An analysis of the potential impact of Brexit on the Irish Life Science Industry

Dissertation submitted in part fulfilment of the requirements of the Master of Business Administration in Finance at Dublin Business School

by,

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Declaration

I, Carolina Cujabante declare that this research is my original work and that it has never been presented to any institution or university for the award of Degree or Diploma. In addition, I have referenced correctly all literature and sources used in this work and this work is fully compliant with the Dublin Business School’s academic honesty policy.

Signed:

Date: 21st May 2018
Abstract

The Irish life Science sector plays a significant role in the Irish Economy, positioning the country as the largest exporter of Life Science products into the European Union. The geographic position and strong relationship between Ireland and the UK have played an eminent role in Ireland’s success. As such, any disruption in the relationship between the two countries will cause economic, political, and social effects. As of the 29th of June 2016, the UK presented a formal decision to leave the European Union, in what was known as “Brexit”. This study aims to find out how the Irish Life Science Industry will deal with this, looking at what major issues are facing the sector in this uncertain environment of change. Although there has been some research done in the area, existing literature showed a lack of research into the Irish Life Science sector itself, in relation to this potential change. Thus, this study will fill such gaps.

The aims of this dissertation were met by an extensive analysis of relevant literature and through the implementation of a qualitative methodology (interviews). The research is based on data collected from major Irish entities in the Irish Life Science industry: Health Products Regulatory Authority (HPRA), Irish Pharmaceutical Association (IPHA), and the Industrial Development Authority (IDA), with collaboration from two pharmaceutical companies. Data collection was carried out through semi-structured interviews.

The key findings of this research are that Irish Life Science industries see Brexit as a reality and are preparing for the worst-case scenario, with labelling, regulatory, and physical changes being the main issues affecting the industry.

The key conclusion drawn from this research was that Brexit would not heavily affect the Irish Life Science sector, but that a social impact, due to a shortage of medicines, was to be expected. Due to the unstable and uncertain nature of Brexit, this researcher recommends further studies be conducted after the agreement between the UK and the European Union goes through in order to achieve more concrete conclusions.
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Chapter 1. Introduction

1.1 Research Background

The Life Science sector is comprised of biopharmaceuticals, pharmaceuticals, and medical device companies, and is the industry responsible for the use of technology and biology to improve healthcare (Lyons, 2017).

The Life Science sector plays a significant role in the Irish economy, positioning the country as a world player and the most extensive net exporter in the European Union (Moran, 2017; Ibec for Irish Business, 2018; IPHA, 2018b). Ireland is home to approximately 120 Life Science companies, including 9 of the 10 world principal corporations, making the country a top location for the industry (IPHA, 2018b).

Figure 1. Irish Life Science Industry

After some discontent regarding European Union rules, in June 2016 the majority of British citizens voted to exit the European Union, in what was known as “Brexit” (Pruitt, 2017). This formal departure is scheduled for the 29th of March 2019 (Boyle, 2015; Hunt & Wheeler, 2017; Lyons, 2017). On the 19th of March of the present year, 2018, the European Union and the UK agreed on a transition or implementation of 21 months after Brexit, until the end of 2020, to provide clarity to people, business, and governments in order to prepare after Brexit (Clarke and Nobilo, 2018).
Due to the geographic location between the UK and Ireland, and the history between the countries, any change in the “Single Market Framework” that both countries have shared, and enjoyed, since 1973, could potentially disrupt the Irish economy also, especially in relation to the Life Science sector (Smith et al., 2016; Brozak, 2016).

1.2 Aim and Objectives of the Research

This study aims to find out how the Irish Life Science Industry will deal with Brexit, looking at what major issues are facing the sector in this uncertain environment of change. Although there has been some research done in the area, existing literature showed a lack of research into the Irish Life Science sector itself, in relation to this potential change. Thus, this study will fill such gaps. Seeing that Brexit is a new, ongoing and uncertain topic, there are limited studies related to any specific implications it would have on the Irish Life Science Industry. The literature that does exist offers some papers related to the UK Life Science industry and Brexit, with some generalisation to the Irish sector. However, the majority are based on projection about possible scenarios, “post Brexit”, such as borders, customs, and the free movement of people (potential outcomes), limited on specific impacts on the Irish Life Science Industry. For that reason, this study aims to improve and fill such gaps with information from the collection of primary data.

As stated by Kavanagh and Farrell (2017), seeing that Ireland is the largest exporter of biopharmaceuticals to the EU, it is a reality that Brexit will affect the sector. The argument is supported by Kazzazi et al. (2017) and Pharmaceutical Executive (2016), who point out that Brexit poses significant problems to the Life Science sector, with companies facing new regulations, causing delays in the distribution of medicines, among other issues. Hence, this study aims to explore the relationship between Ireland and the UK in relation to this industry, such as in supply chain, imports/exports, financial cash flow, among other operations, to find out what, if any, the main issues are that will potentially affect the sector after Brexit.

Primarily, the purpose of this research, is to assess the following - **How does the Irish Life Science Industry view Brexit and what are the major issues facing**
The research question intends to find out, in a potential Brexit scenario, how the Irish Life Science Industry perceives Brexit and what the main issues affecting Irish Life Science Companies are. The research question when investigated will help us understand the unforeseeable implications of a potential Brexit on the Irish Life Science sector, in order to alleviate any negative impact, if any, or identify potential opportunities for the Irish Life Science sector going forward.

The research question will be supported by the following sub-research questions:

1) What are Irish Life Science companies actively planning or implementing in order to prepare for Brexit?

2) On what basis are Irish Life Science companies making those decisions?

3) What impact do these decisions have on the Irish Life Science sector and on the Irish Economy, potentially?

This study is important and relevant because answering the research and sub-research questions will help gather the most relevant data from companies and institutions involved in the sector. In this way, the researcher aims to clarify the position of the Irish Life Science sector in relation to Brexit, to identify the major issues affecting the sector, and to evaluate future strategies, among other implications, that could affect the industry and the Irish economy.

1.3 Organisation of the dissertation

This dissertation is organised into seven chapters:

Chapter 1 - Introduction

This chapter explored the background of the study, highlighting the research and sub-research questions.
Chapter 2 - Literature Review

This chapter will discuss, justify, and contrast and compare relevant literature to gain an overall view of the topic, highlighting any gaps.

Chapter 3 - Research Methodology

This chapter will describe and justify the research methodology chosen, including sampling, data collection, and all the activities carried out in this research. Finally, there will be information on ethics, limitations, and the validity and reliability of the study.

Chapter 4 - Data Analysis and Findings

In this chapter, the primary data collected will be classified by themes and analysed. The findings will be illustrated and related to the research and sub research questions.

Chapter 5 - Discussion

This chapter will review and interpret the findings to compare and contrast it with the literature review, concluding with a detailed explanation of the answers explored in relation to the research and sub-research questions.

Chapter 6 - Conclusions and Recommendations

This chapter will analyse and link the findings with the aims and objectives of the investigation, to draw upon a general conclusion. Additionally, it will explain how the literature review will support the findings. This chapter will highlight some recommendations for the Irish Life Science Industry, in the eventuality of “Brexit”, along with highlighting some contributions of this study to the industry.

Chapter 7 – Self-Reflection on Own Learning

This chapter will be an analysis of the researcher’s learning experiences in the master’s program.
1.4 Scope and limitations of the research

Seeing that Brexit is a new and ongoing phenomenon, a lack of literature will be the principal limitation of this study. To avoid this issue as much as possible, the researcher will make the necessary efforts to update until the last moment the information collected (secondary research). Additionally, this study cannot develop a general conclusion, as the study finishes before the scheduled date the UK will leave the European Union. Despite this fact, the researcher made all the efforts necessary to get access to Irish Life Science companies, to gather some data on this topic. Thus, the study will be primarily based on the information collected from private and public entities within the industry.

1.5 Industry and major contributions of the research

“Life Science industry is not just critical to the health of the nation; it plays a critical and substantial role in the Irish economy” (IPHA, 2018b).

In recent years, Ireland has shown a healthy recovery, becoming the “fastest growing economy in the European Union” (Ibec for Irish Business, 2017a). As stated before, the UK is Ireland’s closest partner, thus Ireland is facing a unique challenge in relation to a potential Brexit. In this regard, any impact (threat or an opportunity) on the Irish Life Science Industry could extend to the Irish economy, which makes this dissertation’s topic relevant to those working directly or indirectly, current, or future, in the Life Science sector.

This dissertation will investigate the industry, detecting and evaluating any potential impact that could affect the industry, all of which will be relevant in order to help plan ahead and find out the most suitable strategies to help navigate Brexit. Furthermore, the benefit of this research is that it can offer recommendations to the industry. Additionally, as the Irish Life Science Industry offers a variety of employment opportunities, and because it is the researcher’s intent to stay in the country, this dissertation will help provide an understanding of how Brexit could potentially affect the Irish economy and job opportunities.
As Brexit is an ongoing phenomenon, there is a lack of studies related to the Irish Life Science Sector, which makes this research pertinent, and current.
Chapter 2. Literature Review

2.1 Introduction

This study aims to find out how the Irish Life Science Industry will deal with Brexit, looking at what major issues are facing the sector in this uncertain environment of change. Although there has been some research done in the area, existing literature showed a lack of research into the Irish Life Science sector itself, in relation to this potential change. Thus, this study will fill such gaps. In recent years, Ireland has shown a healthy recovery, becoming the “fastest growing economy in the European Union” (Ibec for Irish Business, 2017a). As stated before, the UK is Ireland’s closest partner, thus Ireland is facing a unique challenge in relation to a potential Brexit. In this regard, any impact (threat or an opportunity) on the Irish Life Science Industry could extend to the Irish economy, which makes this dissertation’s topic relevant to those working directly or indirectly, current, or future, in the Life Science sector. With regards to this topic, the literature review is divided into eight themes:

1. Understanding Brexit,
2. Irish Economy,
3. Relationship between the UK and Ireland,
4. Global Life Science Industry,
5. Irish Life Science Industry,
6. Irish Life Science and its Operations,
7. Major issues to be address in a potential Brexit such as: Trade and Commercial Issues, Operations and Supply Chain, Regulatory and Economic Issues, Bilateral Agreements,

2.2 Understanding Brexit

On the 23rd of June 2016, the United Kingdom chose to leave the European Union after more than forty-three years of membership, with 51.9% voting for "Brexit" and 48.1% for "Remain" (EY, 2016). According to Blagden (2017), the decision to leave was the result of “economic and cultural divisions”, cross-border factors, weak public
policies, and corporate governance. The UK’s decision was formally presented to the European Union on the 29 of March 2017.

The UK’s decision to leave does not mean an immediate change, as the inevitable exit from the EU will happen through procedures established in article 50 of the Lisbon Treaty. Article 50 stipulates that the process to discuss the agreements of the exit will take two years at least, and the process includes two separate negotiations: withdrawal negotiations and the future relationship between the UK and EU. The latter is expected to be longer (EY, 2016; Smith et al., 2016). On the 19 of March of this year, the European Union and the UK agreed a transition period of two years “from 29 March 2019 to 31 December 2020” (Pwc, 2018c). During the transition period, the UK will be able to negotiate its own deals with other countries, but it cannot be put “into force until after the transition period” (Deloitte, 2016; Pwc, 2018c). In the same way, during the negotiations period, the UK will still be under European Union regulations and enjoy its benefits, but the country will not have the right to participate or vote on issues affecting the European Union. Currently, there are four main issues that are still outstanding: Agreement on future trade, Resolution for future trade relations, Irish borders, and “Governance of the withdrawal agreements” (Pwc, 2018c). However, as stated by Merler (2018), the transition deal is not fully guaranteed, until the successful conclusion of the issues above.

The majority of the literature agrees that Brexit is one of the biggest potential economic threats to the UK and European Union. Due to its geographic position, Ireland faces the highest risk. However, the magnitude of the impact is highly unpredictable, because it is the first time that a country has decided to leave the EU since its creation, thus there are no historical references or an established process to refer to (EY, 2016).

2.3 Irish Economy

Before the Financial Crisis, Irish economic performance was recognised by the Organisation for Economic Cooperation and Development (OECD) as an “Economic Success Story”. In 2008, with the collapse of Lehman Brothers, Ireland rapidly fell into
a liquidity crisis that caused the Irish Financial Crisis. In 2010, being unable to borrow, Ireland was forced into an international bailout of €67.5 billion to cover austerity needs (Ruane, 2016).

The majority of literature reviewed refers to the fact that the Irish economy has thrived over the last four years, and is still recovering impressively, an argument firmly supported by Ibec for Irish Business (2017), pointing out that “this time it is most maintainable than before the financial crisis”. Hannon et al. (2011), Ruane (2016), and Ibec for Irish Business (2017a), support that the consistently pro-modernisation of attracting Foreign Direct Investment (FDI) in key sectors and the “second lowest corporate tax in the European Union”, were some of the core reasons for the Irish economic recovery. Additionally, McCoy, (2017) and OECD, (2018) reinforce that it was due to economic policies such as cost-competitiveness, export and domestic demand. In the same way, Flanagan et al. (2017) state that membership of customs unions and the single market were essential to Irish economic success.

Currently, Ireland is the fastest growing economy in the Eurozone, and “the 6th most competitive in the world”, with the youngest and highly educated population in the world (IDA, 2017; McCoy, 2017). During 2017, Ireland’s population reported high levels of living standards and robust growth earnings in the European Union (Ibec for Irish Business, 2017a). Unemployment has declined, and Ireland has the lowest levels of inflation within the European Union (Ruane, 2016; Department of Finance, 2018; OECD, 2018). Additionally, for six consecutive years, Ireland has been recognised as the best country for its FDI (Ibec for Irish Business, 2017a).

On one hand, the OECD (2018) and The Department of Finance (2018), state that, despite the fact that the external debt has been significantly paid, private and public debt still lingers at “pre-crisis levels”, a circumstance that reduces the capability to deal with economic shocks such a Brexit. Connelly (2017) mentions that “Brexit represent the single greatest economic and foreign-policy challenge to the Irish state since the Second World War. There is hardly any area of Irish life that won’t be affected”. Copenhagen Economics (2018) and the European Parliament (2018) argue that Ireland will be the member most affected by the UK’s withdrawal from the EU.
This argument is widely confirmed in the literature. The following table reflects the negative impact that Brexit will have on the Irish economy, in all potential scenarios.

