FLANDERS INVESTMENT & TRADE MARKET SURVEY

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State of the Art

Flanders



LIFE SCIENCES IRELAND

A Global Leader in Pharma, MedTech and Biotech

December 2023

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2. INTRODUCTION

Ireland continues to punch above its weight when it comes to life sciences. The sector directly employs over 50,000 people across medical devices, pharma and biotechnology and exports exceed €45 billion annually. All but one of the world's 25 largest biotech and pharma companies have a significant presence in Ireland, and many of the world's most prescribed drugs are manufactured in the country.

The sector accounts for 32% of Ireland's GDP and has a global reputation for operational and innovation excellence. Leading industry names, including Novartis, AbbVie, Janssen (J&J), Pfizer, Sanofi, Lilly, AstraZeneca, MSD, Bristol Myers Squibb and Takeda have significant operations in the country. Ireland, as the only official English-speaking country within the EU27 is also, for many large American corporates and multinationals, considered as the main gateway to the world's second biggest medtech market - Europe.

3. IRELAND – FACTS AND FIGURES

The annual inflation rate in Ireland fell to 5% in September of 2023, from 5.6% in the previous month, the lowest since February of 2022, and in line with lower energy prices and tighter monetary conditions by the European Central Bank.

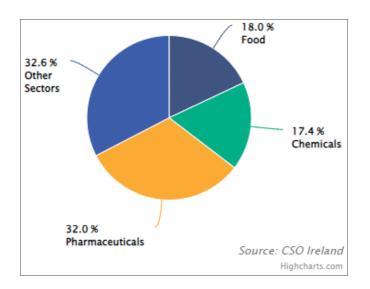
Net exports are the main driver of economic activity in Ireland, which is also supported by resilient private consumption.

Following double digit growth in 2022, GDP is expected to decline by 0.9% in 2023 amid developments in multinational-dominated sectors and normalising domestic demand. It is thereafter forecast to pick up to 3.0% in 2024 and 3.4% in 2025. Following its peak of 8.1% in 2022, consumer price inflation is set to moderate throughout 2024 and reach 2.1% in 2025. The government budget surplus is projected to shrink in 2023 and 2024, before rebounding at around 1% of GDP in 2025.¹

The pharmaceutical sector's growth has slowed after the pandemic-linked boom. The value of production of pharmaceutical products in Ireland decreased by 27.2%, from €58.1bn in 2021 to €42.3bn in 2022.

Also, semi-conductors and contract manufacturing sectors have seen decreased exports. By contrast, the ICT sector - which accounts for more than half of Ireland's services exports - maintains robust growth.

¹ European Commission in Ireland Autumn Economic Forecast 2023 - Economic forecast for Ireland (europa.eu)



Basic Pharmaceutical Products & Preparations (€42.3bn) accounted for the largest proportion of Net Sales Value (NSV) in 2022 at 32.0%. This was followed by Food Products (€23.8bn) at 18.0% of NSV and Chemicals & Chemical Products with an NSV of €23.0bn (17.4%).

Doing Business in Ireland

In the most recent figures from 2020, published by World Bank Group, Ireland ranked 24th in the World and 8th in EU on the Ease of Doing Business Index. 2

To maintain this good score, the Irish Government and the Industrial Development Agency (IDA) have emphasised the importance of minimising regulatory issues - to make Ireland a more attractive location in which domestic and foreign investors can set up and develop their operations. Improving Ireland's business environment and enhancing the reputation as being 'business friendly' has led many foreign goods and service providers to set up in Ireland rather than the UK.

Other considerations for FDI attractiveness are the quality of the workforce with particular reference to its flexibility. Also, a strong work ethic and high levels of education; political and tax stability, Being an English speaking member of the Eurozone with accessible tax benefits and grants for IP and R&D, are all elements that make Ireland a top destination.

Ireland has therefore succeeded in building an international industry ecosystem that is diverse in its activities and enjoys a world-leading reputation in several sectors such as aircraft leasing, insurance, banking and investment management. The same can be said for its Life Sciences sector, similar to Flanders, Ireland has provided infrastructure, high level graduates and tax incentives for the multinational medical device and Bio pharma industries to locate in the country with relative ease.

