The Pharmaceutical industry and sustainability:

Assessing the impact sustainability has on the commercial decision making in the Irish Pharmaceutical Industry.

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Master of Business Administration (MBA)

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Abstract

In the past two decades sustainability in Pharmaceuticals has received increasingly more recognition from governments, regulators, shareholders, and consumers about its impact on the environment and the industries sustainability practices. While the literature is abundant with regards to environmental sustainability and corporate social responsibility there is little in the way of research in the area of sustainability and commercial decision makers in the pharmaceutical industry. The status quo of the pharmaceutical industry, and of current academic literature is to focus on manufacturing and supply chain in terms of sustainability. However, in order to truly understand the full extent of the issue of sustainability within this sector, a further analyses of stakeholders involved is required.

This proposed study sets out to ascertain through thematic qualitative analyses, by inductive methods, the understanding of, and the influences upon commercial decision makers in the Irish pharmaceutical industry in regards to sustainability.

A survey was provided to 9 participants (n=9) via Microsoft forms, which had within questions related to the four main objectives of this study, understanding of sustainability, internal influences, external influences and barriers and metrics with regards to sustainability on day to day commercial decision making with Pharmaceuticals.

Results indicated key themes and that there was a distinct lack of awareness and exposure discrepancy amongst the surveyed participants. The majority expressed a lack of direct involvement or knowledge of any sustainability metrics or practices. A gap in knowledge is evident and some participants referred back to manufacturing as the gatekeepers of such metrics. However in contrast the majority of participants were well informed about the main pillars of sustainability.

In conclusion the findings of this research provide a deeper insight into issue of sustainability in the Pharmaceutical industry. As the sample size is small critical analysis exposes weaknesses of the study however what is evident from this research is that some executives within the pharmaceutical industry have large gaps in knowledge with regards to the three main pillars of sustainability and in turn have a reliance on the manufacturing arms of the business to enact sustainable practices.

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1.1 Rationale for research

The rapid pace of change and expectation of the Pharmaceutical (Pharma) industry has led to sustainability becoming a focal point for industry leaders. In 2022 Weaver, O'Hagan and Lamprou stated that '' The global acceptance of human-driven climate change has reframed the future priorities of many industries. Finding solutions to both limit and counteract the climate emergency has become a pressing matter of increasing concern'' (Weaver, O'Hagan et al. 2022). While the Pharma industry is widely accepted to produce lifesaving medications, vaccinations and scientific breakthroughs, available data suggests that the pharma industry is far from a green industry, with 2018 statistics presenting that the industry produced 52 million metric tons of CO2 equivalent that year (Belkhir and Elmeligi 2019). Sustainability as a term covers more than environmental concerns, and throughout this paper it should be considered as an all-encompassing term that involves the contribution towards social, business sustainability, and economic aspects also. Pharma leaders are now being forced to address the enormous expenditure and use of energy and raw materials due to increasing interest rates on borrowing and the significant increase in the cost of energy globally to name but a few.

A number of key factors are now influencing the industry, globally there is a huge push towards a more sustainable way of living and doing commercial business in a multipronged effort to tackle the issues of climate change. Moreover, sustainability has become a massively important to a growing number of individuals and consumers now expect sustainably manufactured items including pharma products. Looking towards industry increasingly corporations are moving towards a greener and more sustainable future, but the question is why such a transition. Both regulators and public opinion have now come to expect and enforce such a change. Recent tenders published by the Irish Health Service Executive dynamic purchasing system via E-tenders have recently assigned upwards of 5% of overall marks of recent tenders for pharmaceutical products to sustainability. Historically sustainability was seen as a manufacturing, supply chain and logistics problem however with the increasing pressure internally and externally the question remains what commercial and business executives in the industry understand of this shift.

Global (Climate change conference COP26), European union (EU), and local initiatives such as the Intergovernmental Panel on Climate Change now highlight the need for immediate and radical change to limit global warming to 1.5 degrees Celsius and points to radical change within industrial manufacturing. COP26, in which the UN pledged a specific goal of '' achieving a low carbon and sustainable health system as part of the new initiative 'The COP26 Health Programme''(Weaver, O'Hagan et al. 2022). Furthermore as a energy intensive industry coupled with soaring energy prices and push towards cheaper medications by public bodies and health insurers, the pharmaceutical industry finds itself forced to act now more than ever in a sustainable way. Ireland as the second highest per capita in respect of greenhouse gas emissions, after Luxembourg in the other EU27, it's a large footprint in both commercialisation and manufacturing of pharmaceuticals has a significant role to play in the overall reduction of these harmful gases. (CSO 2022)

In developed countries such as Ireland life expectancy and the expectations of the population to have medications to tackle chronic and acute illness is increasing. As Ireland has such a high life expectancy (Male 80.5 years, Female 84.3 years), similar to that of the European Union 27 countries it is ever increasing the demand for medications to deal with the rising treatment of chronic illness's concurrently increasing manufacturing and pressures upon the commercialisation of medications (CSO 2022).

When we look towards the Pharma industry we note that this industry has a particular onus to prioritise sustainability, an industry that has a poor track record in doing so as discussed in depth in section 2 of this paper. While it is generally recognised that the pharma industry has committed significantly and has had a major positive impact on people's lives in terms of health and quality of life (QoL), in comparison with the automotive industry literature report pharmaceuticals generating approximately 55% more emissions.(Belkhir and Elmeligi 2019) This highly energy dependant industry is facing huge challenges in balancing product quality and cost reduction with the backdrop of increasing demand. Discussed in depth in section two of this dissertation large gaps remain in the current literature as to the drivers behind commercial pharmaceutical decision making (Marketing, sales, strategic leaders) surrounding day to day business decisions and how sustainability impacts their decision-making process. This paper will explore in depth via qualitative methods the perceptions and opinions of pharmaceutical managers about sustainability, their knowledge of the topic, and sustainability influences on their decision making processes and thinking as leaders.

To note with this as the backdrop of this study the pharmaceutical industry is one which is strictly governed and regulated. Change can only happen as quick as regulation allows for. As one of the most restricted and stringently regulated industries adaptions to sustainability may lag behind that of the trends of other less regulated industries.

1.2 Objectives of the research

The aim of this research is to gain insights into the current sustainability landscape within the pharmaceutical industry from a commercial business perspective. Furthermore this research will explore, within an Irish Pharmaceutical context, what strategies, if any, underpin this shift in business priority towards a more sustainable and green pharma industry. To explore the key drivers that are forcing leaders, within this energy intensive industry, to change business as usual practices, and what levers, both internal and external, are mandating this change. While also obtaining insights from key opinion leaders (KOL's) as to the appetite for this change. Opinions are aimed to be gathered from management and executive level employees currently working in this environment.

The majority of research currently focusses on pharma manufacturing and the ability of the process and energy inputs to effect change and realise sustainability, this paper has identified gaps in the research and asks KOL's and business leaders specifically within an Irish commercial pharma context their understanding of sustainability and what 'green' means for their strategic and day to day business decisions. Furthermore this study examines is this been mandated from managing executives within their respective companies, if regulators, consumers and buyers are forcing this change.