Table 1. Impact of Brexit on the Irish Economy

<table>
<thead>
<tr>
<th></th>
<th>EEA Scenario</th>
<th>Customs Union Scenario</th>
<th>FTA Scenario</th>
<th>WTO Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDP Impact</td>
<td>-2.8%</td>
<td>-4.3%</td>
<td>-4.3%</td>
<td>-7.0%</td>
</tr>
<tr>
<td>Exports</td>
<td>-3.3%</td>
<td>-4.4%</td>
<td>-4.5%</td>
<td>-7.7%</td>
</tr>
<tr>
<td>Imports</td>
<td>-3.5%</td>
<td>-4.7%</td>
<td>-4.8%</td>
<td>-8.2%</td>
</tr>
</tbody>
</table>

(Source: Copenhagen Economics, 2018)

On the other hand, Flanagan et al. (2017), Ibec for Irish Business (2017b), and McCoy (2017) show confidence in the fact that Ireland and its business has substantial bases to cover the impact of Brexit, thus the country “can mitigate the side effect and take benefit of new opportunities across the world, Canada and Europe”. This argument is based on the significant improvements and capacity that Ireland has shown in recuperating from economic shocks. However, to take complete advantage of such opportunities, it is necessary to focus and prepare, as in McEnaney’s (2017) words, the Irish government is not being “ambitious enough” in trying to attract companies based in London.

2.4 Relationship between the UK and Ireland

"Ireland feeds the UK, and they keep us warm at night” (Connelly, 2017).

Previously, in the 1990s, Northern Ireland and the Republic of Ireland had a disruptive relationship. Hence, in 1998 the "Good Friday” peace agreement and membership in the European Union abolished border barriers and regulations between the countries (The House of Lords, 2016; McCoy, 2017). Since 1922, both countries signed a bilateral Common Travel Area (CTA) agreement, allowing the free movement of people between the nations, with social security (Horan and Gilmore, 2016; Irish Government Publication, 2017).
Brozak (2016), McCoy (2017), and Copenhagen Economics (2018), state that close political and cultural ties, land borders, mass movement of people, and strong economic links are some of the main reasons for the healthy relationship between the UK and Ireland. It also highlights the implications therefore of how Brexit could affect such a relationship when the UK choose to leave the EU. Additionally, the UK and Ireland have very close business integrations, which is the reason why both countries are regularly seen as one market. Hence, in comparison with other EU members, Ireland is hugely dependent on trade with the UK and is thus most affected by any such changes in market dynamics (Copenhagen Economics, 2018, pp. 13-14).

Since 1973, Ireland and the UK joined the European Economic Community, therefore, trade between both countries has been governed by customs unions and shared membership of the single market, with no barriers, and stable bilateral agreements, which is based on the similar regulatory and legal framework, language, time zone, and geographic position (Department for International Trade, 2018). Hence, Ireland is still profoundly dependent on the UK as a trading partner (Connelly, 2017; Irish Government Publication, 2017); for example, pharmaceutical products are the most substantial goods exported to the UK (Copenhagen Economics, 2018) (see Chart 3).

Figure 2. Ireland and UK Trade

(Source: Copenhagen Economics, 2018)
Therefore, “Brexit” will affect both countries, politically and economically (Bergin et al., 2016). At this point, Connelly (2017) states, it will have “enormous economic implications”. For instance, the European Union trade agreement with Canada took seven years. Hence, if the UK leaves the single market and the customs union, a new trade agreement could take a long time to be established. If within the two years, the UK does not agree on a trade deal, the UK will have to return to WTO rules, causing an enormous disruption in trade (Connelly, 2017). On the other hand, authors such as Constance (2017) and Kazzazi (2017) do not see the Irish Life Science sector being heavily impacted, as it is a robust sector. Furthermore, the Embassy of Ireland (2018), among other authors, supports the idea that Brexit will not bring about huge implications for Ireland, based on the goodwill of the “Good Friday Agreement”.

However, Brexit negotiations are still ongoing, which makes it almost impossible for the researcher, and others, to find out fully how the relationship of the two countries will be affected and how it will extend to the Irish Life Science Industry. Principally, it will depend on the agreements explained above, concerning trade, financial cash flow, and the free movement of people.

### 2.5 Global Life Science Industry

Considered one of the highest technology sectors, the Life Science Industry is the authority responsible for the production, development, and promotion of medicines (Statista, 2018), with the aim to improve health and quality of life (Efpia, 2017). Hence the industry had made substantial contributions such as reducing death and disability from diseases, extending the life expectancy of patients, decreasing the spending of public health, maintaining stable levels of employment, and generating innovative job opportunities (Phrma, 2012; Muratoglu, 2017). The sector has been historically dominated by multinational companies from the USA, Western Europe, and Japan (Achilladelis and Antonakis, 2001). The industry is a sector heavily regulated, at regional, national, and international levels (Van and Barry, 2008).
As stated by Hannon et al. (2011), the success of the industry highly relies on the challenges related to the costly, risky, and lengthy Research and Development (R&D) of new medicines. Research and Development processes are the reason the industry is investing 20 percent or more of its revenues, to avoid revenue losses resulting from patent expiry (Statista, 2018). To justify the investment, Life Science companies rely on patents, data protection, and Intellectual Property rights (IPR) (International Trade Administration, 2016).

According to Gambardella et al. (2000), the Life Science Industry is primarily operated by multinational companies, and the three different types of firms in this industry are:

- High Research and Development multinational companies with bases in its own country market, and transcontinental borders, which cover 40 to 60% of the global market.
- Small national companies specialised in the manufacturing and sale of non-intensive biopharmaceutical products in their markets, meaning these firms do not invest in the Research and Development of medicines.
- Biotechnology firms, which specialise in the Research and Development of new components, research tools, and technologies.

The Life Science Industry is one of the fastest growing and most important sectors, “increasing long-term economic growth” (Muratoglu, 2017). During 2014, the world’s Life Science Industry reached roughly €965.03 billion, and it is expected to reach €1,159.7 billion by 2018 (Lehnhausen, 2017 cited in Muratoglu, 2017, p. 1). According to Deloitte (2018), the industry forecasts growth in sales of 6.5 percent and $1.06 trillion by 2022, resulting from emerging markets.
In 2017, North America was the world largest market, with 453 billion in sales, followed by Europe, with 214 billion in sales. Hence, the sector contributes significantly to the world economy, providing high wages and quality jobs (Muratoglu, 2017; Statista, 2018). The USA is the most extensive exporter and importer of Life Science products, followed by the European Union (See Chart 1).

Chart 1. Life Science Industry

(Source: Statista, 2018)

2.6 Irish Life Science Sector

Being a member the European Union, being an English-speaking country, a competitive corporate tax rate, and generous R&D tax credit incentives, are some of the factors positioning Ireland as an excellent place to invest in (Hannon et al. 2011; Lyons, 2016 & Constance, 2017).

Between the 1960s and 1970s, Irish policies executed by The Industrial Development Authority (IDA) focused on the attraction of foreign Life Science firms (O’Riain, 2004, cited in Hannon et al., 2011; Van & Barry, 2008). Therefore, “Ireland is the home of 18 of the top 20 Biopharmaceuticals and 18 of the top 25 medical technology companies” (Ibec for Irish Business, 2017a). Since its introduction in the 1950s, the Irish Life Science Industry “has emerged substantially from selling low value-add manufacturing products to a high-tech manufacturing hub for areas such as Biopharmaceutical and medical devices” (see figure below). Therefore, the industry is internationally recognised as one of the leading and advanced sectors in the country,
offering the latest technologies and manufacturing six of the top-selling medicines in the world (Ibec for Irish Business, 2017a; IDA, 2018; IPI, 2018, p. 30). Currently, the sector is growing from the manufacture of Active Pharmaceutical Ingredient (APIs) and the packaging of products (Hannon et al., 2011), with increased services and Research and Development (R&D) (IPI, 2018, p. 30).

Ireland is home to approximately 300 Biopharmaceuticals companies, including plants and Research centres in collaboration with Irish Universities, and 450 MedTech domestic companies (IPI, 2018, p. 30). The Irish Life Science sector has produced significant employment growth; currently, the sector employs around 29,000 people in the country (Lyons, 2016; Kennedy, 2017; IPHA, 2018). During the last two-years, biopharmaceutical companies have invested over €4 billion on projects in the country, generating up to 3,000 new jobs (O’Connor, 2017) and more than €10 billion in the last decade (Kennedy, 2017). According to a revenue analysis, the manufacturing of
pharmaceutical products was the second largest contributor to corporate tax during 2016 (Tancred, 2016, pp. 14-16).

During 2017, Ireland’s exports of Life Science products were 28 percent of all the commodities, with 16 percent to the United Kingdom (MCquinn et al. 2018). In the case of imports of medical and pharmaceutical products, it reached 9 percent (IPI, 2018, p. 30; Trading Economics, 2018), positioning the country as the most significant exporter of Pharmaceutical products and the second largest exporter of MedTech products into the EU (Lyons, 2001; O'Connor, 2017; Copenhagen Economics, 2018; IPI, 2018, p. 30) (See Appendix 1). Moreover, Ireland is the 7th largest exporter in the world (Kennedy, 2017); this position is contradicted by the International Trade Administration report (2016) however, showing that Ireland holds the 17th position; either way, Ireland is still in a prominent position.

Figure 4. US's top five sources of import of Pharmaceutical Products (2015)

| 1. Ireland     | $15.2 billion |
| 2. Germany     | $14.5 billion |
| 3. Switzerland | $9.4 billion  |
| 4. Israel      | $6 billion    |
| 5. India       | $6 billion    |

Source: International Trade Administration report (2016)

Ireland is recognised for its specialisation in the “full business lifecycle”; Research and Development, to manufacturing, sales, marketing and finances activities take place in the country (Ibec for Irish Business, 2018). Ireland has a range of companies covering areas such as hospital and healthcare products, diagnostic, ophthalmic, vascular, orthopaedic, Research and Development, manufacturing and connected health (Department for International Trade, 2018). Therefore, the Life Science Industry contributes more than €1 billion to Irish corporate tax annually (Lyons, 2016).
Similarly, it manufactures a third of global contact lenses, 45% of the world’s orthopaedic knees, 80% of world’s stents, and over 30 million injectable devices (Ibec for Irish Business, 2017a).

Currently, Enterprise Ireland’s primary goal is to attract and build up start-up companies through funding supports and through innovation in the global market (IPI, 2018, p. 32). According to Kazzazi et al. (2017) and Shahid (2017), the Life Science sector is one of the most robust areas, and not even the Trump administration and its changes to US business, and Brexit, will not cause significant impacts to the industry, which is seen through continued investment and expansion. This argument is supported by O’Connor (2017), who states that the “sector remains strong”. According to Ibec for Irish Business (2018), Irish Life Science Industry trade is balanced between EU and non-European countries, with Irish plants exporting seven times more pharma products to the EU than to the UK (Whelan, 2016). In the same way, Glenn Deirdre, director of Life Science at Enterprise Ireland and Copenhagen Economics (2018), reinforces that Irish Life Science has substantial ties with Europe, mainly with North Europe, as well as America (BusinessNews.IE, 2018). Consequently, Brexit will not drastically affect the sector (Moran, 2017; Ibec for Irish Business, 2018). However, due to the size of the Life Science Industry, Copenhagen Economics (2018, p. 43) suggest that Brexit will cause a reduction in productivity.
Research shows that the Life Science Industry will be one of the sectors hardest affected, based on the strict regulations involving the industry, and the fact that Ireland is the most extensive exporter in the EU, dependant on the UK for trade (Kavanagh, and Farrell, 2017; Copenhagen Economics, 2018).

2.6.1 Understanding Irish Life Science Industry and Its Operations

The Irish Life Science Industry’s operations are divided into three main areas:

- “Pharmaceutical Manufacturing (Small Molecule)”, including drug substances known as Active Pharmaceutical Ingredients (API) and drug products, is known as tableting or formulation.
- “Biologics Manufacturing (Large Molecule)”, including drug substances known as bulk bio and drug products, known as sterile fill finish.
- “Services centres” such as Finance, IT, HR, Global supply chain management operations, regulatory affairs, pharmacovigilance, sales and marketing
support, digital platforms, and clinical trial management, among others (Fanning, 2017).

Life Science is a vital, complex, and strict industry that requires effective regulations, based on the consequences from misuse of medicines and devices. Thus, the Irish Life Science industry is highly regulated under the Rules Governing Medicinal Products in the European Union by the European Medicines Agency (EMA). At the national administrative level, the Health Products Regulatory Authority (HPRA), is the body responsible for regulations related to manufacturing, importing, distribution, marketing, prescription, labelling, pricing, licensing, inspections, and controls (Management Science for Health, 2012).

Since 1995, the European Medicines Agency (EMA) has been based in the UK (London). After the UK’s decision to withdraw from the European Union, the agency has decided to relocate to the Netherlands (EMA, 2018b). The Health Products Regulatory Authority (HPRA) works closely with the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) on many regulatory issues, at bilateral and European Union Levels (HPRA, 2018).

As explained earlier, based on the European Union free market regulations, Ireland and the UK share intrinsic links that fortify their relationship. Therefore, many global Life Science Industry companies have headquarters in Ireland and plants in the UK, or vice versa, involving extensive operations, therefore it is prudent that the relationship remains strong between both countries (Whelan, 2016). The Health Products Regulatory Authority (2018) reinforce this argument and confirm that the Irish manufacturing, licensing and distribution (Supply Chain) of pharmaceuticals and medical devices have critical connections between Ireland and the UK, meaning that both countries are treated as one market (Baker, 2018).

According to Copenhagen Economics (2018, p. 49), Irish trade of Pharmaceuticals products with the UK can take the following avenues:
• The Active Substance is made outside the UK, with manufacturing and packaging of the final product in the UK, to be sent to Ireland.
• The Active Substance is made and manufactured outside the UK, and it is packaged in the UK, before being exported to Ireland.
• The Active Substance is manufactured and packaged in Ireland, and the final product is exported to the UK or the EU, through the UK.
• Finished Products from outside the UK, passing in transit to Ireland.

2.7 Major Issues to be addressed in a potential Brexit

"Prepare for the worst and work hard for the best" – John Bruton.

According to the Department of Finance (2018), the Irish Life Science sector, among other sectors, is expected to be one of the most affected. Hence, Irish Life Science companies need to reorganise business operations links existing within the UK to evaluate issues and opportunities arising from a potential Brexit. An internal review of operations is necessary to plan and prioritise ahead for any impact Brexit has on the Irish industry. However, as each type of company is focusing on specific areas, some companies will be more exposed to Brexit than others (Pwc, 2018b). This argument is reinforced by O’Loughlin (2018), who highlights the difficulty in trying to understand the general impact it would have on the whole industry.