Disruptions from Brexit

The EU-UK Trade & Cooperation Agreement (TCA) has added a layer of paperwork for Flemish exporters into the UK that has been time consuming and expensive. The filing of customs declarations

² World Bank Group 'Doing Business 2020' - <u>www.doingbusiness.org/content/dam/doingBusiness/country/i/ireland/IRL.pdf</u>

and the registering for VAT has added to the workload for the movement of goods into the UK. It has been a similar experience for Irish traders. With a new administration now in place in the UK, discussions are progressing on arrangements for implementing the Windsor Framework within the EU-UK Withdrawal Agreement. It is also the case that the UK authorities have again postponed the date at which regulatory and other checks will be applied to imports.

The latest quarterly business monitor from the economic cross-border body InterTrade Ireland reveals that the overall trading environment is becoming increasingly competitive. The survey, which questioned over 750 firms from across the island, shows that a third of firms have adapted to the new trading conditions post-Brexit, while half say Brexit has had no impact to date. However, 71% of firms report that they do not yet have knowledge of the Windsor Framework requirements.³

Meanwhile at a sectoral level, 63% of manufacturing businesses report they have not investigated the impact of the new agreement. This highlights a growing need for clear and reliable information on emerging trading conditions.

Interestingly, the decline in Ireland-UK trade since January 2021 is driven entirely by flows with Great Britain while Ireland-Northern Ireland trade has increased considerably.

Because of this trading boost and other external factors, Ireland's competitiveness ranking improved to 2nd place in the IMD overall rankings.⁴

Relationships

Business is conducted mostly on an informal basis. Once initial introductions and contracts are confirmed, a casual and 'first name' relationship can be followed with the Irish counterpart. Although Irish is an official language of Ireland, it is not widely used, and all business is conducted in English. Be careful not to refer to the Republic of Ireland as part of the UK, or indeed Northern Ireland as part of Ireland as it is a separate political entity. While the Pharma and MedTech sectors are very competitive, you can be assured of a good trading relationship with Irish sourcers and buyers.

³ InterTrade Ireland Survey - InterTradeIreland survey shows that business landscape on the island is becoming increasingly competitive InterTradeIreland

⁴ International Institute for Management Development World Competitiveness Rankings 2023

4. PHARMACEUTICAL INDUSTRY



Ireland is a major hub for pharmaceuticals production and exports. Exports of Medical & Pharmaceutical Products increased by €642 million (+14%) to €5,297 million in December 2022 compared with December 2021. This represented 36% of total exports. ⁵

The industry employs over 24,500 people directly and supports another 24,500 indirectly. It also attracts significant foreign direct investment and research and development activities. This sector is composed of four main sub-sectors; primary pharmaceuticals (chemical synthesis), secondary pharmaceuticals (final dosage form and packaging), diagnostics, and biopharmaceuticals.

While the MNCs were initially attracted to Ireland for the tax regime, many have stayed for over 40 years, due to the skilled workforce, collaborative universities and the connectivity to North America enjoyed via Shannon Airport. The tax incentives for IP and R&D are attractive, and the gradual implementation of the global/OECD corporation tax agreement is not perceived as a major threat to this sector of the economy.

On 26 April 2023, the European Commission presented its proposal for a revision of the EU Pharmaceutical framework. This revision, which is the first in two decades, aims to improve patient access to innovative medicines across the whole of the EU, while also improving regulatory adoption processes.

Ireland has an exemplary compliance record with regulatory agencies, through the cooperation of the agencies - the Irish Health Products Regulatory Authority (HPRA), European Medicines Agency (EMA) and the Food and Drug Administration (FDA). Any Flemish company wishing to explore the Irish market will discover an open and welcoming attitude towards co-research or co-funding, and that the legislation frameworks and implementations are as advanced as anywhere in Northern Europe.