The primary objective will facilitate the investigation and satisfy of the research questions:

- To obtain, from an Irish commercial pharmaceutical context both the internal and external factors driving in influencing sustainability within a decision making context

1.3 Structure of dissertation

To identify the current research gap, one must specifically identify what this research gap is, therefore a literature review highlighting relevant literature to investigate the current state of play of pharmaceutical sustainability, while also examining internal and external factors influencing commercial decision making and sustainability in both pharma and wider industries. The literature review will then look at specific European and Irish instances of sustainability and national factors causing the rapid shift towards a greener and more sustainable industry. Furthermore, the literature review will investigate up to date literature, while finally gaps in the literature will be highlighted which will inform and enable the research question.

Following the literature review a research question, philosophy, and methodology will be set out. Findings will be laid out and analysed a while a discussion of the findings within the context of the literature will be set out. Furthermore, conclusions and recommendations will be drawn and proposed to end.

1.4 Research Questions

The primary research question is: How is sustainability influencing commercial business decision making in the Irish Pharmaceutical Industry?

To fully assess all this question the research will stringently follow four key objectives to obtain an all encompassing overview of the current state of play in this area.

As the research questions will be intrinsically linked with the four primary objectives of this research a key element is to set out these objectives at an early stage of research. Therefore the primary objectives are listed below:

Objective 1: Sustainability understanding within the Irish pharmaceutical commercial sector

Objective 2: Internal influences on commercial decision making with regards to sustainability

Objective 3: External influences on commercial decision making with regard to sustainability.

Objective 4: Performance indicators, barriers and challenges of sustainability within an Irish context

1.5 Scope

This study was enabled via an inductive qualitative method, which allowed the ability to deduce information from the outcome of responses and viewpoints of nine respondents. Respondents came from a variety of commercial leaders from both Pfizer, Chanelle Pharma, Johnson & Johnson, and AbbVie. The scope of this study is limited to Irish Pharmaceutical commercial key opinion leaders (KOL's). While it is possible to extrapolate findings the scope is limited to this highly specific cohort within Ireland. With pharmaceuticals being a multidisciplinary global business, these are out of scope for this study.

2. Literature review

2.1 Introduction

Building upon the introduction of this dissertation the research questions, background, objectives, and rationale of the pharma industries approach to sustainability, this section explores current and past literature in greater detail and furthermore examines specifically the pharma industry as a whole and sustainability actions within this sector.

There is a rapid increase in the pace of sustainability transformation and 'going green' globally and this is becoming ever more present in the pharmaceutical industry driven by consumer demand for greener and more sustainable products, regulation, shareholders, and procurement of health bodies to name a few. This industry serves a critical role for global healthcare, however more emphasis recently has been shone upon sustainability within this sector. As this is a sector which utilises significant quantities of raw materials a spotlight has be shone upon the industry when it comes to pharma operations due to concerns over resource depletion with the knock on effect of environmental degradation.

Furthermore, corporate social responsibility is gaining greater traction and importance both internally within pharmaceuticals and from external influences also. With such change organisations within the pharma industry must adapt to these influences. Moreover, from an ethical standpoint pharmaceutical sustainability ensures a vital global supply of medications, with the industry mandated to provide essential medications to populations, both human and animal, worldwide.

This literature review aims to explore the current state of suitability initiatives within this sector and identify if gaps exist in commercial decision making.

2.2 Sustainability with the pharmaceutical industry a global view: An Overview

Within the pharmaceutical industry sustainability has now become a driving force for change.

When looking towards patient numbers literature has pointed towards a steep upward trajectory of adult deaths per year due to climate change of 529,000 according to a 2019 Lancet report. (Springmann, Mason-D'Croz et al. 2016) The pharmaceutical industry is reported as contributing approximately 52 megatons of CO2 stemming from its direct operations. However 'This calculation, however, does not begin to cover the additional indirect energy-related emissions arising from the intricacies of its supply chain — from the transportation of vital medicines to the energy demands of distribution facilities for lighting and refrigeration.'(PHARMANEWS INTELLIGENCE)

While this industry is building on the long experience pharmaceuticals has within sustainability, the pace of change remains slow due to the industries high level of regulation. Sustainability within this sector involves addressing a number of issues including environmental, social, and economic impacts, while trying to balance the issues of quality of medications produced, efficacy, accessibility to populations, and affordability. To further examine this issue sustainability it is divided into there distinct areas for the purpose of this dissertation, environmental sustainability, social sustainability and economic sustainability.

2.2.1 Environmental sustainability

It is widely recognised that the pharmaceutical industry has a significant impact on the environment. The literature recognises that the consumption and concurrently the production of pharmaceutical products has increased rapidly within this ever-advancing field. It is estimated that 3,000 compounds are used within pharmaceutical manufacturing and that annual quantity exceeds hundreds of tons.(Carvalho and Santos 2016, Grenni, Ancona et al. 2018) Consequently production, distribution,

and supply chain energy are consumed generating Co2 and other harmful excipients, while literature points more recently towards the emergence of water-soluble and pharmacologically active organic micropollutants or pharmaceutical active compounds (PhACs). Concerns are growing that these containments known as PhAC's are now evident in ecosystems such as freshwater, marine and groundwater.(Grenni, Ancona et al. 2018, Zainab, Junaid et al. 2020) Danner et al in 2019 reported that ''the main concern is that conventional treatment plants are ineffective in removing some of these emerging contaminants (ECs), and new techniques are being sought and studied to achieve their total elimination, particularly advances in mycoremediation''. (Danner, Robertson et al. 2019)

With such large increases of consumption worldwide, associated with the environmental impacts this has, a gap in the literature exists in the disposal of and lack of information surrounding the medium to long term effects on the environment. In 2017 Gil et al worryingly noted that '' The fact that some drugs are marketed without medical prescription or pre-registration and, therefore, are widely consumed worldwide, meaning that they are widely distributed in the environment has contributed to this growing problem.''(Gil, García et al. 2017) While the above is not such an issue within the European Union and within Ireland due to the hight regulation and strong market access processes in place, it does add to the growing environmental concerns.

While water contamination is one of the more specifically identifiable problems documented, in contrast, it is well documented in the literature that shows that environmental impacts as a whole of pharmaceutical is relatively unknown. This is underscored by the scarcity of life cycle assessments with both De Sote et al. in 2017 and previously in 2014 Jinenez-Gozalez and Overcash noting that ''pharmaceutical products are ubiquitous and yet their environmental impacts are scarcely known, with only a limited number of life cycle assessment (LCA) studies available in the literature. While the use of LCA in the pharmaceutical industry is increasing, most studies compare different chemical routes or processes, with very few considering consumer products.''(Jiménez-González and Overcash 2014, De Soete, Jiménez-González et al. 2017) Cradle to gate impact assessments of active pharmaceutical ingredients noted that energy consumption in the production process was the main contributor with the variance between drugs produced ranging from 11kg to 3000kg CO2 eq. per Kg API dependant on the number of synthesis steps involved.(Wernet, Conradt et al. 2010, McAlister, Ou et al. 2016) Additionally when considering packaging carbon footprints for some medications caused 90% of the cradle to gate impact. (Jeswani and Azapagic 2020)

With such an energy intensive process involved in the manufacturing process, coupled with supply chain contributions to carbon footprints, while following on from this the disposal of excipients pharmaceuticals pose a significant risk to environmental concerns and contribute significantly to CO2 emissions, energy consumptions, and resource depletion.

2.2.2 Social Sustainability

Within the pharmaceutical industry social sustainability encompasses various aspects which include ethical marketing, Corporate Social responsibility, and fair and equal access to medicines.