Some studies and academic papers consider the potential implications of Brexit on the European Union and the UK Life Science Industry, with some generalisations to Ireland (Barrett & Lambert, 2015; Bergin et al., 2016; Brozak, 2016; Smith et al., 2016; The House of Lords, 2016; Xu 2016; Constance, 2017; EFPIA, 2017; Hunt & Wheeler, 2017; Kavanagh & Farrell, 2017; Kazzazi et al., 2017; Lyons, 2017; Martino & Pang, 2017; McCoy, 2017; McFarlane, 2017; Clarke & Nobilo, 2018; Ibec for Irish Business, 2018; Pwc 2018a,b). However, the researcher notes there is a significant lack of studies focusing on the Irish Life Science Industry. Therefore, the following themes will highlight the main issues found in the literature reviewed.
2.7.1 Trade and Commercial issues

Border controls and customs duties, involving inspections and declarations, will potentially increase prices and cause disruption in the sector (Pwc, 2018b, p. 89). O’Loughlin (2018) states that “Irish-based pharma companies are having to move away from looking at global trade and related customs matters as being an operational matter to addressing it in a more strategic way”. According to Pwc (2018b), after Brexit, Irish Life Science companies could potentially experience changes such as impacts in cash flow and increases in cost through Value Added Tax (VAT), arising from border controls (currency fluctuations and price of raw material and sales to the UK) (Fanning, 2017); for example, “Irish Pharmaceutical products need to go across the United Kingdom border twice before entering to the rest of the EU” (Xu, 2017).

Regarding customs checks, companies with parallel trade, importing or exporting from Ireland or the UK, will now deal with increases in lead times and cash flow implications (Pwc, 2016, 2018b). As mentioned by O’Loughlin (2018), single market shortages and risk of delays in finishing products or raw materials will disrupt Pharmaceuticals, Medical Devices production, Pharmacies, and hospitals.

2.7.2 Operations and Supply Chain Issues

Most of the papers reviewed support that Irish Life Science companies could potentially face disruption in the supply chain, which will require a restructuration of operations, to guarantee that Wholesale Distribution Authorisation (WDA) is licensed within the European Union (Pwc, 2018b; Department of Finance, 2018). As a result, modifications or establishments of new supply chain procedures will raise costs on Life Science Products (Pwc, 2018b). Currently, many Irish Life Science companies ship finished products to storage in the UK before being distributed throughout Europe. After Brexit, companies might have to build storage in Ireland to avoid tariff and costs (McFarlane, 2017; Kavanagh & Farrell, 2017).

Any medicinal product containing a new active substance, in treatments for cancer, neurodegenerative disorders, AIDS or diabetes, require Marketing Authorisations as a
compulsory process (HPRA, 2018). As stated by Robinson (2016), for more than two decades, the UK’s Medicines and Healthcare Regulatory Products Agency (MRHA) has been chosen and has dominated as a Reference Member State for large marketing authorisation applications. As a result of Brexit, Irish Life Science companies must now look for a new Reference Member State located within the EU (TaylorWessing, 2016).

Based on the above statement, a notified body is an entity whose primary responsibility is to guarantee that manufacturers and Medical devices meet legal requirements. Currently, the UK has six such bodies (Amtac Certification Services Ltd, BSI Healthcare, Lloyd’s Register Quality Assurance Ltd, SGS United Kingdom Ltd, and UL International (UK) Ltd), of which roughly a quarter are used by Irish companies (Connelly, 2017; GOV.UK, 2018). Hence, companies holding authorisations from UK notified bodies need to evaluate alternative options (Kavanagh and Farrell, 2017; HPRA, 2018). At this point, TaylorWessing (2016) views "The UK is a sizeable life sciences market within the EU and applicants will be likely to want to have MAs in both the EU and the UK", which the researcher sees as a new market investment.

In the case of Dual Pack Import Registration (DPR), Robinson (2016) states that many Life Science products in Ireland are registered in the UK and Ireland, without alteration, based on the mutual language and regulations, all part of single market agreements. In this case, as a result of any changes in the regulatory framework, companies could potentially face cost increases in the administrative and regulatory process and face reductions in trade and production (Copenhagen Economics, 2018, p. 50; HPRA, 2018).

2.7.3 Regulatory Issues

The European Medicines Agency (EMA) is a European Union agency, whose responsibility involves the monitoring, supervision, safety, and evaluation of human and animal medicines into the European Economic Area, under a robust and highly sophisticated regulatory system. As stated, the European Medicine Authority (EMA) has been located in London for more than 50 years and after the UK’s decision to withdraw from the EU, the EMA decided to move to Amsterdam. The body has to
continue with its legal role, despite anticipated staff loss (EMA, 2017, 2018b; Connelly, 2017).

According to Kavanagh & Farrell (2017), Copenhagen Economics (2018), and O’Loughlin (2018), the principal issues facing the Life Science Industry, are Regulatory Compliance in areas such as Good Manufacturing Practice, Products Standards, Good Distribution Practice (GDP), Manufacturing and Importations Authorisation (MIA), Wholesales Distributions Authorisation (WDA), and Registration of Active Substances manufacturers, Importers and distributors. This argument is supported by Baker (2018), who forecasts that the impacts in the Life Science Sector would be “almost entirely driven by regulatory divergence and by increasing border costs”.

At this point, it is difficult to assess if the UK Life Science industry will remain regulated by EU laws. Hence, Kazzazi et al. (2017, p. 5) look at the worst-case scenario, whereby the UK will not continue being part of the free movement of Life Science Products or part of the European single market.

Following, are some of the primary procedures that Irish Life companies could potentially have to address:

- **Qualified Person (QP)**, each production batch of pharmaceuticals products must be controlled and certified before being sold, according to Marketing Authorisations by a Qualified Person (EMA, 2017, p. 3).

- **Qualified Person for Pharmacovigilance (QPPV)**, is responsible for the “Overall pharmacovigilance of the medicinal products, with marketing authorisations in the European Union”. Principally, the QPPV is responsible for contacting the authorities, with overview of the safety profile of products (The Rules Governing Medicinal Products in the European Union, 2008 and EMA, 2017, p. 8).

According to the Rules Governing Medicinal Products in the European Union, both the Qualified Person and the Qualified Person for Pharmacovigilance must reside and operate within the European Union (EMA, 2017, p. 8).
• In the case of medical technologies, each production line must be validated, thus, if a company that currently import products from the UK, after Brexit, decided to import a component from another country to avoid cost, it must request a new validation, which currently takes one year to be approved (Connelly, 2017).

• Pharmaceutical products manufactured in the United Kingdom, to be imported to Ireland, will need to adhere to EU regulations (EMA, 2017, p. 3).

Overall, such regulations will hamper Ireland’s exports and worldwide attractiveness as a pharmaceutical hub (Copenhagen Economics, 2018).

2.8 Bilateral Trade Agreements

Based on the close relationship between Ireland and the UK and the importance of the sector to the European Union, there is the possibility for finding and making exclusive agreements in the industry.

The UK Life Science Industry plays a significant role in the EU, which is the reason that some health communities are already looking for ways to avoid any potential damage that Brexit will cause to patients and the industry in the European Union. The request indicates that the EU should keep close cooperation, flexible regulations, and reciprocal arrangements between the EU and the UK to ensure the supply chain of medicines to European patients (EFPIA, 2017). In this case and based on the links that Irish companies share with British Life Science companies, Brexit may not have any implications on the Irish Life Science Industry. As such, bilateral agreements may be the best scenario for the Irish Life Science Industry (Kazzazi et al., 2017).

In another instance, under the World Trade Organization (WTO) agreements, pharmaceutical products have “zero-for-zero” tariffs, which means that in the worst scenario, even in a hard Brexit, there will not be an increase in pharmaceutical trade (Parliament, 2017 and Xu, 2017). At this point, Lord Bridges and Lord Price (cited in Parliament, 2017) conclude, “All WTO members enjoy the benefits of tariff-free trade to signatory countries irrespective of whether or not they themselves are members. The UK will therefore continue to benefit from the tariff eliminations of negotiating
parties”. Hence, “The UK will continue to place zero tariffs on pharmaceutical goods covered by the Agreement” (Parliament, 2017).

### 2.9 Potential Implications of the Irish Life Science Sector and the Irish Economy

#### 2.9.1 Drawbacks

Smith et al. (2016) state that, after Brexit, transactions between the UK and Ireland could disrupt product supply chains and parallel trade, increasing tariffs and non-tariffs (Pwc, 2016; Kavanagh & Farrell, 2017). In the scenario of border barriers, it will cause delays and interruptions, mainly due to the short expiration period of products (Xu, 2017).

Additionally, new regulations or the elimination of dual product labelling for the UK and Ireland may benefit both countries and reduce costs (Lyons, 2017).

Overall, trade is the main issue facing the Irish Life Science sector and, subsequently, the Irish economy. Hence, any change in the trade relationship between Ireland and the UK will result in increasing costs and shortages of medicines, which will be detrimental to the industry, and Ireland; nevertheless, it will all depend on regulatory agreements (Copenhagen Economics, 2018, p. 32). According to Copenhagen Economics (2018), Brexit will have a negative impact on Ireland in any potential scenario.
2.9.2 Advantages

As explained by PWC (2018b), the UK’s exit from the European Union and consequently from the European Medicines Agency (EMA), will increase costs and complicate processes in the UK. As a result, McEnaney (2017) supports that many companies will prefer to operate high regulatory processes such as clinical trials and patent disputes outside the UK. This argument is supported by Gullan (2016), who confirms that Life Science companies based in the UK are looking to continue having access to the EU market, which is the motivation for searching for new centres; “Numerous Japanese Life Science companies with research centres in the UK have already said they will move to where the EMA does” (Gullan, 2016).

In the same way, Kavanagh and Farrell (2017) state that, after Brexit, Life Science products manufactured in the UK will require an import authorisation, before entry to EU markets (HPRA, 2018), which opens up the opportunity for companies relocating into the EU to look at Ireland. The argument is reinforced by literature (Barrett et al.,
2015; Fanning, 2017), who argue that Foreign Direct Investment could increase from companies moving or investing in the country, which at the end of the day will benefit the Irish economy; this argument is supported by the announcement of new investments, relocations, and expansions into Ireland (IDA, 2018). Similarly, McCoy (2017) concludes that, after Brexit, Ireland will be the only English-speaking country in the Europe Union, which is the business language of the world (Brown, 2017), thus the majority of US companies would expand operations into this country, motivated by ease of access to Europe. A such, any potential decline in the UK’s economic activities and uncertainty from European citizens could bring another opportunity to Ireland in the form of attracting more talent and investment here instead (Copenhagen Economics, 2018).

For the Irish medicines regulatory authority (HPRA), Brexit will significantly increase its responsibilities, as they must take over the majority of the workload from the regulatory body in the UK (MRHA) (HPRA, 2018). Hence, positively, in the worst-case scenario of Brexit, the Irish Regulatory Authority would be required to expand its operations, opening up new job opportunities.
Chapter 3. Research Methodology

3.1 Methodology Introduction

According to Saunders et al. (2016, p. 5), research is the methodical process used by investigators to understand something or to increase knowledge, through a logical interpretation and systematic collection of data.

This research aims to analyse the potential impact of Brexit on the Irish Life Science sector and will fill the existent gap on this topic in the literature. As Brexit is a new and ongoing phenomenon, it is vital to gain accurate and relevant information from the Irish Life Science industry.

This chapter will detail the methodology adopted to collect the data in the research and the reasons why it was chosen. Additionally, how the participants were chosen and how the primary data was gathered will be explained. Finally, ethical issues and limitations encountered will also be discussed.

To better understand the research process, this study will follow the “research onion” framework designed by Saunders et al. (2016), which comprises research philosophies, research approaches, research strategies, research choices, time horizons, and techniques and procedures.
3.2 Research Philosophy

As stated by Sekaran and Bougie (2016), a research philosophy is a basic worldview or belief system that guides the investigation, as well as the development of knowledge and the nature of the developed knowledge, thereby making the appropriate selection of a research philosophy a part of a research methodology. According to Saunders et al. (2016, p. 124), research philosophies are assumptions and beliefs involved in the process of acquiring new knowledge. These assumptions are divided into Reliable knowledge (epistemological), involving the perception of reality and the way in which the researcher perceives the world around them, and Ontological Knowledge, how the epistemological knowledge is adapted in order to research the study. In brief, epistemology is a branch of philosophy that deals with the nature and sources of knowledge, as well as the limitations of knowledge in the area of study (Baran and Jones, 2016; Killam, 2013). It is helpful in classifying what
constitutes and does not constitute knowledge. Ontology, on the other hand, refers to the researcher’s view/understanding of the nature of reality. In addition, there is Axiological Knowledge, which are personal values that influence the way the research is carried out (Blumberg et al., 2014; Saunders et al., 2016).

Saunders et al. (2016) illustrate in the first layer of the onion the most recognised research philosophies.

- **Positivism** refers to research that is independent, value-free, and gathered by analysing facts from the external world, objectively, and then testing them. Studies that follow a positivist approach are highly structured, normally quantitative in nature, and focus on a specific explanation for a phenomenon (Blumberg et al., 2014, p. 16; Gill & Johnson, 2010).

- **Critical Realism** refers to what humans see, and their experiences, according to sensations or representations that are external and independent. It is usually employed in in-depth historical and social research (Saunders et al., 2014, 2016).

- **Interpretivist** philosophy lends itself more to studies related to the business world. Interpretivism concern human behaviours rather than facts (Bryman and Bell, 2015, p. 28; Saunders et al. 2016 and Blumberg et al. 2014).

- **Postmodernism** attributes more emphasis to language, meaning that what is perceived as reality is created by personal acts of cognition. It analyses and criticises “discursive forms” to explore its impact (Gill and Johnson, 2010).

- **Pragmatism** supports that the investigation starts with a problem, to find a solution for said problem, using credible and relevant methods to collect the data. There is more emphasis on practical results and the research strategy, and design depends strongly on the research question and the research problem (Saunders et al., 2016, pp. 143-144).

