Grant Thornton
An instinct for growth™

Life Sciences

Global trends in the pharma and life sciences industry

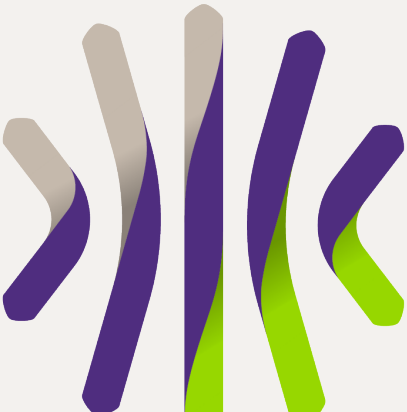
Introduction

Ireland's life sciences industry has grown from very humble beginnings to a position of global significance. The industry's remarkable growth is one of the most impressive Irish success stories and shows no signs of slowing down, with estimates that the sector will create a further **8,400 biopharma** and **4,000 medtech jobs** by **2020**.

Unlike many industries in Ireland, life sciences is truly global in its outlook. In 2016 6% of life sciences sector exports were to the UK, with 42% exported to other EU countries and 52% to the rest of the world, including 29% to the USA alone.

As a player on a global scale, Ireland must seek to identify and anticipate future changes in the global environment and plan accordingly to minimise the threats and maximise the opportunities that those changes will bring.

While change is a constant in modern life it is arguable that the confluence of factors currently impacting globally is creating the most uncertain of periods. Whether considering the potential impacts of Brexit, the emergence of innovative and disruptive technologies or the uncertainty resulting from political upheaval in leading global powers, Grant Thornton can help you navigate and shape this environment to your advantage.



Global opportunities and risks

Commercial implications:

- currency;
- Research and Development (R&D) funding;
- parallel trade;
- reference pricing;
- human capital; and
- demographic trends and growth markets.

Regulatory and legal requirements:

- EMA location;
- supply chains;
- General Data Protection Regulation (GDPR);
- management buyouts;
- cyber threats;
- country specific accounting rules; and
- accounting and compliance challenges.

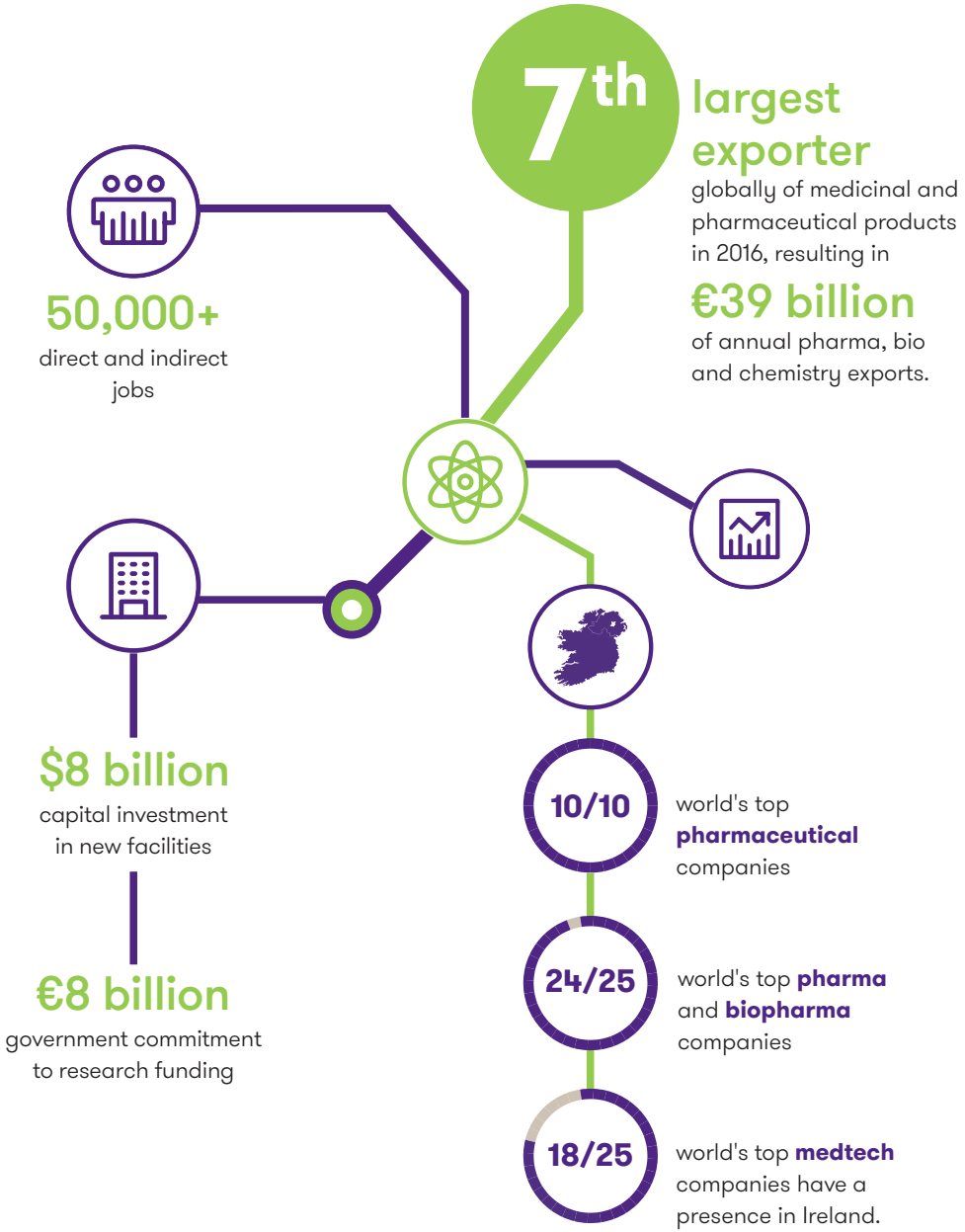
Tax considerations:

- tariffs and trade;
- global tax policy;
- IP rights and contracts; and
- country specific taxation rules.

As part of Grant Thornton's tailored service offering to the life sciences industry, our experts focus on and provide insights on a range of key challenges, such as:

- Brexit impacts on life sciences in Ireland;
- Merger and Acquisitions (M&A) trends;
- models to manage multi-jurisdictional statutory financial reporting requirements;
- global tax policy implications on R&D activities and Intellectual Property (IP) rights;
- the importance of cyber security in the global life sciences sector; and
- effects of Brexit on statutory financial reporting requirements.

Life sciences fast facts



Source: IDA Ireland statistics

Brexit impacts on life sciences in Ireland

The UK's decision to leave the EU and subsequent triggering of Article 50 has generated significant uncertainty across the international life sciences landscape. While an excessive amount of commentary exists around the potential commercial, legal, regulatory and tax implications relating to Brexit, there is a lack of information available regarding its effects on Irish operations in the life sciences industry. Our Brexit impact assessment framework, discussed in the next section, identifies critical risks and opportunities that may impact Irish operations in the industry as a result of the UK's exit from the EU.

One key area of focus for Irish operations is supply chain management. This has typically been hampered by a lack of specialist distribution and storage facilities on the island necessitating distribution through UK channels. Whether your operations' finished goods are distributed or temporarily stored in the UK en-route to mainland Europe, and further afield, or your raw materials suppliers are based in or have links to the UK, there is extensive scope for your business to be impacted by the UK's potential de-harmonisation from the single market. This risk presents your organisation with the opportunity to carry out a root and branch analysis of your supply chain processes and operations in order to help support your future growth strategy and ensure you are prepared for any potential Brexit scenario.

The life sciences industry is somewhat unique in Ireland in that while the fiscal value of trade with the UK is relatively high, there is less direct exposure to the UK as a trade partner when compared to other industries.

There are approximately 5,000 non-EU nationals working across the industry in the UK, a number that is already declining due to concerns over residency status and the industry's future in the UK post-Brexit. This expert human capital may provide a significant opportunity for Irish operations to attract the best talent to these shores at a time when there is strong demand here.