⁵ CSO Exports by Product Category - <u>https://www.cso.ie/en/releasesandpublications/ep/p-gei/goodsexportsandimportsdecember2022/</u>

4.1 APIS AND VACCINES



mRNA vaccines were first widely used against Covid-19, but now their use is being investigated in the treatment of a range of major diseases such as malaria, HIV, TB, Zika and RSV viruses. It's one more example of a potential breakthrough that has the possibility of saving hundreds and thousands of lives in the near future. These breakthrough treatments, aiming to treat, prevent and potentially cure genetic and acquired diseases, are, so far, not available in Ireland.

Research methods are evolving however and there are many promising prospects, from the possibilities offered by personalised medicines, to the potential offered by novel biopharmaceuticals. Flemish companies active in this area would be well advised to present their services to the public hospitals and to the academic research centres (see also below).

4.2 CELL AND GENE THERAPY

There is certainly room for improvement in the medical genetics and genomics services offered in Ireland when compared to other European countries. The new National Strategy for Accelerating Genetic and Genomic Medicine in Ireland ⁶ was published in December 2022. The strategy outlines the planned development of an enhanced patient and family-centred genetic and genomic service that will be coordinated nationally.

KU Leuven collaborates internationally through participation in the <u>1+Million Genome (1+MG)</u> European project; The Irish Health Research Board is investing 400,000 to co-fund Irish participation in this project. This will see Ireland based researchers, clinicians, and other relevant stakeholders collaborating on a roadmap for data infrastructure in Ireland and conducting proof-of-concept work using synthetic data.

A study form May 2021, commissioned by Janssen together with the IPHA and other member companies, has identified the steps required to ensure Irish patients can gain access to these Advanced Therapy Medicinal Products (ATMPs), including CAR-T treatments over the coming years. The study urges a cross-stakeholder approach to realising the clinical potential of cell and gene

⁶ www.hse.ie/eng/about/who/strategic-programmes-office-overview/national-strategy-for-accelerating-genetic-and-genomic-medicine-in-ireland/

therapies, bringing together government, industry, clinical and patient leaders to create a policy on the adoption of cell and gene therapies in the Irish health service.⁷

There will be a need for expertise in this area, Flemish researchers and companies that have commercialised their research, are advised to keep informed with developments as they arise,

5. BIOLOGICS AND BIOTECH

An increasing proportion of new medicines are "large molecule" biologics based. The best point of contact for this area is the <u>Regenerative Medicine Institute</u> (REMEDI), based in the University of Galway. It specialises in multidisciplinary research in fundamental and applied cellular biotechnology and clinical collaborations in corneal stem cell transplant and pancreatic islet transplant for treatment of type 1 diabetes. Remedi benefits from strong industrial and academic partners; Harvard Medical School, Royal College of Surgeons in Ireland and St. Vincent's University Hospital, Dublin.

An example of collaboration in this area is some Science Foundation Ireland-funded research. Published in the current edition of the <u>Journal of Thrombosis and Haemostasis</u>, it is a collaboration between Royal College of Surgeons Ireland, the Endothelial Cell Research Group at Dublin City University and the Centre for Molecular and Vascular Biology at the University of Leuven.

Another centre in this area is the Trinity Biomedical Sciences Institute, based in Trinity College, Dublin. It has a good success with research and is open to collaboration with advanced practitioners. \rightarrow <u>New</u> <u>anti-coagulants discovered in Trinity may help treat Sepsis and Covid-19 (imt.ie)</u>

Clinical Trials

There are seven clinical research facilities and centres across Ireland within an integrated clinical research network known as HRB Clinical Research Coordination Ireland (HRB-CRCI). To date the HRB has invested over €100 million to support the development of strong patient-focused clinical research infrastructure in Ireland, The <u>Clinical Research Facilities</u> provide the infrastructure, facilities, experienced research and specialist support staff. There is also quality oversight for the running of clinical trials, investigations and research studies and for the successful conduct of world class patient focused research. These facilities are open to applications from non-indigenous researchers.

6. MEDTECH

Ireland's MedTech ecosystem provides multiple opportunities for collaboration, asset sharing, supplier relationships and co-investment. The integrated medical technology community spans cutting-edge industry, academic and clinical research groups and government agencies.