The positivist research philosophy adheres to the view that only factual knowledge is trustworthy, and that science is the only way through which truth can be learnt. The philosophy is based on the objective epistemology and the realist ontological view where an individual view the world as made up of distinct and observable events and
elements that interact in an observable, resolute, and regular manner. The positivist research philosophy is based on the position that sees knowledge as tangible and objective, and it prefers scientific, quantitative methods. As a result, the role of the researcher in positivist studies, also known as quantitative studies, is limited to data collection and analysis/interpretation in an objective way (Killam, 2013; Baran and Jones, 2016). In addition, positivist studies adopt a deductive approach (theory-testing), their findings are observable and quantifiable, and they are analysed using statistical data techniques. The typical methods used in such studies are surveys, questionnaires, and random sampling (Killam, 2013).

In contrast, interpretivists are of the view that social reality is subjective and shaped by participants’ perceptions and values, as well as the aim of the researcher. As noted by Sekaran and Bougie (2016), researchers in favour of this research philosophy use an inductive research approach (theory-building approach), specifically the qualitative research methodology, where a small sample of participants are recruited and evaluated to understand a larger group of people. As described by Bernard (2017), qualitative research methodology is an interpretive approach to the subject matter, where special emphasis is on observations and subjective experiences.

The research philosophy chosen in this study is interpretivist, since the researcher aims to get a better understanding of the impact of Brexit on the Irish Life Science sector, based on the information collected from Life Science companies and other private and public-sector entities.

Because of how diverse the Irish Life Science industry is, and the uncertainty of Brexit, this study will not generalise a conclusion for the entire industry (Saunders et al., 2014). However, the researcher will make significant efforts to collect as much data as possible to cover the most significant themes in this area.

3.3 Research Approach

According to Blumberg et al. (2014, p. 19), there are two main research approaches: Deduction and Induction.
The Deductive approach is a rigid process where a conclusion is given based on the evidence, which must be true and valid (the relationship between cause and conclusion). In this approach, the data is collected to evaluate a real theory. In contrast, the Inductive approach is characterised by the collection of data to build a theory instead of testing something. The Inductive approach is typically associated with qualitative research (Blumberg et al., 2014; Bryman and Bell, 2015; Saunders et al., 2016). Saunders et al. (2016, p. 144) discuss a third approach, Abductive, which adopts both the deductive and inductive approach, meaning that data is collected to explore a phenomenon, and identify patterns and topics to generate and test a theory.

The researcher will start with the collection of data from the literature and continue to the collection of primary data from Irish Life Science companies and private and governmental entities. Therefore, the research approach implemented is inductive, as it suits the aim of this study, which is to collect and analyse data to gain a better understanding of the potential issues and position of the Irish Life Science sector as a result of Brexit. Hence, the facts will conclude with a “conceptual framework” (Saunders et al. 2016, p. 147).

3.4 Research Strategy

A strategy is known as the plan necessary to achieve a specific goal. Therefore, the research strategy is guided by the research, sub-research questions, and the aim of the investigation, which must be related to the philosophy, approach, knowledge, access to participants, and time limitations (Saunders et al., 2016; Sekaran & Bougie, 2016).

According to the Research Onion framework, the Research strategy is divided into: Experiment, Survey, Case Study, Grounded Theory, Ethnography, and Action Research (Saunders et al., 2016). The research strategy implemented in this study was Survey, based on the method of data collection (semi-structured and open-ended interviews). The research plans to explore, compare, and describe the implications of Brexit on the Irish Life Science Sector, according to the information collected from Life Science companies and entities involved in the sector (Kumar, 2014, p. 171). This method was
chosen because it allows the researcher to collect data on many types of research questions, to achieve the aim of the study, which is to gain a better understanding of how Brexit will affect the Irish Life Science Industry (Sekaran and Bougie, 2016).

3.5 Research Choice

The research design refers to the structure or framework implemented to collect and analyse the data. The research design is always grounded in the research and sub-research questions, and it outlines the procedures for each research step (Bryman & Bell, 2015; Blumberg et al., 2014). There are two distinct research choices - quantitative and qualitative. Quantitative research involves the collection of data in the form of numbers and figures. In contrast, qualitative research is characterised by the collection and interpretation of data, typically using words rather than quantification (non-numerical data) (Biggam, 2015; Bryman & Bell, 2015).

This study employed a qualitative approach, to understand, discover, and clarify the position of the Irish Life Science sector in relation to Brexit, which is an ongoing and complex topic, without defined “borders” and with few studies centred around it (Hair et al., 2016). The research will be based on the information recovered from Life Science companies and private and public entities within the industry, established in Ireland, to gain a better understanding. The adoption of this method will allow the researcher to be more flexible and to modify procedures and questions during the process, which means it will be a non-standardised process. Hence, the research will not contain statistical procedures (Gill and Johnson, 2010; Saunders et al., 2016).

3.6 Time Horizon

The fifth layer of the onion is the time horizon, which is related to the duration of the study (Saunders et al., 2016). Cross-sectional studies gather data to answer the research question in “one-shot”. Its focus is on a specific phenomenon at a precise point of time and it frequently employs qualitative or mixed methods and a survey strategy. In contrast, longitudinal studies investigate human behaviours or phenomena at different stages and times, which means the data is collected over a
longer period to investigate “development and change” (Saunders et al., 2016; Sekaran & Bougie, 2016).

This research adopted a cross-sectional approach, based on the time available to conduct the research and the ambiguity surrounding Brexit (Saunders et al., 2016). As Brexit negotiations are still ongoing, and this research offers a current point of view on the Irish Life Science sector, the situation, and conclusions, could change in the future, thus this study does not allow for the implementation of a longitudinal study.

3.7 Sampling - Selecting Respondents

A sample refers to a section of the population carefully chosen to represent or be representative of a larger cohort of people. As is shown in the figure below, there are two types of sampling techniques: Probability and non-probability sampling (Bryman and Bell, 2015, p. 728).

Figure 7. Sampling Techniques

(Source: Saunders et al., 2016)
Probability sampling is a precise procedure that ensures the collection of data from an entire population, with the aim of guaranteeing a non-zero selection. The sample is selected from a sampling frame. In contrast, non-probability or non-random sampling is employed in surveys and case study research, due to the absence of a good sampling frame. It allows the researcher to choose the population to be sampled, and is characterised by imprecision (Blumberg et al., 2014; Saunders et al., 2016).

Taking into account the high number of Life Science companies established in Ireland and the impossibility of contacting all of them, the sampling technique used in this research was non-probability sampling, based on the accessibility of the lead companies established in Ireland. As there is no specific sample size, the researcher will collect as much data as possible from the most valuable sources (Kumar, 2014, p. 171; Sekaran & Bougie, 2016).

Hence, the sampling technique chosen is self-selection sampling - volunteer sampling (Saunders et al., 2016). To gather better information and due to the inexact probability of collaboration and accessibility from the companies, the researcher chose to contact the first 50 organisations listed in the Irish times top 1000 (2018) and the Business & Finance Magazine (2018). The researcher considers entities such as the Irish Pharmaceutical Healthcare Association (IPHA), the Health Products Regulatory Authority (HPRA), and the Industrial Development Authority (IDA), as playing an important role in the industry, thus their involvement is necessary for the successful completion of this research.

3.8 Data collection

Data collection involves the selection of appropriate methods to obtain the information needed, according to the research question, time, objectives, and strategy. The four principal methods for collecting primary data are interviews, observation, questionnaires, and experiments (Sekaran and Bougie, 2016). In order to achieve the aim of the proposed study, the researcher must use the appropriate data collection tools and techniques. According to Parahoo (2014), the choice of data collection method in any study should be guided by the nature of research and specific
information required to answer the research questions. In addition, the data collection instruments used in the study should be in line with the research design, research methods, and research philosophy adopted by the researcher (Parahoo, 2014).

As the purpose of this study is to analyse the impact of Brexit on the Irish Life Science Sector, the researcher considered that the most appropriate method to collect primary data would be interviews, as it would allow more relevant and in-depth information to be gathered from the Life Science industry. Qualitative interviews tend to be less structured than quantitative interviews. In qualitative interviews, the researcher seeks to gather detailed answers (Blumberg et al., 2014). As shown in the figure below, qualitative interviews are grouped into two types: semi-structured and unstructured.

Figure 8. Qualitative Interview

In semi-structured interviews, the researcher has a list of questions, an “interview guide”, with areas to be covered, which can be answered in any order. This type of interview is recommended if the research has a clear focus. As such, the primary data will be gathered through semi-structured interviews to get a closer and more detailed understanding of the implications that Brexit could bring to Life Science companies established in Ireland, with information on how they are preparing for it. The literature
review showed a lack of detailed, relevant, and reliable data on the Irish Life Science Industry; thus, it is the aim of this study to gather information from the Irish Life Science companies to fill such gaps. As such, semi-structured interviews were chosen to allow the researcher to add, omit, or change questions according to the answers given, in order to glean more information and data from the subjects. To gather the most pertinent data on this matter, the researcher will carry out interviews with The Irish Pharmaceutical Healthcare Association (IPHA), the Health Products Regulatory Authority (HPRA), and the Industrial Development Authority (IDA).

To collect the interview data, the researcher used a recording device (personal mobile phone). The researcher contacted by phone and email the CEO and senior managers of 50 organisations listed on the Irish times top 1000, (2018) and the Business & Finance Magazine (2018), and the entities mentioned above, to arrange “Interviews”.

### 3.9 Research Ethics

Bryman and Bell (2015, p.131) state that, “ethical precepts should never be broken”. According to Diener and Crandall (1978), ethical issues in business research are divided into four categories: harm to participants, lack of informed consent, invasion of privacy, and deception (cited in Brymand and Bell, 2015, p. 134).

This study was developed according to the above issues and according to the Ethical Guidelines for Research with human participants and procedures for Ethical Approval of Dublin Business School, following the premise that:

- All the participants must give written consent to collaborate in the study (See Appendix 4)
- Confidentiality and anonymity will be guaranteed.
- The data will be protected according to data protection laws.
- The research will not harm any of the participants.
- The data must be reported as is, without alterations.
Electronic Communications must also adhere to ethical guidelines.

### 3.10 Research Limitations

As Biggam (2015) states, there is no "student dissertation that is problem free or not limited". The first limitation this study encountered was the limited sampling size of the population. Despite the fact that the researcher contacted 72 Irish Life Science-based companies, only seven companies replied, stating they would not be participating. By the end, only two accepted. However, due to the flexibility that the inductive approach affords, and the time constraints, the researcher decided to mitigate the limitations and contacted the most recognised entities working in the industry (IPHA, HPRA and IDA), to help gather relevant information and get a broader idea of the problems facing the Irish Life Sciences sector. The study was carried out over three months, which was a limitation in relation to contacting more companies and getting more precise data. As a result of the lack of responses from bodies/entities, the researcher modified the questionnaire, which unfortunately will not generalise a conclusion or provide enough accurate data to generalise for the industry as a whole.

Lack of experience and knowledge in the sector was a significant limitation to the questionnaire’s design, and in carrying out the interviews and analysing the data. Nevertheless, the researcher prepared and practiced the interviews as best she could, which helped dilute this limitation.

### 3.11 Validity and reliability

Validity and reliability are distinct types of procedures to measure the potential, rigour, and value of the research, according to specific principles (Mason, 1996, cited in Bryman and Bell, 2015, p. 400). Reliability is the degree to which an idea is stable and consistent, while validity refers to the veracity of research measures and the credibility of the conclusions (Bryman & Bell, 2015; Saunders et al., 2016).

The research is valid because it is based on a research strategy, “Survey”, which was tested and tried and already explained and justified in many other studies. The data collection and analysis techniques implemented are appropriate and adequate to the
research (Biggam, 2015, p. 182). As such, the study is trustworthy, authentic, and credible (Creswell, 2014).

In the same way, the research is reliable because it was carried out using the usual methodological methods, and the collection of primary data was documented on audio recordings and in transcripts. Additionally, each participant signed a consent form (Biggam, 2015, p. 183).

However, due to the fact that Brexit is an ongoing and difficult phenomenon, and the primary data was collected from interviews, which rely on personal opinions, there is a risk of bias and inaccuracy in the answers (Saunders et al., 2016, p. 206).
Chapter 4. Survey Research Data Analysis and Findings

4.1 Introduction

Data analysis in qualitative research involves refining and summarising the data collected to allow themes to emerge (Hair et al., 2016). This chapter will describe and analyse the data collected and highlight the main findings. The data collected from the interviews will be grouped into themes to identify patterns and connections amidst the findings. The data collected will be reviewed to discard any information not necessary (Hair et al. 2016, pp. 303-309). As mentioned in the previous chapter, primary data was collected from three public and private entities in the Irish Life Science Industry, and two Pharmaceuticals companies.

4.2 Survey Participants

Primary data was collected from the following entities:

- **Irish Pharmaceutical Association (IPHA)** - oversee the international pharmaceutical industry in Ireland and abroad. Additionally, they control codes of practice and advertising for the industry (IPHA, 2018).

- **Health Products Regulatory Authority (HPRA)** - a governmental entity, whose main role is the regulation of medicines, medical devices, and other health products, to “protect and enhance public and animal health” (HPRA, 2018).

- **Industrial Development Authority (IDA)** - an independent “state-sponsored” body in charge of attracting Foreign Direct Investment (FDI) to Ireland (IDA, 2018).

- Interviews with two Pharmaceutical companies (names not disclosed) are also part of the primary research, and each company will be identified as **PC1** and **PC2**.
4.3 Data Overview

To better understand the primary data collected, it will be summarised and classified according to themes. The following table contains the data from the three entities mentioned earlier – IPHA, HPRA, and IDA.

Table 2. Data Display of entities

<table>
<thead>
<tr>
<th>THEME 1:</th>
<th>Q1, Q2, Q6, Q7 and Q15.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brexit and Impacts in the Irish Life Science Industry:</td>
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<table>
<thead>
<tr>
<th>THEME 2:</th>
<th>Q4, Q5, Q12 and Q13.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irish Life Science Relationship with the UK:</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>THEME 3:</th>
<th>Q3, Q8, Q9, Q10, Q11, Q17 and Q18.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plans, Expansion and Relocations:</td>
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<table>
<thead>
<tr>
<th>THEME 4:</th>
<th>Q14 and Q16.</th>
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<tr>
<td>Impact on the Irish Economy:</td>
<td></td>
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4.4 Data Analysis and Findings from entities (IPHA, HPRA and IDA)

4.4.1 Theme 1: Brexit and Impacts in the Irish Life Science Industry

**Q1. In your opinion what will be the potential impact of Brexit on the Irish Life Science industry?**

The **IPHA** sees Brexit’s effect on the Pharmaceutical Sector to be mainly focused on customs administration and potential tariffs. If there is no deal, the UK will go under
WTO rules, where tariffs are low, thus there will be no real impact on tariffs because the VAT is low.