The UK benefits from 15% of Research and Development (R&D) funding sourced from the EU. There is the potential for this funding to be distributed across the remaining EU member states. As the only other native English speaking country in the EU, the UK is currently a significant competitor to Ireland in attracting global FDI. In a scenario where the UK does not have the same levels of access to the 500+ million market population it may not be as competitive or attractive for FDI, clinical trials participation or market launches.

The Irish government are currently competing with other EU administrations for the European Medicines Agency (EMA) to relocate to Dublin. With a decision expected in October, a successful pitch would represent major opportunities for Ireland and offer platforms for attracting further FDI in existing and life sciences operations seeking geographical alignment to the central regulatory body for the EU.

In light of such uncertainty around the potential outcomes of Brexit negotiations and their wider implications, it is important that you assess the impact on your organisation. At Grant Thornton we can assist you in navigating this environment through the development of a tailored Brexit impact assessment that aligns with your business model and growth strategy.

Elaine Daly
Partner, Head of Life Sciences

Tim Cotter
Associate Director, Business Consulting

The Brexit impact assessment framework

There may only be a handful of mitigating actions that firms can take in the face of any number of Brexit scenarios. We have selected a number of the key Brexit impact areas and highlighted their potential outcomes on life sciences in Ireland.

Trade

Outcomes:

- supply chain disruption;
- change to customs duty and import/export tax; and
- continuity of supply implications.

Potential Brexit mitigations:

- root and branch analysis of existing supply and sub-supply chain.

Regulation

Outcomes:

- EMA relocated from the UK;
- Ireland to have potentially bigger regulatory divergence influence over future policy direction;
- longer lead times for products to market across EU;
- greater complexity surrounding marketing regulation in UK and EU; and
- increased certification requirements.

Potential Brexit mitigations:

- assessment of how the approval of medicines and marketing will change in the UK and EU;
- assessment of physical location of key position holders;
- assessment of portfolio exposure to regulatory imbalance; and
- prompt decision making for known outcomes (eg. relocation of market authorisation holder to EU where applicable).

Intellectual Property (IP)

Outcomes:

- delay to the implementation of the unified patent; and
- reduction in parallel importation into the UK.

Potential Brexit mitigations:

- audit of current IP rights and geographical locations.

Research and Development (R&D)

Outcomes:

- changes to EU and non-EU sponsored funding opportunities;
- larger pool of funding available to EU member states; and
- UK may lose access to database for clinical trials reducing collaboration and slowing medical progression.

Potential Brexit mitigations:

- analysis to ascertain level of funding opportunities available; and
- leverage government initiatives, eg Knowledge Development Box (KDB).

Human capital

Outcomes:

- UK visa requirements are enforced; and
- top EU and non-EU talent looking to relocate from the UK.

Potential Brexit mitigations:

- perform a review and gap analysis exercise of your current workforce;
- identify areas for targeting/ transfer of human capital from the UK; and
- analysis of suppliers/ competitors exposure.

Digital

Outcomes

- UK may not implement EU data protection regulation, restricting collaboration, hampering innovation.

Potential Brexit mitigations:

- potential data protection regulations which the UK may implement should be identified; and
- analysis of exposure to divergent UK data protection regulations.

Merger and Acquisitions (M&A) trends

Last year proved to be an exceptional year in terms of the M&A deals in the life sciences sector, including pharma, medical and biotech. Uncertainty surrounding the impact of Brexit and the change in the US political landscape, along with potential regulatory changes, slowed down deal volume in the latter half of 2016. However, both global deal value and volume in the sector were higher than 2015.

A number of larger recent deals include Boehringer Ingelheim's acquisition of Sanofi's Merial, animal health for €11.4 billion, Mylan's acquisition of Meda, pharmaceuticals for €8.8 billion and more recently Becton Dickinson's agreement to acquire CR Bard, medical devices, for $24 billion. The US has traditionally seen the majority of activity in the sector, however, activity in Europe is gaining pace. In particular, there has been much private equity activity in recent times, both in terms of acquisition and sponsor divestment.