Ethical practices and marketing are a key consideration when considering sustainability within this industry. Trust and credibility are the foundations upon which multinational pharmaceutical companies promote themselves upon. Strict guidance and regulation is in place to ensure the ethical and transparent promotion of medications. Pharma 4.0 is referred to by the '' International Society of Pharmaceutical Engineers (ISPE) that describes the Industry 4.0 shift towards advanced technology including AI and machine learning, cloud computing, and the Internet of Things (IoT).'' (Kneat 2024) In the advent of pharma 4.0 this aids the integration of social sustainability, and studies have shown that with the increasing utilisation of technologies and the presence of information

intensive services this has a yielded a positive enhancement of social sustainability performance. (Djunaedi)

Corporate social responsibility (CSR) is intrinsically linked with social sustainability. A complex matrix remains in the pharmaceutical industry as the industry globally is under immense pressure to both develop and distribute medicines and related products in a sustainable and cost effect way, but in the backdrop the corporate nature of the industry mandates healthy profits. As is true today, Smith 2008 maintained ''As in any industry, producing products and services efficiently means lowering the price, developing significant products and services faster, and improving upon quality initiatives. These companies must continually emphasize effort and investments in R&D in order to remain competitive in the global marketplace''. (Smith 2008)

Early in 2008 Smith stated that '' Pharmaceutical companies must implement CSR principles in their strategies. Profits have a major role in the industry but in order to obtain higher profits in the long run, pharmaceutical companies must build high brand name awareness and therefore high company awareness towards consumers''.(Smith 2008) With increasing pressures on companies within the industry to initiate and progress programs to protect the environment and enhance social welfare evidence of the growing importance of CSR, for example the Government of India has mandated that 2% of 'for profit' organisations net profits are donated to charitable causes.(Chhabra E 2014) A paradox exists within the relationship between pharmaceutical industry and the very nature of its business model, being a profit driven model. Ethical dilemmas and profit motives can sometimes conflict CSR commitments within the profit driven nature of this industry. When examining the key drivers within pharmaceuticals profit maximisation is the cornerstone of this industry and there are many challenges to this driven by costs in research and development, shareholder expectations and the highly competitive landscape that these multinational companies work within.

2.2.3 Economic Sustainability

In order to address the ever increasing pressures of environmental sustainability, economic sustainability must be achieved. Such sustainability is the ability of a company to maintain viability from both profitability and financial perspectives. As economic sustainability is the long term goal of the majority of pharmaceutical companies it is intrinsically linked to both CSR and Environmental sustainability.

Another key element within the industry is constant innovation driven by Research & Development (R&D). R&D holds such significance in maintaining economic sustainability that in the United States it is reported that 17% of sales is invested into this space.(Bryman 2016) However with such investment this is set against the backdrop of high failure rates which poses challenges to profitability. Further challenges exist as this industry operates on a global market where local policies, consumer preferences, competition, and access to medicines all vary. With significant investment required to decrease the industries footprint pricing strategies play a crucial role in maintaining revenue generation set against the backdrop of balancing affordability.(Danzon and Towse 2003) As discussed previously when operating in such a highly regulated environment it is imperative that companies have the agility to navigate regulatory pathways efficiently.

A number of aspects are encompassed when considering sustainability in the pharmaceutical industry. However conflicts exist within the balance between an industry driven by finance and profits and implementing sustainable practices. The evolution of sustainability within Pharmaceuticals has been well documented from a manufacturing perspective. Literature points towards a number of key innovative solutions to reduce pharmaceutical industry contribution to

emissions and promote more sustainable research and development (R&D) and sustainable business practices.

2.3 Environmental Sustainability in manufacturing & Extended partnerships

The evolution of sustainability within Pharmaceuticals has been well documented from a manufacturing perspective. Literature points towards a number of key factors that can aid the reduction of the pharmaceutical industries contribution to emissions and promote more sustainable research and development (R&D) and sustainable business practices.

A number of key developments and points to note in this area are discussed below.

2.3.1 Green Chemistry

Green chemistry is referred to as a 'transformative philosophy that champions efficiency, safety, and environmental consciousness to dramatically reduce waste, curb energy consumption, and minimize the use of hazardous chemicals by harnessing the potential of safer, more sustainable chemical reactions and processes.'(PHARMANEWS INTELLIGENCE) Companies are encouraged to prioritise synthesis in an eco-friendly way. These methods aid in the reduction of harmful by-products. Products produced in this fashion also aid in ushering a new era for safer compounds that are more readily biodegradable which in turn reduces the ongoing persistent environmental pollution from these products. In 1998 Anastas and Warner noted that green chemistry has the ability to minimise environmental impacts while in turn maximising efficacy and safety.(Anastas 1998) While more recently in 2017 it was reported by Clark & MacQuarrie that by '' adopting green chemistry practices, pharmaceutical companies can reduce the use of hazardous substances, lower energy consumption, and decrease the generation of harmful by-products''.

2.3.2 Waste minimisation

Streamlining production processes has a dual action upside for pharmaceutical companies as it decreases costs and reduces hazardous by-products. Recycling and the reuse of certain compounds reduces the need for raw materials, and limits disposal. Research has shown that ''currently, it is estimated that for every kilogram of drug made, around 100 kg of waste is produced, making it a hugely inefficient process.''(University of Bath)

2.3.3 Energy efficiency & Green Packaging

The cornerstone of advancing sustainability both from a economic and environmental perspective within the industry is decreasing energy usage, running in tandem with large scale investment into its technology is pivotal. The life cycle of drug manufacturing and commercialisation is a complex one, with complicated research, manufacturing, and distribution processes. These processes pose unique energy demands primarily attributed to the requirement of precise environmental conditions, the necessity of temperature control and the rigorous needs of sterile working environments. Energy efficiency via energy management solutions, alternative fuels and on site generation of power are seen by manufacturing plant management teams as the first steps in initiating this transition. '' The challenge of maintaining high product quality while reducing production costs can be met through investments in energy-efficient technologies and energy-efficiency practices.'' (L. Shamkishore 2011)

Statistics show that 4.83 billion prescriptions have been dispensed this far this year. This in turn has associated packaging and an impact on sustainability.(Statista) Literature is critical of the industries reliance on 'recyclability' and concludes that this is no longer enough to address this issue. Pharmaceutical companies must adopt more sustainable methods in its packaging methods.

2.3.4 Extended producer responsibility

Fundamental to the circular economy within the pharmaceutical with regards to end to end process is Extended Producer Responsibility. This approach offers an increased level of sustainability by incentivising and mandating the responsible stewardship of products throughout their lifecycle. The OECD defines ''Extended Producer Responsibility (EPR) as an environmental policy approach in which a producer's responsibility for a product is extended to the post-consumer stage of a product's life cycle.'' (OECD) This policy has two fundamental suggestions as per the OECD:

- Transfer responsibility (fully or partially) upstream away from end users / municipalities to the producer in this case pharmaceutical companies
- Incentives are provided to producers who design their products in a environmentally responsible way

2.4 External influences on Sustainability in the Pharmaceutical Industry

A number of external influences exist from consumer perceptions, regulatory pressures to governmental mandates. Within Europe the European Federation of Pharmaceutical Industries and Associations (EFPIA) group sustainability under the heading of Environment, Health, Safety and Sustainability. This heading encompasses the protection of health and safety for its employees while referring to the public and environmental concerns. Fundamentally EPHIA recognises the ever increasing rate of resource consumption throughout the world in an unsustainable manner. Moreover EPHIA messaging is that an '' increased focus on environmental sustainability is key for the future health of our planet.''(EFPIA) Pharmaceutical companies who join EPHIA are mandated to strive to ''strive to invent, produce and distribute new medicines and vaccines in a safe and environmentally responsible manner.''(EFPIA) Although the main focus is upon manufacturing and distribution a greater push is being placed into a circular economy approach