The **HPRA** point out that as Ireland is not part of the mainland of the EU, it will complicate trade. Labelling and access to drugs that are small in production will be a problem for the industry, meaning shortages of medicines in Ireland.

The **IDA** state that 99% of multinational companies will not be impacted by Brexit because most of their sales are worldwide. Multinationals manufacture for all markets.

**Q2. How much of a challenge does Brexit represent to the Irish Life Science industry?**

The **IPHA** state that Brexit will not have a big impact, but there will be friction in relation to trade. Additionally, customs administration and paperwork will add costs for companies. According to the **HPRA**, Brexit will have a big impact because the UK conducts about 20% of its business within the EU (Regulatory). Brexit is a big problem for companies with sites in the UK, in relation to batch release and quality control. Companies will have to relocate these sites into the EU. However, as the EU and UK negotiations are still ongoing, the companies are finding it hard to decide if they need to move or not; 18 months is not enough time to move.

According to the **IDA**, companies will have to move a lot of testing and batch releases of products and services from the UK to follow EU regulations and requirements, which could mean they decide to move these services to Ireland.

4.4.2 **Theme 2: Irish Life Science Relationship with the UK**

**Q4. What are the links, if any, and how close are the links between the Irish Life Science Industry and the UK?**

The **IPHA** points out that, at the moment, 65% of medicines that come into Ireland came from or through the UK. The **HPRA** make the point that the industry has a huge relationship with the UK and that the amount of business the UK conducts within the EU is quite large, thus, the impact on companies will be big.
The IDA states that regulatory affair teams and commercial teams for some companies, such as in the approval of drugs, who are based in the UK, will have to move to the European Union. Ireland and the UK label their drugs together (One market); however, after Brexit, Ireland and the UK might not be able to continue doing so.

Q5. **In your opinion, how would Brexit affect business operations with the UK?**

According to the IPHA, everything depends on the regulatory and legal status of medicines and what medicines are allowed into the Irish market. It is a medium sized problem, as, at the moment, medicines are labelled and can be sold in the UK and Ireland and still meet the requirements of the HPRA and the EU. It just means that when the UK leaves the EU, Ireland and the UK will not be able to share labelling.

Ireland will have to reorganise supply chains (Transit agreements) regarding these drugs by teaming up with France or other countries to share labelling duties, which will come with additional costs. To sell drugs in the EU, companies must be based in the EU. Therefore, they will have to move out of the UK if Brexit moves ahead as planned.

The IDA supports that the approval of the drugs for sale in the European Union because a large amount of drugs approved are labelled in different languages in each country. As Ireland has a small population, it could be too costly to label the drug for a small number of drugs just for the Irish market and for specific small patient populations. Thus, they will need to import the products from elsewhere.

Q12. **Does the UK depend heavily on Irish Life Science companies?**

The IPHA pointed out that Ireland made some products for the UK market, but not a lot.

Q13. **Does Ireland depend more on the UK Life Science Industry?**

The IPHA could not give a full answer but explained there are companies like GlaxoSmithKline (GSK) who make a lot of their products in the UK, but they added that this dependence was not a big problem.
Theme 3: Plans, Expansion and Relocations

Q3. What changes, if any, have companies already made to modify or diversify its business structure after Brexit was announced?

The IPHA notes that companies will need to make changes on the supply chain side and avoid sending products from Europe to Ireland through the UK.

The HPRA point out that there are administrative and physical changes, such as clinical trials and batch release sites that must be done in the European Union. Additionally, legal requirements for each product are necessary, to fulfil the EU regulations.

The IDA believes Irish companies could look at the UK as a 3rd market, meaning companies could set up manufacturing and sale of their products in the UK that will only be for the UK market. From Ireland’s side, companies could potentially move some of their business activities to Ireland, which were in the UK, to be able to sell to the EU. International companies that have their bases in the UK could stay in the UK from a regulatory point of view, but, post-Brexit, they could look for a new location in Ireland.

Q8. What plans, if any, has the company been developing?

The IPHA argue companies are planning for a hard Brexit to make sure it does not affect them. All plans will depend on the agreements between EU and the UK after Brexit, but nobody knows for certain. Irish customs and revenue will advise pharmaceutical companies and wholesalers on how to become authorised economic operators, which would mean becoming a trusted trader, to limit the number of checks that authorities have to do. Therefore, the impact will be low to medium.

Q9. Since Brexit was announced, is there any increase or reduction of expansions, relocations, or investments from Pharmaceuticals companies in Ireland?

According to IDA, it is pretty much the same, with just a slight increase. They note that what is more important is Trump’s administration, rather than Brexit, because tax
changes in the US have made new companies look at setting up in the US now instead of Ireland. The companies already in Ireland will stay, but new companies will be harder to attract now because of changes in US business.

**Q10. What is the percentage of Irish based Life Science companies, willing to change any of the operations from the UK to Ireland? (i.e. Reference Member State, Marketing Authorisations, Qualified Person or any other regulatory issues?)**

The HPRA state there are no figures, because companies are not saying what they are planning for, at the moment. They note it is a slow process.

**Q11. What are the reasons motivating those decisions? (change or adjusted in business operations)?**

According to the IPHA, the reasons include minimising risks, to keep with regulations and drug supply chains without interruptions.

The IDA point out that companies that do not have bases in the EU will prefer to relocate to Ireland. In addition, if they want to keep the relationship with the companies they are working with, it makes sense to move to Ireland.

**Q17. As a result of Brexit, do the HPRA have any plans to extend or expand operations?**

The HPRA state they are looking to get more members to come to Ireland and are waiting for companies to come to them. They think companies will choose Ireland because of the relationship they have with them already and our reputation. To continue labelling on some products, companies, which have big operations in the UK and a small office in Ireland, could move more services to Ireland.

**Q18. How many, if any, new announcements from Pharmaceutical or Medical device companies planning to expand, relocate, or invest in Ireland has not been published?**

The IDA pointed out that it is an ongoing process. They noted that the last big announcement was MERK (MSD), which is going to create 350 jobs. A lot of the packaging agents and contract manufacturers are moving from the UK to Ireland.
because they do not have an EU location. The IDA pointed out that they did not see this happening before, and it is good for Ireland. The largest independent package company in the UK, Wasdell and Almac, have announced big investments in Ireland. The IDA stated that they expect more packaging companies will relocate to Ireland.

4.4.4 Theme 4: Impact on the Irish Economy

Q14. Given the importance of the Life Science industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they?

The IPHA responded that it could be good to get some legal staff from the UK to Ireland. However, the UK leaving the EU and its 60 million people leaving the single market is not good, as the opportunities are very small, with regulatory and administrative changes being more negative than positive. As the Irish market is small, there will be a short supply of medicines to Ireland.

The HPRA noted there is a gap that will need to be filled after Brexit, and that they will try to fill it. They noted that, for Ireland, Brexit is more of a challenge than an opportunity.

The IDA explained that Irish companies would have more problems because they conduct a large part of their business with the UK, while, for the international companies, there will be more an opportunity. Britain will have to become very competitive now, reducing the tax on the products or offering credit for investment in Research and Development, which could be a risk for Ireland. Patients in Europe will not get access to specific drugs, which is the major issue.

Q16. How could Brexit affect the Irish Life Science industry extending to Irish economy?

The IPHA points out that it will not be a big impact in the short term, based on our population, which is 4.5 million. However, if regulations change in the EU, it could be costlier, and markets such as Canada and India will be more competitive. If nothing
changes in regulatory standards, then most likely nothing will change, but if England changes its direction to target markets outside the EU, it could have an impact.

The **HPRA** stated that the movement of products between EU and the UK could be a problem in relation to customs. Financial challenges for companies will be more than those encountered in the normal day to day work. However, the economic impact in Ireland is hard to tell, but companies are here for Ireland’s low tax rate, so they will not leave.

The **IDA** explained that Irish patients could have a problem in getting some drugs based on the labelling of products and the drugs approval processes.

### 4.5 Data display of Life Science Companies (PC1 and PC2)

**Table 3. Data display of Companies**

<table>
<thead>
<tr>
<th>THEME 1:</th>
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<tbody>
<tr>
<td>Brexit and Impacts in the Irish Life Science Industry:</td>
<td>Q1, Q2, Q10 and Q11</td>
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<table>
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<tr>
<th>THEME 2:</th>
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<tr>
<td>Irish Life Science Relationship with the UK:</td>
<td>Q3, Q4 and Q5.</td>
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<tr>
<th>THEME 3:</th>
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<tbody>
<tr>
<td>Plans, Expansion and Relocations:</td>
<td>Q6, Q7, Q8 and Q9.</td>
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<tr>
<th>THEME 4:</th>
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</table>
4.6 Data Analysis and Findings from Companies (PC1 and PC2)

4.6.1 Theme 1: Brexit and Impacts in the Irish Life Science Industry:

1) In your opinion what will be the potential impact of Brexit on the Irish Life Science Industry and your company?

   **PC1.** I consider that big players such as big pharma and multinational companies might be major impacted for Brexit, grounded in their headquarters locations into the UK, but it will depend on the different operations each company have. Our focus products are on areas of complex conditions with small patient populations, which is the reason I believe Brexit will not cause a major impact on our company.

   **PC2.** We think that Brexit will not really affect us because we ship product all over the world and the UK is just one market of many markets.

2) How much of a challenge does Brexit represent to the Irish Life Science industry, and for your organisation?

   **PC1.** I do not consider Brexit could be a challenge for our organisation because we do not share too many operations with the UK and we already have a task force in Oxford working to develop any plans in the case to be necessary. I do not believe Brexit will be a challenge to the industry.

   **PC2.** It will be a medium to small challenge.

10) What are the significant economic effects of any change in the business operations? (example: Labourer, production and trade)

   **PC1.** I do not consider the company will have a significant economic impact because I believe the company will not relocate the offices from the UK, due to we are an Irish Company with headquarters in the country, and we have offices around the world.

   **PC2.** I think we will see some cost but more admin duties if there is a customs union introduce, but at the moment nobody really knows.
11) In your opinion, what changes do you expect in profit after Brexit?

PC1. As we do not move a massive quantity of products, I do not believe Brexit could bring big changes in our profit.

PC2. Because we are more of a global player and we ship products all over the world I feel Brexit will not really affect our business.

4.6.2 Theme 2: Irish Life Science Relationship with the UK

3) Currently, does your organisation have operations in the UK?

PC1. Yes, we have operations in the UK.

PC2. Yes, we share operations with the UK.

4) What is the nature of these links and how close are the links between the Irish and UK operations?

PC1. We do some packaging with the UK, but it will not be a difficult task to fix.

PC2. I would say we have close links with the UK and we are working in avoid as much is possible disruption on supply channels.

5) In your opinion, how would Brexit affect business operations with the UK?

PC1. I do not see any implications of Brexit, meaning Brexit does not upset the company at the moment.

PC2. I cannot really say how Brexit will affect the business in the UK until we see what deal the UK will do with Europe, but with the EMA leaving London and if the UK leaves the EMA and start their own governance body. It would mean drugs would be approved in the EU before the UK and that would mean people in the UK could have to wait up to 2 years for those drugs to get UK approval.
4.6.3 Theme 3: Plans, Expansion and Relocations:

6) What changes, if any, has the company already made to modify or diversify its business structure after Brexit was announced?

**PC1.** Currently, we have not made any change, but the company has a task force working, and they will develop the strategies necessary to prepare the company for a potential Brexit.

**PC2.** I cannot really talk about that at the moment, because anything is definitive yet.

7) What changes, if any, will need to be made in business operations such as manufacture, importations, exportation and supply chain of medicines?

**PC1.** I consider the priority of the company might be to relocate the QPPV, but it will not be a big issue due to it just a position. I believe the company will require the relocation of our distributor partner from the UK, but there is not any plan yet. As I explained already the companies does not share too many operations with the UK, and in the case of packaging of products, which could be one of the operations the company share with the UK, I believe the task force will develop the right strategy.

**PC2.** We will more likely have to get more admin staff to deal with regulatory changes and customs if there are introduced.

8) What plans, if any, has the company been developing?

**PC1.** Currently, the task force is working on it.

**PC2.** It was answered in the question above.

9) What are the reasons motivating those decisions? (change or adjusted in business operations).

**PC1.** Well, the company will make changes if the task force decided it and just they will have the reasons.
PC2. The company want to avoid as much as possible any disruption on the supply chain.

4.6.4 Theme 4: Impact on the Irish Economy

12) Given the importance of the Irish Life Science Industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they?

PC1. I personally consider Brexit could bring more opportunities to Ireland than threats. Ireland could be the option for many companies wishing to relocate to the EU, a situation that will bring more job opportunities and prospects to the country.

PC2. I could see both opportunities and threats; there is much work we have to be done. I do not know, we will know better in about a year or two time.

13) How could Brexit affect the Irish Life Science Industry extending to Irish economy?

PC1. I do not believe Brexit could drastically affect the Irish Industry due to it’s a robust sector. The opposite I consider it could elevate the attractiveness of the country to Foreign Investment and will increase the job opportunities among others.

PC2. We will only really know when we see what agreements will be between the EU and the UK, but I believe will be a disruption on the supply chain. Maybe, indigenous companies will be more impact for the strong links they have with the UK.
Chapter 5. Discussion

5.1 Introduction

In the following chapter, the research and sub-research questions, and their answers, will be analysed. As stated, the findings will not be generalised to all companies in the Life Science sector due to the small sampling size.

5.2 How does the Irish Life Science Industry view Brexit?

Mostly, the Irish Life Science sector does not see Brexit as a huge challenge. There are some issues that the industry could potentially face, but based on the size of the industry, it will not be a substantial impact. One of the reasons why all the participants considered Brexit will not cause significant damage in the industry is because the majority of multinational companies, as cited by IDA, "manufacture for all the world market", and not only the UK. Hence, Brexit's impact will depend on the links that each company shares with the UK.

In the same way, the primary data and literature have revealed the high possibility that companies with operations in the UK will not move and indeed will expand operations into other European countries; this is because of the high market population that the UK represents.

Even though Brexit is up in the air, the Irish Life Science Industry are preparing for the worst. Nevertheless, there is the possibility of non-impact in tariff in the scenario of The World Trade Organization (WTO).