While big pharma M&A activity is expected to continue to be strong, R&D activity in biotech is increasing across traditional clusters in Germany, France, UK and Switzerland, along with countries such as Italy and Sweden.

Ireland has long been recognised as a centre of excellence in the life sciences sector and has seen some large M&A deals recently, including Johnson & Johnson's acquisition of Galway based Neuravi, medtech for stroke patients, with an undisclosed deal value.

Financial support in the form of venture capital, angel investment and accelerator funds for developing life sciences companies, is now widespread with funders such as Seroba Life Sciences, Kernel Capital, Fountain Healthcare Partners and SOSV actively funding deals in the Irish market. In the first half of 2017 alone, over €150 million has been funded across circa 25 deals of various sizes in the sector in Ireland, across medtech devices, diagnostics and bio/pharma. Despite ongoing challenges, the sector continues to be buoyant with continued high levels of deal activity expected in the sector.

Sources: Mergermarket, IVCA (Deal values to be corroborated)

Jim Mulqueen
Partner, Corporate Finance

Ann Marie Costello
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Models to manage multi-jurisdictional statutory financial reporting requirements

Global organisations need to continually evolve to meet expectations of stakeholders. With market demand, tax planning, supply chain management and product regulation in the mix, the life science industry is complex and requires careful navigation. Geographic footprint adds further complexity, introducing financial reporting and compliance requirements that are often considered non-core business activities.

Multi-jurisdictional statutory financial reporting has become more onerous. Trends in this area have seen many organisations centralise this compliance process in an effort to drive standardisation to achieve cost savings and a more consistent and robust process across all jurisdictions. Centralising this process has created new challenges as expertise historically situated in country is moved to a central location, often diluting the deep country expertise housed internally in the past.

In dealing with this new challenge, organisations have adopted different models ranging from building a dedicated team of in house experts at a central location, to a fully outsourced solution involving third party experts or a hybrid model combining aspects of both.

The key decision for companies in this situation is to determine which model fits best with the strategy of the organisation.

Fergus Condon
Partner, Financial Accounting and Advisory Services

Global tax policy implications on R&D activities and IP rights

A trend we expect to see in the future is the convergence of operational and tax strategy. For companies in the life sciences sector, broadly this means that where you do your R&D is where your valuable IP will sit. If you decide to move your IP to a different country, it is likely to be in conjunction with a shift in R&D or part of your R&D, to that country.

This is all part of an expected closer alignment in the future between taxable profits and real substance. The ability to park your IP and your profits in a remote tax haven will be much more difficult in the future, with many countries already taking action to counter such tax strategies.

Interestingly, a 'hard Brexit' could also see IP and R&D activities move away from the UK if it means that access to valuable grants under the Horizon 2020 programme is curtailed. An estimated 16% of the funds that UK life science companies spend annually on research comes from EU grants.

Closer to home, the 25% R&D tax credit continues to be a valuable asset for many companies. As the relief is closely monitored by Revenue, having adequate supporting documentation is critical.

The first tax returns claiming the new Knowledge Development Box (KDB) will be filed in **September 2017.** We don't expect to see significant take-up in the relief initially but over time it should serve to entice more R&D activities to Ireland and thus will be attractive to both indigenous and overseas companies operating here.

In conclusion, there has never been more change in the global tax climate, with developments here, in the EU, US and elsewhere reshaping the tax landscape in a fundamental way. While this does represent a challenge for many large groups, a positive for Ireland is that our tax environment makes us a compelling choice for life sciences companies, with an exceptionally strong reputation as a key part of our offering.

Peter Vale
Partner, Tax

Liam Kenny
Director, Tax

The importance of cyber security in the global life sciences sector

Cyber attacks

Since 2010 the healthcare industry has become the largest target of cyber security attacks, surpassing all other industries by 36% in security related events. Critical company data such as R&D, medical trial information, manufacturing know-how, as well as products and pricing, is highly sought after in cyber attacks.

