish Medtech Association recommends:

- Invest ambitiously in the IDA Ireland-led large-scale advanced discrete manufacturing centre in Limerick, by topping up the €12 million already invested with the €30 million needed to address innovation gap, support collaboration and commercialisation.
- A well-coordinated governance structure is put in place for Ireland's Advanced Manufacturing Strategy, which includes proper human capital and legislative investment under the DBEI-led Future Manufacturing Ireland umbrella, as well as the appropriate industry-body representation for the discrete manufacturing sectors.
- Improve connectivity and set in place the relevant physical infrastructure to support advanced manufacturing by investment in digital infrastructure (high speed broadband, 5G, fibre) and modernising Ireland's industrial infrastructure as a priority because to bring the benefits of the ongoing digital, clean energy, low carbon and circular transformations to citizens.

How Ireland will benefit

The presence of an advanced discrete manufacturing centre of scale will offer discrete manufacturing businesses of all sizes and from all relevant sectors access to world-class equipment, expertise and collaborative opportunities. This critical piece of national infrastructure is needed as a matter of urgency due to the immediate impact of Industry 4.0, and will affect Ireland's ability to compete internationally and locally for such investment, as well as developing the skills-base and training needs for industry. Our nearest competitor, the UK has already seen the value of investing in advanced manufacturing with an annual budget of £100 million for the Catapult centres already reaping results, for every £1 of government funding the UK economy is seeing a net benefit of £15 with growth in the industry and jobs added.

Nurture entrepreneurship and support disruptive innovation

As many as four out of five medtech companies in Ireland are a startup or SME. Medtech is the most innovative industry in Europe with nearly 14,000 patents filed with the EPO in 2018. The role of startups is different in the medtech community compared to other industries. The medtech innovation cycle is led by startups 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 startup 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 startups 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.
- Reform of the Key Employee Engagement Programme (KEEP), 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.
- Reform of the Employment Investment Incentive Scheme (EIIS) including an increase in the limit on investments to €2 million to drive investment.
- Increase direct supports to stimulate greater industry innovation and enhance innovation collaboration between industries, universities and IoTs, and SMEs through schemes like the Disruptive Technologies Innovation Fund.

How Ireland will benefit

Ireland is a good place to start a business, but many small companies struggle to make it big. More needs be done to foster entrepreneurship in education, and through business supports to make Ireland not only an attractive place to start a business, but also to grow a business. There is currently a shortage of capital to support medtech companies in Ireland, the next Government must look at all options available to support the growth and development of early stage medtech companies. This includes a need for bolder initiatives to facilitate cooperation between sectors such as pharmaceuticals, biotechnology and ICT to use technological innovations to help patients. 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 (EIIS) 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 startup communities where the latest transformative medical technologies are developed.

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 will have a major impact on the future of our FDI-driven growth model with Ireland standing out as one of the top locations for medtech investment in Europe. 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:

- Convene a new Commission on Taxation to ensure that the tax system is sustainable in the decades ahead. This should address issues such as corporate tax, the taxation of indigenous business, environmental taxes, property taxation and the coherence and competitiveness of Ireland's personal taxation system.
- Respond to the challenges of BEPS by providi ng certainty on the 12.5% corporate tax rate, 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.

Make Ireland a leader for gender leadership in manufacturing

Data from Ibec's Research Unit shows an improvement in female participation across most sectors and management levels between 2001 and 2018. However, it is clear that the concentration of one gender in certain occupations (horizontal segregation) or in certain grades or levels (vertical segregation) remains a challenge. Female participation as Head of Function in Engineering increased modestly from 5% to 6%, while in manufacturing female participation rates have decreased from 15% to 3% between 2001 and 2018. We need to tackle pervasive stereotypes by providing role models and increase the number of women in leadership roles from the first rung to executive leadership level.

The Irish Medtech Association recommends:

- Make gender leadership a priority and ensure Government achieves objectives set-out in 'National Strategy for Women and Girls 2017-2020' and 'Better Balance for Better Business'.
- Support labour market participation of women with appropriate gender pay gap reporting, fair tax treatment of second earners, and bringing Ireland's low adult-to-child ratio for childcare in line with other European countries.
- Ensure girls aren't cut-off from medtech and STEM careers by collaborating with guidance counsellors to promote routes to these careers and role models, with better access to STEM courses and qualified teachers.

How Ireland will benefit

Closing the gender gap could add €12 trillion to global GDP by 2025 (Women Matters, 2017) and increasing the number of women in leadership has a positive impact on profits, innovation as well as governance. To 'Make Ireland a world leader for gender leadership in STEM' was identified by member companies as priority in the Irish Medtech Association "Future skills needs analysis" 2020 report. Tackling gender imbalance will help businesses attract and retain the best talent, building the teams they need for a highly competitive and challenging world as well as better represent the people they serve.

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 worldclass 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.

The Irish Medtech Association recommends:

- Leverage the National Training Fund to support enterprise-led skills development programme and enterprise - education engagement
- Commit to rebuilding a sustainable higher education funding model that allows for core funding, programmatic funding, infrastructure investment, and industry -academic collaboration
- Increase investment in research in higher education to boost Ireland's capacity for innovation under the new national strategy for innovation
- Develop a national strategic approach to lifelong learning, supported by a fit for purpose career guidance service
- Invest in relevant skills and employability to support business transformation

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 s 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. Already, 216 apprentices have signed up from 74 companies, of which 55% are small and medium enterprises with sector breakdown of 55% medtech, 2% pharma and 43% engineering. However, there has been an annual decline in numbers participating. The costs incurred on the employer to take on apprentices are not sustainable and more needs to be done to make it accessible to SMEs who find the cost of paying offsite apprentices to be insurmountable.

The Irish Medtech Association recommends:

- Develop a scheme for business to offset the cost of training to encourage greater enterprise engagement and long-term sustainability of Generation Apprenticeship programmes
- Establish greater parity between the new apprenticeships and the craft apprenticeships, as highlighted in the Joint Oireachtas Committee report on 'The Role of Apprenticeships and Work Permits in Addressing Ireland's Skills Needs' published May 2019
- A payment of €7,000 from the Government to companies per apprentice per year to cover the off the job costs

How Ireland will benefit

With a sustainable funding model, these programmes will help the Department of Education and Skills' ambition to deliver 50,000 apprenticeship and traineeship registrations by 2020. The medtech and polymer sectors are drivers of regional growth and investment. Ireland is 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, with the polymer industry employing 7,000 people. 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.

About Ibec

Ibec is Ireland's largest lobby group representing Irish business both domestically and internationally.

Its membership is home grown, multinational, big and small, spanning every sector of the economy. Together they employ over 70% of the private sector workforce in Ireland. Ibec and its trade associations lobby government, policy makers and other key stakeholders nationally and internationally to shape business conditions and drive economic growth. It has over 230 professional services staff in seven locations including Brussels and has 38 different trade associations in the group.

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Notes

Notes

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