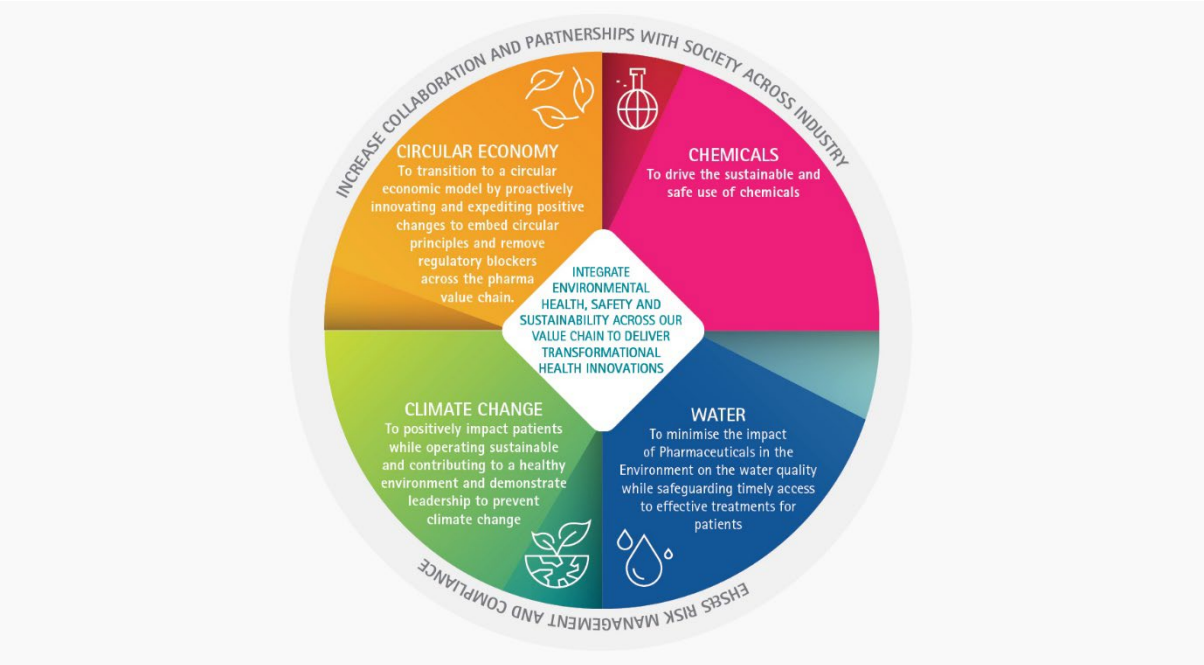

Figure 1: EFPIA Circular Economy flow

A number of further external influences exist which will be discussed in depth below including regulatory environments, consumer demand and perceptions, supply chain, shareholder and

investor pressure, technological advancements in manufacturing, which was discussed in section 2.4, competitive landscape, and perception and reputation

2.4.1.1 Regulatory environment

With environmental concerns on the rise throughout all industries regulation has concurrently become more active and risen. From the ground up the European union mandates environmental impact assessments. These assessments have a far reaching remit which span from throughout the production process through to the release of Active Pharmaceutical ingredients into the environment.(Europa 2020) With UNESCO recently referring to the outputs of pharmaceuticals as emerging pollutants the European Commission subsequently published a strategic approach to Pharmaceuticals in the environment. This report has far reaching consequences when it comes to environmental pollution and CSR.

2.4.1.2 Consumer demand & perceptions

Studies have suggested that the impacts on the environment can be influenced significantly by consumer behaviour. A study by Jeswani and Azapagic in 2019 suggested that in regards to consumer behaviour that '' in addition to making environmental improvements through product development and supply change management, companies, government bodies and consumer organisations should also focus on providing consumer guidance to help lower the environmental impacts of personal care and pharmaceutical products.''(Jeswani and Azapagic 2020) One of the main points of Jeswani and Azapagic noted that changing behaviours of consumers with regards to toothpaste, an over the counter pharmaceutical product, could reduce the carbon footprint of toothpaste by 57 times.

''In today's changing business world, companies cannot be measured on profits alone. The external environment can play a major role in the perceived value and success of an organization. Managers should be concerned about social responsibilities, since it gives the company a right to exist based on their responsiveness to the external environment''. (Smith 2008) Environmentally aware consumers are now demanding products and brands that are made in a sustainable and environmental way.

2.5 Gaps within the literature

The following gaps in the literature have been identified by the author.

The literature falls short when considering the perceptions of pharmaceutical executives and their perceptions of sustainability and the full scope of CSR. Moreover, the link between sustainability within pharmaceutical manufacturing and commercial divisions is ill defined. While literature is abundant and well investigated with regards to sources of energy consumption, supply chain, resource depletion, and the disposal of excipients and waste, little is known about the perceptions of pharmaceutical management in a commercial setting with regards to sustainability. In a major systematic review of Environmental sustainability of 24 articles by Milanesi, Runfola and Guercini, their thematic analysis showed four distinct fields in this field of study '' of the ecological dimension as follows: cleaner production, green supply chains, green human resource management (HRM), and green materials.''(Belkhir and Elmeligi 2019) This literature contends that there is limited attention to both the factors influencing commercial decision making within the sector and social sustainability. This is somewhat surprising given the role of creating well being for a global population that has been attributed to this industry.

2.10 Literature review conclusion

An abundance of literature is evident in the space of manufacturing, supply chain, and corporate social responsibility, however as stated minimal literature is available when specifically concerned with commercial decision making and its impact on sustainability in the pharmaceutical sector. As Corporate social responsibility, social sustainability and environmental sustainability are intrinsically linked, and this warrants further research into this area. In such a highly complex scenario the greater the research and findings, the more improved the sustainable circular economy within pharmaceuticals will become.

In conclusion this literature review highlights the complicated and multifaceted nature of both the pharmaceutical industry and sustainability, two topics of significant importance and intricacies. Aside from the moral imperatives of achieving sustainability within this sector, the strategic necessity of achieving this success, would have significant impacts on environmental, social and economies globally.

The studies reviewed underscore the recognition of the impacts the industry has across all areas of sustainability. Growing evidence supports a fully circular economy within this sector. Such evidence warrants the need for full recognition from all stakeholders from within the industry and externally also. Areas of study that have been well researched an cited include green chemistry, energy efficiency, waste disposal, supply chain and environmental impacts. This being said barriers remain within the industry including regulatory, consumer habits, and financial concerns. Addressing these barriers will require concerted efforts from stakeholders both internal and external to the industry.

Finally, literature again and again suggests that sustainability within this industry is multifaceted, complex and a dynamic process requiring continuous improvement and adaptation from all involved. This review provides valuable insights into the current state of play and shines light upon areas for further research and understanding.