While a selected few life science companies are up to date on their cyber security, many still use older, unpatched, sometimes even legacy systems, which are some of the easiest networks to break into. In terms of pharmaceutical companies, nothing is more valuable than the formula for one of its new drugs. It is estimated, that a loss of €800 million arising from cyber security breaches and predominantly theft of IP in its pharmaceutical, biotechnology and healthcare sector.

Supply chain

In today's world, dependency on third parties as part of the supply chain has increased such that many operations are outsourced to third parties. This has also increased the risk to most organisations as security of external parties are out of their control. Cyber security of any one organisation within the chain is potentially only as strong as that of the weakest member of the supply chain. This will particularly affect Irish organisations, as they are part of a bigger supply chain cycle with organisations based in United States, Asia Pacific and Europe. The life sciences industry is global and cyber attacks, once implemented, commonly cross several borders. While there have been attempts to standardise cyber security across the globe with standards, frameworks and guidance, there are no common global directives currently in place in terms of regulations and legislations.

GDPR

The life sciences sector is a heavily regulated industry and with the introduction of new security regulations, specifically GDPR, a cyber security breach will result in huge financial and reputational losses due to the nature of data in life science organisations. Loss of customer data and/or IP due to a security breach can potentially aggregate to, if not exceed, the value of an organisation's tangible assets.

With the potential for the UK to be positioned as a third country outside of the EU, the UK would require a determination of adequacy by the EU Commission in order for data to be exchanged between UK and EU post-Brexit. The House of Lords has recently indicated that this may be a challenge, given the UK's Investigatory Powers Act and similar data retention requirements.

Although medical data has some exceptions under GDPR, the transfer of health information is subject to particular protections. The sharing of information relating to individuals, for R&D or drug trials purposes may be problematic.

Next steps

It is recommended that an organisation look after their cyber security posture and implement controls to protect them from various attacks.

Recommended next steps for your organisation:

- assess your information security posture to identify any gaps and develop and implement a strategy to remediate such gaps;
- perform a technical security assessment/penetration tests to close technical gaps;
- understand different regulations that are applicable to your organisation and determine the requisite compliance level, eg all organisations need to **comply with GDPR by May 2018** which is of huge importance for organisations in the life sciences industry due to the nature of the data they possess;
- create a supply chain risk register to define the levels of dependence on third parties and security controls in place by third parties to protect their data; and
- organisations also need to make sure they have the appropriate security controls in place and further comply with security requirements set out by firms that they do business with, as part of the supply chain.

Mike Harris
Partner, Cyber Security

Effects of Brexit on statutory financial reporting requirements

It has been well recognised for over a year now that Brexit, although creating opportunities for many organisations, will result in significant challenges for others. It will often be the case that these challenges will have a financial reporting impact that finance teams will need to navigate. As well as the obvious currency related impacts of a more volatile GBP, we have already seen clients reassessing certain asset values (tangible, intangible or financial assets/investments) for indicators of impairment. Any resulting impairment charge are likely to have material impacts on reported results and financial disclosures relating to all of these.

Life sciences companies are also assessing a potential additional layer of regulatory approval of drugs or devices due to Brexit, resulting in requirements for additional working capital and longer term financing. This will have a consequential knock-on effect of likely interest rate volatility, possible use of financial instruments, compliance with banking covenants and the comprehensive financial statement disclosures. These should all be planned based on a detailed impact assessment.

Recent and impending effective dates for accounting standards dealing with revenue recognition, lease accounting and financial instruments require detailed analysis to understand and plan for the impact on statutory reporting. For example, there may be significantly different revenue recognition patterns arising from contracts to licence IP or similar patent rights.

Add to that the recent company law changes relating to directors' compliance statements, requirements for audit committees, consolidation requirements and non-filing structures and it's clear that there is a huge amount for organisations to deal with from a financial statement perspective.

At Grant Thornton we encourage clients and businesses to engage early with their auditors to avoid unexpected surprises or differences in interpretation.

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