5.3 What are the major issues facing the sector in the uncertain environment of Brexit?

It is argued that the main issue that Brexit poses is its uncertainty, which means that companies are waiting for agreements before beginning any change; however, as stated by the HPRA, "18 months are not enough" to execute any plan.
As the Life Science sector relies heavily on regulations, the major issues facing the industry are in relation to regulations, which is considered a high impact area due to the administrative process that Irish Life Science companies have to carry out.

Throughout the primary and secondary research, the strong regulatory links that the Irish Life Science Industry has within the UK was confirmed, with the primary issue facing the sector being the relocation of sites. However, it will depend on the links that each company has with the UK; it was emphatically stated that “some companies will be more affected than others” and just a few companies will be profoundly impacted. However, the pharmaceuticals interviewed stated that Brexit would not have a significant economic impact on their companies.

5.4 What, potentially, is the major impact Brexit will have on the Irish Life Science industry?

It will depend on the agreements between the UK and EU. Currently, the most significant impacts that the Life Science Industry perceive are:

**Redefining tariff and trade:** The relationship with the UK in the Life Science Industry, which is mainly due to the geographical position of Ireland and the commercial bridge that the UK represents to Ireland, will have to change.

**Increase in cost of labelling:** After Brexit, Ireland will not be able to continue “One market” labelling with the UK, which according to the IPHA, will have a medium impact on the Industry, due to the close links Irish companies have with the EU.

**Regulation:** Brexit will cause a notable impact, due to the modifications and changes that companies could potentially face in order to abide by EU regulations. According to European Union regulations, Irish Life Science companies must have the legal recognition, market authorisation, and batch release and clinical trials in the EU. Currently, the UK’s Medicines and Healthcare
Products Regulatory (MHPR), conducts 20% of its business in the EU. After Brexit, these activities must be readdressed, which could be a challenge due to the short time companies will have to carry out the necessary processes.

**Customs Administration:** it will cause delays and a shortage of medicines, which will have economic and social impacts. Therefore, companies will have to reorganise supply chains, depending on the agreements of Brexit. According to the IPHA, the impact will be low to medium. Irish customs and Revenue are currently advising companies to become authorised operators (trusted trader), with the intention of limiting the checks that authorities will have to do.

### 5.5 What are Irish Life Science companies actively planning or implementing in order to prepare for Brexit?

First at all, companies are finding it difficult to decide or execute any plans, based on the uncertainty of Brexit, mainly in relation to the costly high process related to relocations. As cited by the IPHA, Irish Life Science is planning for a hard Brexit, and “hoping for the best”. According to the IDA, after Brexit was announced, investment by Life Science companies in Ireland has increased slightly, in comparison to previous years. However, the IDA confirmed that, as some negotiations are ongoing, further information cannot be revealed.

### 5.6 Investments, Relocations and Expansions

During 2018, there has been significant interest from large packaging companies and contract manufacturers from the UK looking to locate to Ireland, which it is something that never happened before. Below, are some of the most significant Irish Life Science announcements of relocations and expansions from 2017.
Table 4. Investments from 2017

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>INVESTMENTS</th>
<th>NEW JOBS CREATION</th>
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<tbody>
<tr>
<td>Takeda</td>
<td>€ 25 million</td>
<td>70 Jobs</td>
</tr>
<tr>
<td>Mallinckrodt</td>
<td>€ 10 million</td>
<td>40 Jobs</td>
</tr>
<tr>
<td>Henkel</td>
<td>Not disclosed</td>
<td>400 Jobs</td>
</tr>
<tr>
<td>Allergan</td>
<td>€ 42 million</td>
<td>Not disclosed</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>€ 200 million</td>
<td>Not disclosed</td>
</tr>
<tr>
<td>Therevance Biopharma</td>
<td>Not disclosed</td>
<td>30 Jobs</td>
</tr>
<tr>
<td>Merck</td>
<td>Not disclosed</td>
<td>350 Jobs</td>
</tr>
<tr>
<td>Janssen</td>
<td>Not disclosed</td>
<td>200 Jobs</td>
</tr>
<tr>
<td>Sk Bioteck’s</td>
<td>€ 1 billion</td>
<td>350 Jobs</td>
</tr>
<tr>
<td>Regeneron</td>
<td>$ 100 million</td>
<td>300 Jobs</td>
</tr>
<tr>
<td>Wasdell Group</td>
<td>Not disclosed</td>
<td>300 Jobs</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>€ 80 million</td>
<td>600 Jobs</td>
</tr>
<tr>
<td>Beckman Coulter</td>
<td>Not disclosed</td>
<td>70 Jobs</td>
</tr>
<tr>
<td>1783</td>
<td>Not disclosed</td>
<td>70 Jobs</td>
</tr>
<tr>
<td>Wuxi Biologics</td>
<td>€ 325 million</td>
<td>Not disclosed</td>
</tr>
<tr>
<td>Almac</td>
<td>£ 30 million</td>
<td>No disclosed</td>
</tr>
</tbody>
</table>

(Source: IDA, 2018)

5.7 On what basis are Life Science companies making those decisions?

Life Science companies with operations in Ireland are making decisions based on the manufacturing, regulatory, and commercial links they have with the UK and the necessity to continue following EU regulations, to minimise risk and avoid as much disruptions as possible in the supply chain. As the IPHA stated, 65% of medicines in Ireland come from the UK. Additionally, as stated by the HPRA, the regulatory body
has an excellent reputation and relationship with companies, bringing with it the high possibility of companies wishing to choose Ireland as a member state.

5.8 What impact have those decisions on the Irish Life Science sector and on the Irish economy?

The worry from all participants was aimed at the short supply of medicines in Ireland, which is more of a social rather than an economic impact, meaning any change in the supply chain and regulations will cause a shortage of medicines in Europe and Ireland. Hence, any regulatory changes would be detrimental to the sector due to the cost involved.

The IDA believe Irish companies could look at the UK as a 3rd market, meaning the companies will set up the manufacturing and sale of their products in the UK that will only be for the UK market. International companies that have bases in the UK could stay in the UK from a regulatory point of view, but, post-Brexit, they could look for new locations to invest in. This could bring economic advantages and job opportunities to Ireland.

On the other hand, a long-term Brexit could cause a reduction in Irish GDP, based on the level of trade with the UK. In the same way, Brexit could bring disadvantages to the European market; in the case of costly regulations, Ireland could be less competitive than other non-European countries, to the UK. Overall, all the participants agreed that Brexit would not cause notable damage to the industry, due to its solidity.
Chapter 6. Conclusions and Recommendations

6.1 Introduction

As stated in the introduction, the overall aim of this study was to improve and fill the gaps that were existent in the literature, and to explore the relationship between the UK and Ireland to find out how the potential issue of Brexit will affect the Life Science sector. The explicit objectives were to:

- Identify how the Irish Life Science Industry views Brexit and what the major issues facing the sector are in the uncertain environment of Brexit.
- Explore what Irish Life Science companies are actively planning or implementing in order to prepare for Brexit.
- Identify on what basis Irish Life Science companies are making those decisions.
- Evaluate the impact of those decisions on the Irish Life Science sector and on the Irish Economy.

Hence, this chapter will summarize the findings to produce general conclusions and provide some recommendations for future research.

6.2 Conclusions

The conclusions set forth herein are based on findings from the primary and secondary data collected during this study.

6.2.1 Research Objective 1: Identify how the Irish Life Science Industry views Brexit

- This research has concluded that the Irish Life Science Industry is a robust sector in Ireland, led by multinational corporations, with operations all around the world, with the UK being only one market; as stated by the IDA, “99% of the multinational companies manufacture for all the world market”. Hence, any potential impact from Brexit will not cause huge damage to the sector.
• The primary data shows that, despite the uncertainty of Brexit, the Irish Pharmaceutical Sector view Brexit as a reality and they are preparing for a hard Brexit; however, the uncertain nature of future agreements between the UK and the EU are affecting the implementation of plans and decisions.

• The Irish Life Science sector is recognized by its diversity of operations, meaning that some companies could be more affected than others, depending on products and different connections with the UK.

6.2.2 Research Objective 2: Identify the major issues facing the sector in the uncertain environment of Brexit.

• As was already explained, the main issue affecting the sector is the uncertainty of Brexit and the unknown agreements between the UK and the EU in the future, which is causing delays in decision making and plans for companies.

• Based on the geographic position of Ireland and the UK, the similarities that both countries have, as well as the small population of Ireland, both countries are seen as one market, with the majority of Irish Life Science companies having positioned some of their main regulatory operations in the UK.

• As was shown throughout the study, the Life Science sector is severely regulated by the European Medicine Agency (EMA). Therefore, companies will have to untangle the existing links with the UK in order to comply with European rules. There are administrative and physical changes that have to be done, but the majority are administrative, which do not require high economic investments.

• The major administrative changes that the Irish Life Science sector has to implement and modify to comply with EMA regulations are those relating to Marketing authorisation holders (MHA), Qualified Person (QP), and Qualified Person Responsible for Pharmacovigilance (QPPV), which are administrative positions that require high investment.
• A major issue facing some parts of the industry will be the relocation of sites (which will require high investments); however, it will depend on the links that each company has with the UK and the size of the company. Sites such as those related to testing batch release and quality control must be based within the European Union, which is a problem if the UK leave the EU.

• Ireland and the UK jointly collaborate on the packaging and labelling of medicines. After Brexit, Irish companies will not be able to continue this and it will cause increases in cost.

• The Irish Life Science sector will have to modify the distribution channels of products and avoid using the UK as a commercial bridge, or it will increase costs in tariff and trade.

6.2.3 Research Objective 3: Explore what Irish Life Science companies are actively planning or implementing in order to prepare for Brexit.

• All participants in the industry are planning for a hard Brexit and are “hoping for the best”. There is an influx of companies discussing, with the HPRA, the possibility to move regulatory operations to Ireland, but only a small percentage have confirmed this, so far. Unfortunately, due to the confidentiality of the sector, it was not possible to get more detailed information.

• There is a small increase in Irish Life Science investment in Ireland, compared to previous years. According to the information collected, roughly €1.813 million is the total of new investment after Brexit was announced, which will create around 2.780 extra job opportunities (excluding the non-disclosed amounts) (see Table 4).

• From 2017 onwards, the most significant investments in the Irish Life Science industry are packaging companies, such as PCI Pharma Services, Wuxi Biologics,
and Almac, which are big players in the UK. As stated by the IDA, this investment is something that did not happen before.

- Based on the significant market population that the UK represents, and its recognized experience in the Life Science sector (leading global hub), there is a high possibility that companies based in the UK will expand operations around Europe but keep its main operations in the UK.

6.2.4 Research Objective 4: Identify on what basis Irish Life Science companies are making those decisions

- The Irish Life Science sector is preparing for the worst-case scenario. To avoid disruption and in order to follow EMA regulations, they may be willing to relocate regulatory operations into Ireland.

6.2.5 Research Objective 5: Evaluate the impact of those decisions on the Irish Life Science sector and potentially on the Irish Economy

- The Irish Life Science sector plays a crucial role in the Irish economy, therefore, any impact in the sector will impact the Irish economy. This study has shown that the potential impact of Brexit on the Irish Life Science sector will be medium to low.

- In the short term, regulatory changes will have medium to high impact, based on the short time that companies have to execute plans, due to the uncertainty of agreements.

- In the long term, regulatory changes will be highly positive for the industry in Ireland in that companies may relocate here, bringing investments and job opportunities. However, there is a possibility of a decrease in Irish GDP, related to UK trade.

- The major impact expected from Brexit by the sector will be a social impact, due to the shortage of medicines in Europe, United Kingdom, and Ireland. Due to the uncertainty of Brexit and the short time that companies and regulatory bodies will
have to execute new processes, it will heavily affect access to medicines, which would be detrimental to specific populations requiring special treatment.

6.3 Recommendations

This research study has provided insights and perceptions and has highlighted potential issues affecting the Irish Life Science sector and Ireland in a potential Brexit.

- Further research could be conducted after an agreement between the UK and the European Union, and after Brexit, including a wider range of participants and more Irish Life Science companies, including packaging companies, with the aim of assessing more specific and factual information.

- As access to companies was the main limitation of this study, further research could be in collaboration with any of the participants in this study (HPRA, IPHA, and IDA). It could be beneficial to the industry to see the implementation of surveys or questionnaires, to extend the sampling size, as the lack of significant sampling size of companies is the main reason for the slightly weak results in this study.

- Possibly, I would like to recommend the college take into consideration that, for international students, who do not have any contacts in the country, it is difficult to get significant target companies most of the time. Hence, a list of companies able to collaborate with or a suggestion of a more receptive industry might be included in the programme literature in the future.

- Irish politicians should increase efforts to improve the infrastructure in the country to attract more FDI. At this point, it is necessary to remind that the European Medicine Agency (EMA) has decided to move to Amsterdam and that Ireland had the opportunity to host this entity, but the infrastructure of the country was not conducive to such a move. In the same way, many companies do not choose Ireland based on the lack of housing, schools, and other factors.
6.4 Conclusion

The purpose of this research was to assess the following - How does the Irish Life Science Industry view Brexit and what are the major issues facing the sector in the uncertain environment of BREXIT? The research question sought to investigate, in a potential Brexit scenario, how the Irish Life Science Industry perceives Brexit and what the main issues affecting Irish Life Science Companies are. In recent years, Ireland has shown a healthy recovery, becoming the “fastest growing economy in the European Union” (Ibec for Irish Business, 2017a). As stated before, the UK is Ireland’s closest partner, thus Ireland is facing a unique challenge in relation to a potential Brexit. In this regard, any impact (threat or an opportunity) on the Irish Life Science Industry could extend to the Irish economy, which makes this dissertation’s topic relevant to those working directly or indirectly, current, or future, in the Life Science sector.

This research has helped us understand the unforeseeable implications of a potential Brexit on the Irish Life Science sector, in order to alleviate any negative impact, if any, or identify potential opportunities for the Irish Life Science sector going forward.

The research question was supported by the following sub-research questions:

1) What are Irish Life Science companies actively planning or implementing in order to prepare for Brexit?

2) On what basis are Irish Life Science companies making those decisions?

3) What impact do these decisions have on the Irish Life Science sector and on the Irish Economy, potentially?

In conclusion, the Irish Life Science sector does not see Brexit as a huge challenge. There are some issues that the industry could potentially face, but based on the size of the industry, it will not be a substantial impact. One of the reasons why all the participants considered Brexit will not cause significant damage in the industry is
because the majority of multinational companies, as cited by IDA, "manufacture for all the world market", and not just the UK.