3. Methodology

3.1 Introduction

This section lays out how research was carried out into the area of Sustainability in the pharmaceutical industry within an Irish commercial setting. The research explored perceptions and opinions by key opinion leaders (KOL's) within the Irish Pharmaceutical Industry with regards to sustainability. Redman and Mory define research as a ''systematized effort to gain new knowledge''. (Redman and Mory 1923) The goal of this research is to gain an understanding of the current state of play of sustainability in Ireland, and to assess the appetite for change with KOL's of the pharmaceutical industry. Moreover, this cross sectional research design by qualitative methods aims to explore the internal and external factors at play, with regards to sustainability, when it comes to commercial business decisions within this industry.

The term 'research methodology' is broken down into three distinct approaches design, conduct and analyse of the chosen topic. Furthermore, this methodology allows researchers to analyse findings, validate, and ensure the reliability of their findings in an impartial manor. It acts as a blueprint for conducting research guiding and outlining the steps to be taken to complete research. This indispensable framework ensures synchronisation between each chosen principle and technique.

3.2 Proposed research methodology

According to Queirós, Faria, Almeida in 2017 notes that research adopts both qualitative and quantitative methodologies in the modelling and analysis of numerous phenomena. Moreover this paper makes reference to the fact that ''Scientific methodology includes the study of the methods or the instruments necessary for the elaboration of a scientific work (Almeida, Faria et al. 2017)''. However previously, in 2013, Flanagan claims that the qualitative method utilised is the most powerful tool to discover truths, explore new theories and perform empirical validation.(Flanagan 2013)

On the other hand quantitative research is focused upon objectivity, and is more suitable when the data is appropriate to quantify. This approach is frequently utilised when the possibility of collectable quantifiable measures, identifiable variances, and inferences can be made from a sample of a cohort or population. Formal instruments are used for data collection and analysis is numerical and analysed via statistics. In 2012 Marin and Bridgmon examined quantitative research and state that ''samples are generally large and considered representative of the population, the results are taken as if they constituted a general and sufficiently comprehensive view of the entire population''. (William E. Martin 2012)

Furthermore as the topic in question is one of a complex reality, a qualitative methodology was decided upon for this paper. Qualitative research is concerned primarily with a greater understanding of a given problem while this research methodology does not prioritise or is not concerned with numerical representativeness. The purpose of qualitative methodology is to generate comprehensive and descriptive insights to comprehend the diverse facets of the issue being analysed.

When considering the research onion this study adheres to Saunders, Lewis, and Thornhill's methodology which was developed in 2007. (structure depicted in figure 2 below). This methodology allows for a structured flow to enable the construction of a theoretical framework for research. (Saunders 2009) While later in 2016 Muranganwa notes that the research onion concept creates a firm basis for development of coherent and justifiable research design. Raithatha (2017) claims that on the basis of the research onion model an appropriate research methodology can be designed

step-by-step, thus it can be used as the main academic research model.(Muranganwa and Thinyane 2014, Raithatha 2017)

3.3 Research Philosophy

Johnson and Clarke in 2006 noted that as business management researchers we need to be aware of the philosophical commitments we make through our choice of research strategy since this has significant impact not only on what we do but we understand what it is we are investigating (Johnson, Goodman et al. 2023). Saunders, Lewis, and Thornhill in 2007 proposed that a number of stages must be considered and developed as an overarching methodology know as the ''research onion'' which breaks down and sets a pathway for researchers to appropriately address the research question posed. (Almeida, Faria et al. 2017) The research presented within will follow the methodology of the research onion.

Research onion

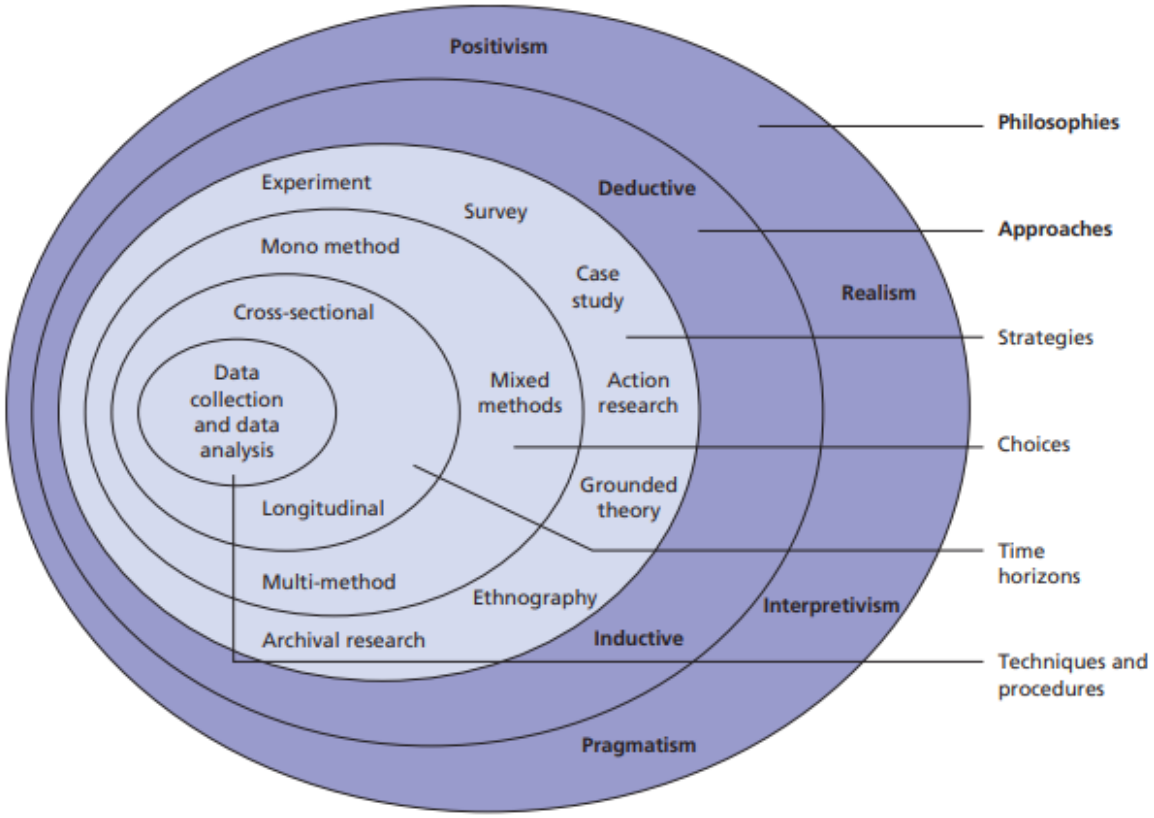

Figure 2 The Research 'Onion' (Saunders, Lewis, and Thornhill, 2007) (Saunders 2009)

3.4 Research approach

When examining the research onion proposed by Saunders et al. the second layer of the onion refers to both deductive and inductive approaches. Most commonly deductive testing refers to quantitative whereas inductive development refers to qualitative. However most recently in 2024, Fife & Gossner state that ''qualitative research is often equated with inductive analysis, researchers may also use deductive qualitative approaches''.(Stephen T. Fife 2024) Traditionally qualitative research is looked upon as ''an inductive bottom-up approach to data analysis'', but authors argue that deductive approaches to qualitative research should be utilised for previously published

literature whether empirical or non empirical, to be re-examined, refined or a change in ideology. (Kyngäs 2020)

The author having examined the specific core objectives of his research has decided upon a simple inductive approach, primarily to gain the experience and perceptions of the survey participants in an area of research that has little to no previous literature published.