The cluster that has developed in the greater Galway area around the industry is an example of how the sector has developed and benefited the local community. There are approximately 40 medical

⁷ Janssen, PWC, IPHA Study - <u>pwc_cell_and_gene_therapies_pathfinder_study_pdf (janssen.com)</u>

technology companies in Galway producing products such as catheters, cardiovascular products and anaesthesia equipment.



Ref. Galway City Innovation District - <u>https://gcid.ie/</u>

This cluster has been largely led, since 2011, by BioInnovate Ireland, a network of academic, clinical and industry partners. It promotes interaction with leading names in software, engineering and industrial technology. Interestingly, more than 50% of medtech companies based in Galway have dedicated R&D facilities.⁸

Al is changing the future of virtually every industry, it is the medtech sector in particular that is capitalising on this emerging technology. The number of Al-based patent applications filed by the sector in 2022 has almost quadrupled since 2018.⁹

This growth in the industry can be easily seen in the success of countless innovations, investments and start-ups advancing within the space, both in Ireland and further afield. Earlier this year, Galwaybased Xtremedy Medical won the MedTech Innovator accelerator for its surgical devices that aim to address deep tissue and bone infections. Galway is also home to many other successful medtech start-ups, including the start-up, MedScan3D, which develops patient-specific anatomical models from various human body scans.

There are real opportunities for Flemish sub-contracting companies to offer services in this area. Galway offers world-class research centres with focus on medical devices, advanced materials and smart manufacturing.

⁸ Bioinnovate - What We Do - <u>www.bioinnovate.ie/what-we-do/ecosystem.html</u>

⁹ Marks and Clerk AI Market Report 2023 - <u>www.marks-clerk.com/insights/news/medtech-sector-sees-surge-in-ai-patent-applications-marks-clerk-ai-report-2023-reveals/</u>

7. OPPORTUNITIES

<u>Hardware Supply and Services</u> Clean room supply and setup. Specifically, the provision of hardware for the safe manufacture of monoclonal antibodies. Also product bioburden auditing. Companies offering modern engineering process design skills, new measurement and control technologies, i.e. techniques such as continuous processing, the use of process analytical technology, and the introduction of modular plug-and-play processing equipment. 3D printing, instrument companies. Single use Bioreactors are replacing stainless steel vessels.

<u>Services</u> – Flemish companies that offer data science solutions, artificial intelligence and machine learning systems expertise are also in demand. Assistance in driving medical decisions, early detection and enhanced therapeutic medical devices. There is also a demand for Technical Services Consulting in this field.

<u>Funding</u> – The state and private investor funding sources in Ireland are open to non-indigenous applications. There are many ways to access capital, for example through Venture Capital funds; the following companies with a Belgian connection received seed funding from the large Irish VC, <u>Fountain Healthcare Partners</u>.

- 1. Dualyx -> <u>www.dualyx.com/</u>
- 2. Inflazome (now part of Roche Pharmaceuticals) -> <u>www.roche.com/</u>
- 3. Kandy Therapeutics (now part of Bayer Pharmaceuticals) -> <u>www.bayer.com/en/</u>
- 4. Syndesi Therapeutics (now part of Abbvie) -> <u>www.abbvie.com/</u>
- 5. Amarin -> <u>https://amarincorp.com/</u>

<u>Talent</u> – There is demand for companies offering workforce recruitment options to support the skills demands within the sector. E.g. skills and employee benchmarking services, and to headhunt leaders in risk management and operational excellence.

<u>Academic</u> - Flemish academic institutions can collaborate with Irish high-quality research. Irish startups and the multinationals have always worked closely with universities to develop new healthtech solutions. Incubators, academies, science parks and technology clusters foster innovation from early stages. Expertise is required in end-to-end development and commercialisation for medical devices and combination products. See the list of academic centres below for more information.

<u>Data Services</u> - In the context of cybersecurity threats and new regulations on the ethical use of data, Ireland wishes to become best-in-class in protecting data and enabling the ethical use of data. Predictive design, compliance and control technologies will be in high demand among the larger hospital-based organisations, Tier 1 companies and indeed state contracts will be put to tender for these important services.