In the same way, the primary data and literature have revealed the high possibility that companies with operations in the UK will not move and indeed will expand operations into other European countries; this is because of the high market population that the UK represents.
Chapter 7. Reflection

7.1 Introduction
As stated by Honey and Mumford (2006), “Learning is the most significant capability necessary to develop the next step and continue the process of learning”. Learning is a “life-long process” that happens when people know something they did not know before, through insights and skills. There are two diverse ways for how people learn – those that are taught and those by experience (Mumford and Honey, 1992).

This chapter is a self-assessment report based on the researcher’s experiences and the learning process during the master’s program.

7.2 Learning Styles
According to Honey and Mumford (1992), there are four different learning styles:

- **Activist Learners** are proactive and open minded, preferring being involved in new experiences rather than in long-term processes. Activists choose to avoid situations related to learning achievements and things outside their comfort zone. Activists tend to act first and deal with the consequences afterwards.

- **Reflector Learners** are very cautious learners who acquire knowledge from the “back seat”, meaning listening, observing, and evaluating every side of the situation, before giving an opinion or making a conclusion, which is the reason for why they tend to delay projects.

- **Theorist Learners** prefer to analyse facts and their philosophy is that everything must be logical and make sense, or it must be rejected.

- **Pragmatist Learners** have an interest in techniques and theories, but their primary concern is making things work in a real and practical way. Pragmatists are known for being positive and optimistic, with a ‘can do’ attitude.
Knowing learning styles is significant because it can help students be better learners, which in the researcher’s opinion is the only way to find and maintain a job, being competitive and growing with experience.

After taking the learning style questionnaire, the researcher realised she is an Activist learner, with some inclinations toward the pragmatist approach.

7.3 Researcher background

Moving to Ireland was a challenging decision in my life, due to my lack of English. In 2013, due to the economic situation in Venezuela, I decided to look for other opportunities in Ireland. It has been a cycle of positive and negative experiences, which has been my life in Dublin so far.

I arrived in Ireland, with experience of being a lawyer from my home country. Law is an exciting profession that gave me all the skills necessary to succeed as a professional, but it was not an easy task. I decided to expand my horizons and decided to join a Master of Business Administration in Finance course here in Ireland, with the intentions to match it to my background in law, with the goal of obtaining a job in the compliance sector.

7.4 Master of Business Administration in Finance

From the first moment I arrived in Ireland, my primary goal was to learn English as soon as possible, mainly to reduce the amount of time doing menial and underqualified jobs. This took me three years, but I would say the experience increased my focus to achieve what I wanted - “A job opportunity in the field of compliance”.

After an overview of the opportunities in the country, I decided to undertake a master’s in business administration in Finance because I considered my legal enforcement experience would help me on the way towards securing a job within compliance.

I must recognise that returning to study after almost ten years, when I first completed a master’s in Criminal Law, was not a smooth experience, based mainly on the
language barrier. Despite the fact I feel incredibly proud of myself for all the achievements in my life, I have to say that my principal weakness is still my English especially in this academic world of argumentation, and I know I must continue working on it, now also on a professional level.

During the first semester, I did not get the results I expected, but I correctly understand it was as a consequence of the above limitations. As an activist learner, with a leaning to the pragmatist style, the pressure and short time to submit assignments was the most challenging part for me. I have to recognise that working under pressure is not one of my best qualities and I can get very anxious, which I know I have to work on. However, in the same way, finishing each assignment gave me the satisfaction of improving my knowledge, and progressing my oral and written communication skills, and my ability to criticise and analyse pieces of work.

After the summer and looking back over the experiences, I started to focus more on achieving better results. I am now researching faster, my written skills are better, and in fact, my results improved accordingly. During the second semester, I had the opportunity to work with students from different cultures, backgrounds, and ages, which was not easy, because I am quite a perfectionist as an “Active Learner”, though I learnt to understand my classmates, communicate and express my ideas with facts more, and to be a team leader. Hence, working in groups strengthened my teamwork skills, as well as helping me work under pressure, and communicate and lead better.

7.5 Dissertation

In the first semester, I decided to do begin my dissertation on the Life Science Industry, based on my own personal interest of getting an insight into the industry. I decided then to match this field to an ongoing topic, such as Brexit. After consulting with some lecturers, I received two different opinions: “Interesting topic” or “not relevant”, based on the fact that Brexit is not yet a reality. In this way, I decided to take the positive side and invest my time and resources in a topic that would be useful to my professional future, given me the opportunity to gather substantial knowledge
about the whole economy of Ireland and giving me insights into a vast and significant industry such as the Life Science Industry. Additionally, understanding Brexit helps me gather information on the UK and the different regulations within the European Union and the relationship between the UK and the EU. Hence, despite the fact that this study did not produce concrete results, I did not regret my decision because this dissertation has contributed to my professional knowledge.

The obstacles and challenges I encountered on the way to finishing the dissertation have served to strengthen my problem-solving attitude and encouraged me to find the right way to complete goals. I got frustrated with the fact that I could not get access to the number of Irish Life Science companies I was expecting, but in the same way, that situation gave me the strength to plan and find a valid and convincing solution to continue. Having to modify the objectives and fix it within all the work already done was not an easy task, but that experience helps me to improve my initiative, problem-solving skills, and recognise that my efforts are not be wasted. I believe I did try every means possible to get access to more companies, in a professional way.

In the end, I learned that everything I do is my own responsibility, and I have to continue no matter what obstacle is in my way. However, I do sincerely regret not contacting the companies beforehand, because it would have given me some indication to modify the topic or get another sampling size. After all, the reason why I decided to analyse a higher target industry is that I am an ambitious person, who is passionate about taking risks (Activist Learner), which I believe is still a positive attitude to have in achieving realistic goals.

After enough effort, I got support from two Life Science Industry companies. Conducting the interviews was the most stressful, but exciting, part of the dissertation. It was a learning experience and I learned from my mistakes. As English is not my first language, it took long hours to transcribe interviews and sometimes I found it difficult to just copy an email address received by phone, which makes me consider that, despite the fact I have studied English for four years, I have to put more effort into socialising with native speakers to fully master English. Additionally, a lack of
knowledge about the industry was a disadvantage in doing the interviews, but in the same way, I am proud of the decision to leave my comfort area and taking the risk, as I have gathered much knowledge of the industry and met excellent professionals in the industry.

Deciding when to stop the collection of data, due to time constraints, was another big challenge I faced because up until the last moment I found significant information, which I wanted to add to my research. However, being able to analyse and evaluate what was relevant or not increased my decision-making and improved my research skills, which were the primary skills needed to become a Compliance Analyst.

This thesis has been the most rewarding challenge in my whole educational experience in Ireland. It was an up and down process, where I faced frustration and isolation, but at the same time it showed my capabilities and I got the most out of my academic experience, which was necessary to help me in my professional journey.
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McEnaney (2017) ‘How Brexit could be a GOOD thing: We’ve heard all the gloom about the UK’s EU departure, but what of the opportunities? Our writer argues that if we use our guile, Dublin can be an economic centre to rival London SATURDAY ESSAY [Eire Region]. Daily Mail; London (UK). Database: Business Insights: Essentials (Accessed: 09 April 2018).


## Appendices

### Appendix 1: Good Exports and Imports classified by commodity

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Exports</th>
<th>Imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Food and live animals</td>
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<td>907</td>
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<tr>
<td>4 Meat and meat preparations</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>5 Dairy products and milk's aggs</td>
<td>158</td>
<td>158</td>
</tr>
<tr>
<td>6 Fish, crustaceans, molluscs and preps thereof</td>
<td>81</td>
<td>81</td>
</tr>
<tr>
<td>7 Cereals and derived products</td>
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<td>34</td>
</tr>
<tr>
<td>8 Vegetables and fruits</td>
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<td>23</td>
</tr>
<tr>
<td>9 Sugar, sugar preparations and honey</td>
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<td>11</td>
</tr>
<tr>
<td>10 Coffee, tea, cocoa, spices and condiments</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>11 Feeding stuff for animals</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>12 Minerals and articles therefor</td>
<td>210</td>
<td>210</td>
</tr>
<tr>
<td>13 Crude materials, except fuels</td>
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<td>103</td>
</tr>
<tr>
<td>14 Animal oils and fats</td>
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<td>5</td>
</tr>
<tr>
<td>15 Animal and vegetable oils, fats and waxes</td>
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<td>0</td>
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<tr>
<td>16 Animal and vegetable fats and oils processed</td>
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<td>0</td>
</tr>
<tr>
<td>17 Chemicals and related products</td>
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<tr>
<td>18 Organic chemicals</td>
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<td>1,225</td>
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<tr>
<td>19 Inorganic chemicals</td>
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<tr>
<td>20 Coal, coke and briquettes</td>
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<tr>
<td>21 Petrochemicals and related products</td>
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<tr>
<td>22 Manufactured goods classified chiefly by material</td>
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<tr>
<td>23 Wearing apparel and made-up articles</td>
<td>25</td>
<td>25</td>
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<tr>
<td>24 Machinery and transport equipment</td>
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<tr>
<td>25 Miscellaneous manufactured articles</td>
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<td>3,128</td>
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<tr>
<td>26 Motor vehicles (including air-cushion vehicles)</td>
<td>400</td>
<td>400</td>
</tr>
<tr>
<td>27总输出（包括空运在内）</td>
<td>897</td>
<td>897</td>
</tr>
<tr>
<td>28 Total output (including air-cushion vehicles)</td>
<td>897</td>
<td>897</td>
</tr>
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</table>
Appendix 2: Interview Industrial Development Authority (IDA)

1) In your opinion what will be the potential impact of Brexit on the Irish Pharmaceutical industry?

The first thing to say I can only talk about the multinational companies because that is the only companies I deal with. I can say that 99% of the companies will not be impacted by Brexit because most of there sales are worldwide. They are manufacturing for all the world markets. There maybe will be 2 or 3 companies that export a large amount of products to the UK, they should be worry and making plans to deal with Brexit. I do not know which international companies that with be affected but the number is small. On local companies you would have to talk to enterprise Ireland for that information.

2) How much of a challenge does Brexit represent to the Irish Pharmaceutical industry?

International companies that have their base in the UK, could stay in the UK from the regulatory point of view, but additionally, post Brexit they could look for a new location which is an opportunity to Ireland, due to Ireland will have to move a lot of testing and batch releases of products and services from the UK to follow the EU regulations and requirements, which could mean they might decide to move these services to Ireland.

3) How many, if any, new announcements from Pharmaceutical or Medical device companies planning to expand, relocate or invest in Ireland has not been published?

I cannot tell you what it is not on the website, we are an ongoing business, and we work with a pipeline with many companies. We have some discussion, going on, and always we have companies on the list. The last big announcement was MERK (MSD) that is going to create 350 jobs.

A lot of the package agents and contract manufacturers are moving from the UK to Ireland because they do not have an EU location, which we did not see it happening
before, and it is good for Ireland. In the same bases, the largest independent packager in the UK a company call Wasdell and Almac have announced big investments in the country. We expect it will be more packaging companies relocating to Ireland.

4) What are the links, if any, and how close the links are between the Irish Pharmaceutical Industry and the UK?

At the moment the regulatory affair teams and commercial teams for these companies are based in the UK at the moment and will most likely have to move. The approval of the drugs for sale in the European Union, because a large amount of drugs approved are labelling in different languages in each country, but at the moment Ireland and the UK are combined and label their drugs together. After Brexit Ireland and the UK might not be able to continue doing that. As Ireland has a small population, it could be too costly to label the drug for a small amount of drugs for the Irish market and basically for specific drugs for small patient populations. They will need to import the products from somewhere.

5) In your opinion how would Brexit affect the business operations with the UK?

Extra regulations on importing and exporting could be more costly by new tariffs with the UK. On international companies, the cost will not be big because they do not sell much to the UK from Ireland they sell more worldwide. The impact will be more on small companies.

6) What are the major issues of those connections impacting Irish Pharmaceutical on a potential Brexit?

Regulations are the main issues for the industry. The UK will have to follow the EU regulations without having a saying on making them if they want to sell to the EU.
7) Do you consider that European Medicines Authority (EMA) relocation from the UK, will affect Irish operations?

With the EU medicine agents moving from the UK to Amsterdam, it will mean that a lot of the regulatory processes of companies will move from the UK to Amsterdam. That situation will break the bridge from Ireland to the UK. Also, the transition period, that we take to the new staff do the professional work they do now. It will mean a long time in approving drugs.

8) What changes, if any, might Irish Pharmaceuticals companies need to be made?

They could look at the UK has a 3rd market, meaning the companies will set up manufacturing and sale of their products in the UK that will only be for the UK market. From Ireland side companies might add some activities to Ireland, which traditionally was in the UK, to be able to sale to the EU.

9) What are the reasons motivating those decisions? (change or adjusted in business operations)

Companies that do not have bases on the EU will prefer to relocate to Ireland. Also, if they want to keep the relationship with the companies, they are working with, so it makes sense the will prefer Ireland.

10) What are the significant economic effects of any change in the business operations?

There will be some cost of the regulatory changes for companies, but I do not see a big economic impact in Ireland. I think which is more important will be the social impact.
11) Since Brexit was announced, is there any increase or reduction of expansions, relocations or investments from Pharmaceuticals companies in Ireland?

It is pretty much the same, just slight increase. What we are finding more important is Trump’s administration rather than Brexit, because tax changes in the US have made the new companies look at setting up in the US. The companies already in Ireland will stay, but new companies will be harder to get because of the change in the US.

12) Given the importance of the pharmaceutical industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they:

The Irish companies will have more problems because they do a big part of their sales to the UK, while for the international companies will be more of an opportunity. Britain will have to become very competitive reducing the tax on the products or offering credit for investment in Research and Development, which could be a risk for Ireland. Packaging agents are moving from the UK to Ireland to be in the EU, which we did not see happening, which is good for Ireland. Patients in Europe will not get access to specific drugs, is the major impact.

13) How could Brexit affect the Irish Pharmaceutical industry extending to Irish economy?

Irish patients could have a problem in getting some drugs because of labelling of products and getting the drugs approved.
Appendix 3: Interview Irish Pharmaceutical Healthcare Association (IPHA)

1) In your opinion what will be the potential impact of Brexit on the Irish Life Science industry?