3.5 Research Strategy

Examining the third layer of the research onion, research strategy represents the choices faced by a researcher, with these choices having a significant impact on the subject matter at hand. This layer can be referred to as the general way in which the researcher chooses to collect their main data, alternatively they may decide to use numerous methods to collect data to meet their research objectives. In the case of this thesis the author decided upon a mono method qualitative study by means of survey for data collection. Survey participants presented their perspectives via a Microsoft forms survey.

When examining all approaches to their research strategy the author considered and deliberated utilising multimodal techniques for this study, obstacles were presented in the way of time limitations, therefore a mono method qualitative study was carried out. A key criteria to this study is to understand the participants in depth insights into the objectives of this study. Mixed methods, both quantitative and qualitative, were considered but due to the limited accessibility of pharmaceutical leadership the afore mentioned approach was deemed the most feasible.

As this research is fundamentally intending to generate knowledge grounded in human experience a monomethod of research was opted for as part of the initial strategy. While thematic analysis has many advantages providing the author with a highly flexible approach which in turn provides rich and detailed, yet a complex account for the data as described by Braun & Clarke 2006 (Braun and Clarke 2006). Furthermore, Braun and Clarke purported thematic analysis is a more accessible form of analysis from which different perspectives of research participants aiding in the generation of unanticipated insights and shining light upon similarities and differences.

However some disadvantages are noted within the literature with regards to thematic analysis due to its flexibility which can lead to inconsistency and lack of coherence in developed themes. That being said a paper by Holloway & Todres in 2003 stated that ‘’consistency and cohesion can be promoted by applying and making explicit an epistemological position that can coherently underpin the study’s empirical claims’’.(Holloway and Todres 2003) The author therefore has decided to take a thematic analysis qualitative approach guided by the overarching methodology of the research onion.

3.6 Qualitative data primary collection

The aim of this study is to better understand the internal and external factors effecting commercial pharmaceutical managers and executives within an Irish context. Furthermore, gaining the perspectives of these individuals will take use an inductive method and data will be gathered via online survey. In 2017 Queirós et al in 2015 noted that the objectives of a ‘’qualitative methodology intends to understand a complex reality and the meaning of actions in a given context’’.(Almeida, Faria et al. 2017)

A survey was conducted in March 2024 (n=9). The survey examined pharmaceutical executives attitudes towards sustainability within commercial decision making. Data and responses were collected, anonymously, via Microsoft Forms.

When conducting such research via survey it requires particular attention to methodological considerations to ensure the content and rigour of findings is both reliable and valid. A number of areas were examined in order to produce structured data collection. Open ended questions are imperative to elicit detailed responses from participants. Questions should be given considerable thought in order to promote participants to express thoughts, feelings and experiences in their own words.(Babbie 2020) With a specific cohort in mind convenience sampling was employed.

In conclusion qualitative data obtained through surveys offers a considered and robust way in which to explore and report human experiences perceptions and behaviours delivering meaningful insights.

3.7 Population

There are several key considerations when examining the population for which is to be tested. Consideration must be given to defining the population of study, the justification for the population choice, while contextualizing is also of paramount importance. Moreover there are a number of well defined and tested approaches for sampling strategy and this must carefully be considered prior to data collection as per layer three of the research onion.

The author utilised a convenience sampling approach when considering the population to be tested. Each participant was contacted individually and asked if they would participate in this study, if the person was agreeable their contact details (Email) was taken and a survey via Microsoft forms was disseminated. The participants had a number of weeks over the course of late March to early April 2024 to complete the survey, which took on average 15 mins to complete.

Convenience sampling allows researchers to easily access participants while concurrently minimising costs associated with recruitment and data collection (Etikan 2016). Such sampling offers advantages in terms of timelines and efficiencies allowing for shorter timeframes to conduct research. Disadvantages include the lack of diversity of perspectives due to the reliance on a homogenous population. The author is aware of Bryman's findings, in 2016, which found that while convenience sampling offers these advantages, researchers should remain mindful of its limitations, including potential biases, limited generalizability, and susceptibility to sampling errors.(Etikan 2016)

However as this study defined specific objectives within a niche cohort this will enable the advantages of convenience sampling within the selected population. Furthermore Convenience sampling is generally utilised in situations such as this where the author finds themselves in, within the pharmaceutical industry in Ireland.

The population is described in the below table:

Participant characteristics (n=9):

Participant	Gender	Age range	Seniority level	Years of experience
P1	Male	45-54	Senior / Experienced	20 years +
P2	Male	55-64	Executive / Leadership	20 years +
P3	Female	45-54	Executive / Leadership	20 years +
P4	Male	45-54	Executive / Leadership	20 years +
P5	Male	25-34	Mid – level / Intermediate	0-5 years
P6	Male	35-44	Senior / Experienced	0-5 years
P7	Female	45-54	Executive / Leadership	15-20 years
P8	Female	25-34	Executive / Leadership	5-10 years

P9	Female	45-54	Executive / Leadership	20 years +

Table 1: Participant characteristics

3.8 Analysing Qualitative data

Kyngas in 2019 described at length how to perform inductive content analysis, explaining this methodology as a means to analyse open, half structured data such as the data gathered in this study. '' Inductive content analysis utilises the process of abstraction to reduce and group data so that researchers can answer the study questions using concepts, categories or themes.'' (Kyngäs 2020) Inductive content analysis allows the author to provide a systematic approach that will uncover such themes and patterns. The author utilised this methodology as a framework when designing, carrying out, and analysing data obtained during this study. Of benefit to this study is a number of characteristics that qualitative content analysis enables, firstly its users are able to avail focus on subject and context, while emphasising differences between and similarities within categories. Furthermore this methodology allows the use of themes which can been see as expression of latent content, for example what the text is talking about. (Graneheim and Lundman 2004)

Qualitative methodologies such as the afore mentioned inductive content analysis are commonly used to investigate complex phenomena. This research methodology is ideally placed as '' Qualitative approaches share a similar goal in that they seek to arrive at an understanding of a particular phenomenon from the perspective of those experiencing it''.(Vaismoradi, Turunen et al. 2013)

Pitfalls with thematic analysis exist, and are reported Braun & Clarke in 2006 as poorly demarcated, rarely acknowledged however widely used in qualitative analytic methods. In 2006 both authors proposed a methodology to describe the phases of thematic analysis to address this issue. See below in figure 3. (Braun and Clarke 2006)

Phase	Description of the process
1. Familiarizing yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Figure 3: Thematic Analysis a phased approach (Braun & Clarke, 2006)

In conclusion surveys were carried out via Microsoft forms and the results were analysed utilising thematic analyses by qualitative methods. Themes obtained via this analysis are discussed in the results and discussion sections of this study.

3.9 Ethical Issues

The author considered the ethical implications of such a study. Of the upmost importance was confidentiality and informed consent. However a number of issues were considered during the design phase of this study. To define research ethics Moe et al. in 2024 noted that ''research ethics refers to the moral principles – including values, norms, and institutional requirements – that govern the conduct of research.''(Moe, Uhrenfeldt et al.) And when examining it from a European context the European Commission provides a robust description of what research ethics encompass stating that '' Research ethics also encompass the wider social responsibility of researchers to ensure that scientific and technological development benefits society'' while authors go further to say that ethics are closely related to human rights.(Beyrer and Kass 2002, European Commission 2013)

Consent – Surveys were sent on a voluntary basis with fully informed consent obtained prior to commencement of the survey. A detailed explanation was provided as to the aims of this research. The voluntary nature of their involvement was stated and their right as a participant to withdraw from the study at any time without penalty.