<u>Sustainability Audit Services</u> - Consultants on wastewater management, solvent and plastic use minimisation and carbon reduction advisory. While there is good expertise in Industry 4.0 in Ireland, notably in the Pharma and Food sectors, the rapid advances in Pharma 5.0 practices in the manufacturing sector require more knowledge from overseas, particularly from the Flemish eco system which has a large concentration of manufacturing in the Life Science sector.

<u>Manufacture Subcontracting</u> - There has been a clear trend towards greater use of contract manufacturers by MedTech companies with nearly 80% looking to improve collaboration according to pre Covid-19 research. ¹⁰ In parallel with increased technological innovation and more complex business models, the Covid-19 pandemic has accelerated the demand for collaboration.

<u>Supply Chain</u> - In a European context, cross border supply chains in a fragmented market are easily disrupted. While the Irish supply chain service providers have strong expertise in white glove supply chain, there is always a market for specialist service for sensitive pharmaceutical products.

8. CONCLUSION

Only a strong EU-based (bio)pharmaceutical manufacturing industry will be able to effectively address the security of medicines supply and production and help achieve overall sustainability of healthcare in Europe. Flexible biotechnology manufacturing, which will allow faster and lower cost production; The ability to manufacture and supply sufficient products for the EU population and by extension to the Global South.

In the context of falling inflation rates and Irish business optimism, it is worth exploring this market more. Flemish exporters and innovators can find enthusiastic partners in Ireland if they are willing to branch out. Irish firms are being encouraged to consider diversifying out of and away from UK markets. The ideal scenario would be a switch from UK to EU sources for healthcare and other products and services in the medium or long term. This would involve a push by Flemish exporters to introduce their services in a proactive manner.

The Dublin office of Flanders Investment and Trade remains at your service to answer any queries and create introductions to Irish service providers and innovators in this vibrant area.

9. PUBLICATIONS / ORGANISATIONS / ASSOCIATIONS

Publications

Made In Ireland is an information resource industry publication to reflect and promote the design and production engineering exploits of Irish companies: <u>www.madein.ie/</u>

The 'Irish Times Top 1000' has a guide outlining the largest organisations in Ireland, both North and South, covering all market sectors. This listing is compiled and verified by the Irish Times newspaper business team, published once a year, and can be consulted on the following website: www.top1000.ie. General information is freely available, but there are also several subscription options, for a deeper understanding of the listed companies and for networking purposes: www.top1000.ie/products

¹⁰ IBEC Medtech Strategy 2025 - <u>www.ibec.ie/connect-and-learn/industries/life-sciences-and-healthcare/medtech-strategy-</u> 2025/excellence-through-collaboration

Manufacturing and Supply Chain Magazine is an industry magazine that covers developments in 3D Printing, Medical Devices, Electronics, Energy, Innovation, IT, Materials Handling, and others: www.manufacturing-supply-chain.com

The Irish Medical Times brings News on clinical trials and general medical information: <u>www.imt.ie</u>

Academic Institutions (non-exhaustive overview)

• National Institute for Bioprocessing Research and Training

NIBRT trains over 4,500 people annually, offering practical based training for industry in cell and gene therapy development and manufacture.

It developed two new courses 2020:

- Fundamentals of Stem Cell Therapy Manufacture (in collaboration with CCMI).
- Advanced Cell Therapy Technology Course (in partnership with GE Healthcare).
- <u>Centre for Cell Manufacturing Ireland (CCMI)</u>

Dedicated GMP cell therapy manufacturing facility with capacity in adenoviral vectors and adult mesenchymal stem cells.

• <u>Synthesis and Solid-State Pharmaceutical Centre (SSPC)</u>

SSPC is a leading hub of Irish research expertise developing innovative technologies to address key challenges facing the pharmaceutical and biopharmaceutical industry. Their in-depth scientific and engineering research expertise aids companies who need tailored solutions to their bespoke challenges. SSPC has supported 54 industry projects since 2019.

• BioInnovate Ireland

Based in University of Galway and affiliated with Stanford University, Bioinnovate pioneers a 'needs led' innovation approach (process) towards Medical Device development.