The impact of Brexit on the Pharmaceutical Sector will come from two different places. Look at it as a matrix. So, what we have here is the Pharma commercial and Pharma manufacturing, and then, you have trade regulatory for commercial (manufacturing). The trade affects for us on the Pharma commercial side is to do with customs administration and potential tariffs. With a no deal, we will go under WTO rules, where tariffs are low, there will be no real impact on tariffs because VAT is so low.

2) How much of a challenge does Brexit represent to the Irish Life Science industry?

Customs administration and paperwork will add costs to the companies. It is not a big impact, but it is friction on the trade.

3) What changes, if any, has the companies already made to modify or diversify its business structure after Brexit was announced?

Yes, they have to do changes. On the supply chain side, companies might have to avoid sending products from Europe to Ireland through the UK.

4) What are the links, if any, and how close the links are between the Irish Life Science Industry and the UK?

We know at the moment 65% of the medicines that come into Ireland came from or through the UK. That is going to change because customs administration and so on, supply chain issues to do with transit agreements with the UK going outside and what products can you mix together in the one consignment from the EU and non-EU countries.

5) In your opinion how would Brexit affect the business operations with the UK?
Companies are getting ready for that and are arranging what products can but shipped to Ireland from the UK or not.

When you come to the regulatory side of things, it depends on the approve fully of the release of medicine and the legal status of medicines. Meaning what medicine is allowed in the Irish market. Now, this is a problem and most likely a medium problem, meaning that medicine labelled in a box at the moment can be sold in the UK and Ireland and meets the requirements of the HRPA and the EU. It means when the UK leaves the EU, Ireland and the UK will not be able to share labelling. This labelling for the English language for the EU which covers Ireland, EU and Malta. Unless the UK joins the EU regulatory rules, it will not be possible to share the same labelling. This will come down to drugs that will not meet the minimum requirements for it to be cost-effective to make for Ireland and Malta.

We will have to reorganise supply chain with these drugs by teaming up with France or whoever in the EU to get drugs labelled and there will be a cost for that. For selling drugs in the EU, the companies must have its legal entity and marketing organisation holder based in the EU. So, they will have to move out of the UK.

6) **What are the significant economic effects of any change in the business operations?**

Some people will move from the UK to Ireland and the EU. It comes just to administrative costs that are not too big. On the Manufacturing side, I do not know much, but what I heard the cost is low because there are not high cost on tariffs. Companies already deal with third countries an administrative cost will not change. On the regulatory side of things, Brexit will not affect the industry.

7) **What are the major issues of those connexions impacting Irish Life Science on a potential Brexit?**

Tariff and Tax are not that big so will not be a problem. Administrative will be the biggest problem, but cost should be low. On Manufacturing the regulatory will not change so there will not be a risk, but any the regulatory system changing in the EU and the UK will mean supply chains with change, mainly in the minimum order quantities for batch, so companies must prepare to risk adverse.
8) What plans, if any, has the company in process or developing?

Companies are having a cost of planning for the worries when Brexit happens. I hear companies are taking planning for the hard Brexit to make sure it does not affect them. This all plans will depend on the agreements between EU and the UK after Brexit, but nobody knows.

Irish customs and revenue will advise pharmaceutical companies and wholesalers on how to become authorised economic operators, which in other words would mean to become a trusted trader to limit the number of checks that authorities that would have to do. So, the impact will be low to medium.

9) Do the UK depend heavy on the Irish Life Science companies?
There is some product made here for the UK Market. But not a lot.

10) Does Ireland depend more on the UK Life Science Industry?
I do not know GlaxoSmithKline (GSK) made many products in the UK but not all of them, but I do not think it is a big problem. The increase in administrative cost I do not think will change the price of the drugs. The cost is not big enough to increase the costs of the drugs.

11) What are the reasons motivating those decisions? (change or adjusted in business operations)?

Minimize the risk, to keep with regulations and keep drug supply chains going with no interruptions.

12) Given the importance of the Life Science industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they?
It could be good to get some legal staff from the UK to Ireland. But with the UK leaving the EU with its 60 million people leaving the single market is not good. The positives are very small. The regulatory changes and admin is a more negative than positive.
Irish market is small, and there will be a short supply of medicines to Ireland.

13) Do you consider that European Medicines Authority (EMA) relocation from the UK, will affect Irish operations?

It could, but that depends on the deal the UK does with the EU. They could make a deal, and the UK will copy the EU regulations, which would mean no real impact, but if the UK does not do that if could cause problems, but I do not know until Brexit happens.

Also, it could be an impact in the whole European Pharmaceutical Industry, is EMA take long times in the authorisations of new medicines.

14) How could Brexit affect the Irish Life Science industry extending to Irish economy?

It will not be a big impact in the short term, based on our population, which is 4.5 million but based on the point of view of trade and investment. The reason I think Ireland will be affected is on the amount of trade between Ireland England, with is € 63 billion, and any change will have a GDP effect. This is a theory, not a fact, meaning if regulations change it could mean Ireland and the EU will be costlier, than Canada and India for example will more competitiveness markets than Ireland, based on the regulations. If nothing changes in regulatory standards most likely nothing will change. But if England changes its direction to target markets outside the EU, it could have an impact.
Appendix 4 - Interview Health Product Regulatory Authority (HPRA)

1) In your opinion what will be the potential impact of Brexit on the Life Science industry?

Speaking on the side of the regulatory authority. It will have a big impact because the UK do about 20% of the work in the EU network. That work is divided amount the member states and Ireland is open to take on more work on the way medicine are regulated in Europe. 
Yes, it will be a big impact because of the location of Ireland not being on the mainland of the EU. There will be a big problem with the labelling of drugs and get access to drugs that are in small production, meaning shortages of medicines in Ireland.

2) How much of a challenge does Brexit represent to the Life Science industry?

It is the biggest problem with companies having sites in the UK in the areas of batch release and quantity control. It will have to be relocated to the EU. As the EU and UK negotiations are going on, the companies are finding it hard to decide if they need to move these areas or not, and 18 months is not enough time to move.

3) What changes, if any, has the companies already made to modify or diversify its business structure after Brexit was announced?

They will have to change the legal procedures to Ireland with is huge procedures for each product complete with the EU regulations. Also, doing clinical trials would have to be done in the EU, like batch testing and the way they move products and released. There is a mix of administrative and physical changes, such as clinical trials and batch release sites.

4) What are the links, if any, and how close the links are between the Irish Life Science Industry and the UK?
The industry has a huge relationship with the UK. The amount of work that the UK do within the European Union network is quite large, and so the impact on companies and us is big. It is not just manufacture, the UK is a scientifical adviser to Ireland. The UK is involved in commitments in a huge level.

5) What is the percentage of Irish based Life Science companies, willing to change any of the operations from the UK to Ireland? (ie. Reference Member State, Marketing Authorisations, Qualified Person or any other regulatory issues?)

I can not give you figures, because companies are not saying what they are planning for at the moment. They come and discuss with us, but there is a little-confirmed. It is a slow process. Some companies can come to us or another member states into the European Union.

6) What are the significant economic effects of any change in the business operations?

The relocation of any physical site and maintenance of the supply chain will be the biggest cost. Following for the process to meet EU regulations. That is what companies are so slow in doing anything until agreements are made.

7) As a result of Brexit, do the HPRA has any plan to extend or expand operations?

We are looking to get more memberships to come to Ireland. If we have the time to get ready for it. We are more waiting for companies to come to us, we are negotiating fees to encourage them. I think companies will choose Ireland because of the relationship with have with them already and our reputation. To do labelling in some products, companies that have big operations in the UK and a small office in Ireland could move some services to Ireland.
8) Given the importance of the Life Science industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they?

There is a gap that will need to be filled after Brexit, and we will try and fill it. The supply of drugs in Ireland could be a problem. For Ireland, Brexit is not a celebrating thing. I see Brexit more as a challenge than an opportunity.

9) How could Brexit affect the Irish Life Science industry extending to Irish economy?

Movements of products between EU and the UK could be a problem with customs. Financial challenge for companies will be more than the normal day to day work. Everyone will be heating, but it will depend on the relationship with the UK. However, the economic impact in Ireland is hard to tell, but companies are here for Ireland low tax rate, so they will not leave.

10) Do you consider that European Medicines Authority (EMA) relocation from the UK, will affect Irish operations?

No, it is better for EU countries because Amsterdam is more in the centre of Europe. The process might be a bit slow during the transition period because EMA will have to get new staff because not all staff will move to the Netherlands, but it should be OK.
Appendix 5: Pharmaceutical Company (PC1)

10) In your opinion what will be the potential impact of Brexit on the Irish Life Science Industry and your company?

I consider that big players such as big pharma and multinational companies might be major impacted for Brexit, grounded in their headquarters locations into the UK, but it will depend on the different operations each company have. Our focus products are on areas of complex conditions with small patient populations, which is the reason I believe Brexit will not cause a major impact on our company.

11) How much of a challenge does Brexit represent to the Irish Life Science industry, and for your organisation?

I do not consider Brexit could be a challenge for our organisation because we do not share too many operations with the UK and we already have a task force in Oxford working to develop any plans in the case to be necessary. I do not believe Brexit will be a challenge to the industry.

12) Currently, does your organisation have operations in the UK?

Yes, we have operations in the UK.

13) What is the nature of these links and how close are the links between the Irish and UK operations?

We do some packaging with the UK, but it will not a difficult task to fix.

14) In your opinion how would Brexit affect the business operations with the UK?

I do not see any implications of Brexit, meaning Brexit does not upset the company at the moment.
15) What changes, if any, has the company already made to modify or diversify its business structure after Brexit was announced?

Currently, we have not made any change, but the company has a task force working, and they will develop the strategies necessary to prepare the company for a potential Brexit.

16) What changes, if any, will need to be made in business operations such as manufacture, importations, exportation and supply chain of medicines?

The QPPV is a qualified person for pharmacovigilance, who is responsible for the safety of the products marketed for the company. According to EU regulations, this position must be located in the European Union, and currently, our QPPV is based in the UK. I consider the priority of the company might be to relocate the QPPV, but it will not be a big issue due to is just a position, and the potential locations could be Ireland or Italy, where used to be located.

I believe the company will require the relocation of our distributor partner from the UK, but there is not any plan yet.

As I explain already the companies does not share too many operations with the UK, and in the case of packaging of products, which could be one of the operations the company share with the UK, I believe the task force will develop the right strategy.

17) What plans, if any, has the company in process or developing?

Currently, the task force is working on it.

18) What are the reasons motivating those decisions? (change or adjusted in business operations).

Well, the company will make changes if the task force decided it and just they will have the reasons.
19) **What are the significant economic effects of any change in the business operations? (example: Labourer, production and trade)**

I do not consider the company will have a significant economic impact because I believe the company will not relocate the offices from the UK, due to we are an Irish Company with headquarters in the country, and we have offices around the world.

20) **In your opinion, what are the changes do you expect in profit after Brexit?**

As we do not move a massive quantity of products, I do not believe Brexit could bring big changes in our profit.

21) **Given the importance of the Irish Life Science Industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they?**

I personally consider Brexit could bring more opportunities to Ireland than threats. Ireland could be the option for many companies wishing to relocate to the EU, a situation that will bring more job opportunities and prospects to the country.

22) **How could Brexit affect the Irish Life Science Industry extending to Irish economy?**

I do not believe Brexit could drastically affect the Irish Industry due to its a robust sector. The opposite I consider it could elevate the attractiveness of the country to Foreign Investment and will increase the job opportunities among others.
Appendix 6: Pharmaceutical Company (PC2)

1) In your opinion what will be the potential impact of Brexit on the Irish Life Science companies and on your company?

I can only speak for what impact Brexit will have on our company; I can not really speak on behalf of any other company and their opinions. We think that Brexit will not really affect us because we ship product all over the world and the UK is just one market of many markets.

2) How much of a challenge does Brexit represent to the Irish Life Science companies, and for your organisation?

There will be a challenge, but it would be medium to small. We could face problems in the areas such as Customs Union. The paperwork and administration would increase most likely because the UK would be no longer in the Customs Union and we would have border checks. We do not know if that would be the case until we see what agreements are made between the UK and the EU. Another problem could be sending our product to the EU. At the moment when sending products from Ireland to the EU or vice versa a lot of the products but not all would pass through the UK. Depending on the arrangements between EU and the UK this practice might have to change. This is not just a problem for the pharma industry this would be a problem for all industries in Ireland and the EU. We are paying close attention to this.

3) Currently, does your organisation have operations in the UK?

Yes we share operations with the UK
4) **What is the nature of these links and how close are the links between the Irish and UK operations?**

I cannot really say what operations are done in the UK and here at this moment, but I would say we have close links with the UK and we are working in avoid as much is possible disruption on supply channels.

5) **In your opinion how would Brexit affect the business operations with the UK?**

I cannot really say how Brexit will affect the business in the UK until we see what deal the UK will do with Europe, but with the EMA leaving London and if the UK leaves the EMA and start their own governance body. It would mean drugs would be approved in the EU before the UK and that would mean people in the UK could have to wait up to 2 years for those drugs to get UK approval.

6) **What changes, if any, has the company already made to modify or diversify its business structure after Brexit was announced?**

I cannot really talk about that at the moment, because anything is definitive yet.

7) **What changes, if any, will need to be made in business operations such as regulations, manufacture, importations, exportation and supply chain of medicines and medical devices?**

I cannot say much about what we are doing now. However, we will more likely have to get more admin staff to deal with regulatory changes and customs if there are introduced.

8) **What plans, if any, has the company in process or developing?**

I think I just answered that question.
9) What are the reasons motivating those decisions? (change or adjusted in business operations)

Well as I said, I can not really talk about that, but basically the company want to avoid as much is possible any disruption on the supply chain.

10) What are the significant economic effects of any change in the business operations? (example: Labourer, production and trade)

I think we will see some cost but more admin duties if there is a customs union introduce, but at the moment nobody really knows.

11) In your opinion, what are the changes do you expect in profit after Brexit?

Because we are more of a global player and we ship products all over the world, I feel Brexit will not really affect our business.

12) Given the importance of the Irish Life Science industry to the Irish economy, do you think Brexit offers both threats and opportunities, and if so what are they?

It would be better if it was not happening, but in the long term, I do not know. We will know better in about a year or two time.
I could see both opportunities and threats; there is much work we have to be done.

13) How could Brexit affect the Irish Life Science industry extending to Irish economy?

I feel I answered that in the last question. We will only really know when we see what agreements will be between the EU and the UK, but I believe will be a disruption on the supply chain. Maybe, indigenous companies will be more impact for the strong links they have with the UK.