Confidentiality & Anonymity- Data collected throughout this survey remained fully confidential, with no identifying data was collected. Data was subsequently stored on an encrypted excel sheet. Participants were assured of the anonymity and confidentiality of all responses gathered. Furthermore the any publications with regards to this research would yield no identifiable features.

Data Security – All data collected via Microsoft forms was stored on password protected electronic devices further backed up in encrypted cloud storage platforms. Only the author has access tot this data and if requested authorised college personnel of the National College of Ireland only.

Ethical approval – This research project was approved by the faculty at the National College of Ireland. All procedures related to this research were carried out in accordance with the National College of Irelands guidelines and standards.

In conclusion this section provides an in depth overview of all ethical considerations that were taken into account by the author to conduct qualitative research, demonstrating the authors full commitment to upholding ethical standards.

3.10 Limitations to research

The author notes that the sample size is small (N=9). Such a small sample size may present findings of limited representativeness, while limiting the applicability of findings to a larger context. With a small sample size it may limit the representative nature of the studies findings to the broader pharmaceutical organisation. As such a small sample size increases the risk of bias both by the participant and author. As this is a convenience sample the likelihood is that the researcher may have inadvertently picked participants who were readily accessible. In instances such as this literature states that researchers may interpret data in such a way as to confirm preconceived notions due to narrower opinions and data gathered during their study. As a small scale exploratory, the author was constrained by resources. When examining online surveys they offer both accessibility and convenience but often result in limited sample sizes as is the case for this study.

When analysing the content analysis results can sometimes be challenging to report when utilising content analysis '' because the researcher can only describe part of analytical process exactly, and rely on their past insight or intuition to explain other parts of the analysis''(Kyngäs 2020). As is often the case in small scale exploratory studies can be constrained by resources. Within this study the uniformity of roles of participants varied, which may have lead to specific perspectives of that perspective based upon their own position at that point in time instead of offering and overarching

view of the wider organisations commitment to sustainability. However the author believes that the range of data gathered coupled with the literature review gives and overall comprehensive view of the perceptions, understanding, and motivations behind sustainability within the Irish commercial pharmaceutical industry.

In order to address the limitations posed by this study the author has utilised mitigation strategies to overcome these challenges by incorporating credibility of findings, and via a relevant literature review and methodological considerations. Reassuringly to this author the research proports that in the case of even individual case studies can provide reliable indicators for the direction in which future research should go and small sample sizes can provide '' a new, deep and nuanced understanding of previously unexplored phenomena''. (Boddy 2016)

4 Results and findings

4.1 Introduction

The literature points towards a definite upward trend in the importance of decision making within business in a sustainable and green way. However while it is well documented that pharmaceutical manufacturing is making large strides towards a 'greener future' this research examines whether this is a factor when examined in a pharmaceutical commercial context. This author utilised an inductive content approach and was able to form a more in depth understanding of the research participants viewpoints. Moreover the author further broke down the data gathered by analysing internal (Within company) and external (Outside company) forces at play influencing sustainability within the context of sustainable decision making. The results were obtained from pharmaceutical management and executives across Ireland's Pharmaceutical industry. Fundamentally this section intends to extrapolate and define connections within the data obtained from participants and existing literature.

Questions were presented in a number of closed questions to obtain demographic and a participant profile to add context to the following open ended questions which is presented below in section 4.2. Afterwards section 4.3 presents the identification of recurring themes or patterns known as coding via inductive methods aligned with the four key objectives of this study.

4.6 Descriptive Statistics of The Sample

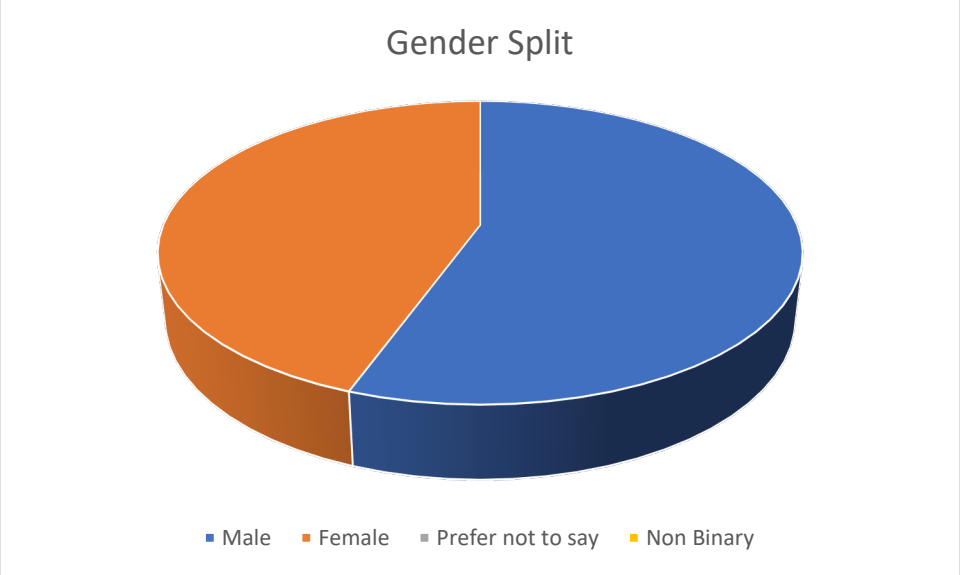

Figure 4: Split by gender of Participants (Options Male, Female, Non Binary, Prefer not to say)

With N=9, 56% of respondents were male with the remaining 46% female as illustrated in figure X above. As a mandatory questions other options provided were 'Non binary' and 'Prefer not to say' with 0% of respondents opting for those answer selections.

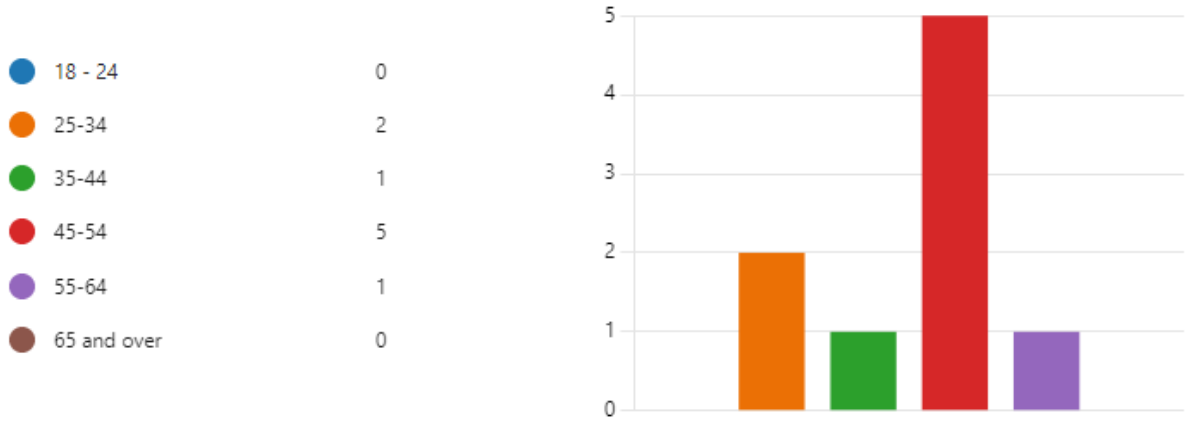

Figure 5: A bar chart of survey participant's age

The majority of participants were within the 45-54 year old age range with 56% in this range followed by 25-34 age range with 22%, 11% in both 35-44 and 55-64 age ranges, while there was no participants in the 18-24 and 65 and over age ranges.