• Pharmaceutical Manufacturing and Technology Centre (PMTC)

Situated in the <u>Bernal Institute</u> in the University of Limerick, the PMTC is the National applied research Centre providing advanced technology solutions for the pharmaceutical manufacturing sector.

• <u>CONFIRM (Smart Manufacture Research)</u>

Smart Manufacturing Centre, collaboration with experts in areas of analytics, robotics, machine learning, AR/VR.

• <u>Tangent (Trinity's Ideas Workspace)</u>

Home of the EIT Health Partners, works closely with the Irish public health service, the HSE.

Advanced Manufacturing Training Centre of Excellence

Runs courses in Cleanroom tech, Process Analytical Tech, QC for (Bio) Pharmaceutical Manufacturing and Validation, among others.

• <u>NovaUCD</u>

NovaUCD is the hub for new ventures and entrepreneurs at University College Dublin. NovaUCD is a purpose-built, state-of-the-art incubation facility for knowledge-intensive companies.

Other Organisations (non-exhaustive overview)

• Health Service Executive (HSE)

Comparable to the NHS in the UK, it is a state organisation, responsible for the provision of public health and personal social services. It is funded centrally through the Government Department of Health, has over 60,000 employees and an annual budget of over €16 billion. They are the main purchaser of goods and services in the public health system and responsible for decisions regarding the reimbursement of new drugs.

The Corporate Pharmaceutical Unit (CPU) of the HSE is advised by the National Centre for Pharmacoeconomics (NCPE) in assessing the clinical effectiveness and value for money of new medicines.

The HSE operates a procurement process for buying goods or services. You can find information on the process through the link below.

Office of the Head of Procurement, Dr. Steeven's Hospital, Dublin 8, Ireland. Tel: +353 1 635 2251 Web: www.hse.ie/eng/about/who/healthbusinessservices/procurement/ Email: ohop@hse.ie

• <u>Science Foundation Ireland</u>

SFI brings together 6 Centres for Research Training that includes 11 higher Education Institutes and 90 industry partners. It trained over 600 postgraduates last year in areas such as data science, genomics and advanced networks for sustainable societies.

Irish Medtech Association and BioPharmaChem Ireland

Industry representative bodies under the umbrella of IBEC, the Irish employers body. These organisations lobby government and run conferences and training for the life sciences leaders and employers.

• <u>HealthTech Ireland</u>

HealthTech Ireland is an independent trade association for manufacturers, developers and distributors of health technology products and solutions to the health system in Ireland.

• National Standards Authority of Ireland

The NSAI sets and regulates Irish standards, in line with CE and ISO standards for products and business systems. NSAI also maintains certification and metrology standards in the country.

• Knowledge Transfer Ireland

KTI is a branch of the Government Department of Enterprise, Trade and Employment, which is responsible for commercialising and monetising high level research.

Irish Digital Engineering and Advanced Manufacturing (IDEAM)

IDEAM is an industry cluster based around the mid-west region that concentrates on digitalisation and green manufacturing practices.

Health Products Regulatory Authority

The HPRA regulates the standards and CE markings of products and services. Publishes a guide to market entry for medical software products.

• Digital Manufacturing Ireland

Industry-led national organisation that enables Irish-based manufacturers to access, adopt and accelerate new digital technologies solving real-world challenges and driving future competitiveness.

10. EVENTS

BioPharma and LifeSciences Connected Live 25th January 2024

BioMedica Spring 2024 – date tbc

Manufacture & Supply Chain Ireland Conference & Exhibition 28th - 29th May 2024

Making Pharma 11-12th September 2024

Medical Technology Ireland 25th-26th September 2024

<u>All Ireland Lab and Cleanroom Expo</u> 7th November 2024 – date tbc.

11. DISCLAIMER

The information in this publication is provided for background information that should enable you to get a picture of the subject treated in this document. It is collected with the greatest care based on all data and documentation available at the moment of publication. Thus, this publication was never intended to be the perfect and correct answer to your specific situation. Consequently, it can never be considered a legal, financial or other specialized advice. Flanders Investment & Trade (FIT) accepts no liability for any errors, omissions or incompleteness, and no warranty is given or responsibility accepted as to the standing of any individual, firm, company or other organization mentioned.

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