Figure 6: Pie chart of the distribution of Length of Service of respondents

Of those surveyed 55% of participants had 20+ years of service / experience in the Irish Pharmaceutical industry, with 22% having 0-5 years, and 11% had 5-10 years and 15-20 years respectively.

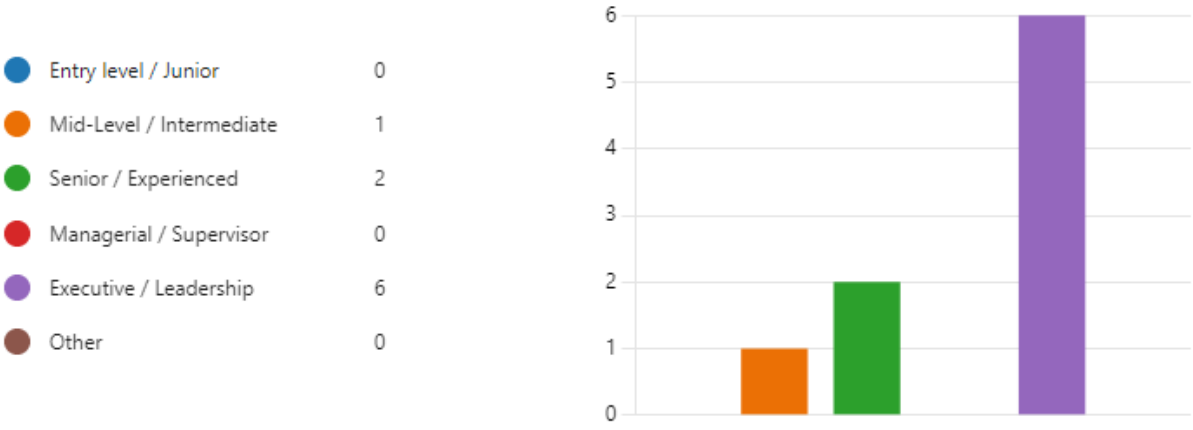

Figure 7: Bar Chart displaying the level of seniority within the participants respective Pharmaceutical Company

Respondent were asked to select from a list of levels within their respective companies from the following limited list: Entry level/ Junior, Mid-level / intermediate, Senior / Experienced, Managerial / Supervisor, Executive / Leadership, and other. 66.66% of respondents were executives / leaders within their pharmaceutical organisations, while 22.22% were Senior or experienced, with the remaining 11% were mid level / intermediate in position.

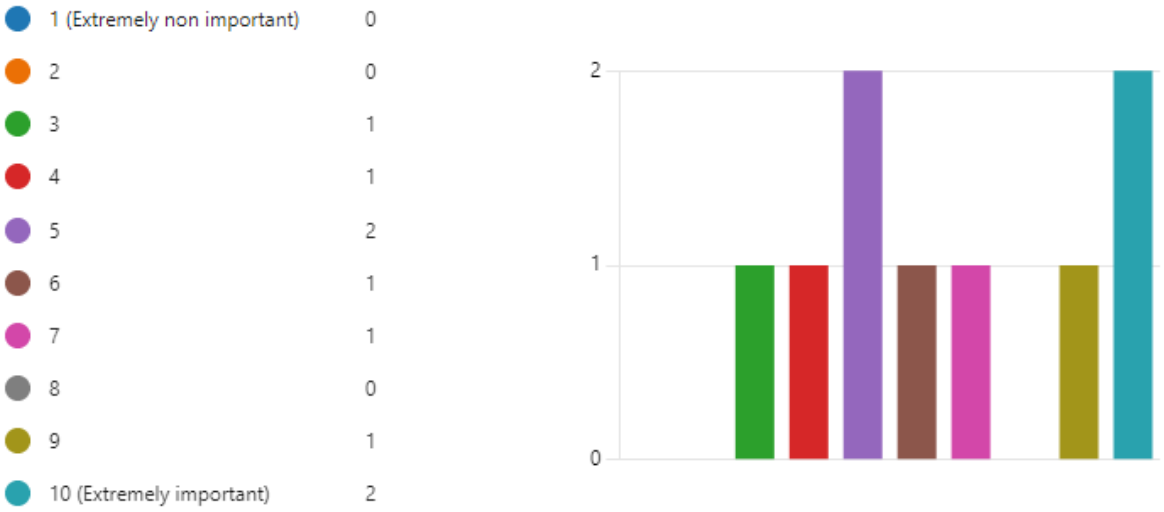

Figure 8: Participants perception of importance of sustainability in commercial decision making

Respondents were asked to rate how important do you believe sustainability is in commercial decision-making within pharmaceutical companies? 22.25% rated this as extremely important, 22.25% were neutral, with a further 22.25% rating as varying degrees of non important and the remaining 33.25% responding this as somewhat important.

4.3 Qualitative research findings

All findings contained within this literature are based upon surveys that were completed by participants over the duration of late March to April 2024. Survey questions and consent were gathered anonymously via Microsoft forms. Questioning within the survey was aligned stringently to the four main objectives of the study that are described in section 1.2.

4.3.1 Objective 1: Sustainability understanding within the Irish pharmaceutical commercial sector

The primary aim of the first objective of this study is examine leadership with the industries knowledge, familiarity, consideration of, and economic viability of sustainability within commercial decision making.

4.3.1.1 Familiarity

Participants were asked about their familiarity of sustainability within the pharmaceutical industry with and even split of responses between being familiar and being not very familiar. Of interest only one participant from Abbvie noted that they were 'very familiar' with sustainability. Thematically participants in the majority were not familiar with sustainability from a commercial perspective. The polarisation of answers obtained with regards to familiarity of sustainability are noted in particular from the answers given by participant 7 who responded ''not very'' familiar whereas participant 6 responded '' Very, Everyone at AbbVie plays a role in lowering our environmental footprint to ensure that we put people, communities and society first in our daily actions.''

4.3.1.2 Sustainability in decision making (drug development and commercialisation strategy)

Considering response within and Irish context the general responses culminated in a lack familiarity within this area versus a definitive understanding and implementation. A broader focus appears to be on this area but in response one cohort of participants opinions reported that this was an area of little focus or consideration while the second cohort were definitive in their response that the process was of the upmost importance and consideration . In a smaller number of participants noted that this was a key consideration from drug development through to the full life cycle. Again polarity was observed within the answering for example participant 4 responded '' They are considered but how much of an influence they really have is uncertain'' but in contrast participant 6 responded '' Sustainability forms part of the New Product Introduction preparation and is scored when selecting equipment etc for new products . As part of the commercialization strategy supply chains are reviewed to ensure that the carbon footprint is as low as possible.''

4.3.1.3 Economic viability of Sustainability initiatives

The third pilar of this the first main objective investigated participants attitudes toward assessing economic viability of sustainability initiatives in pharmaceutical commercial decision making. It was evident that two predominant themes emerged between participants who were unsure / had no knowledge with the remainder placing responsibility with the manufacturing arm of their respective companies. With participant 2 stating '' This does not occur in the commercial arm as we'd anticipate that all of these considerations would be dealt with in manufacturing''. However one outlier in terms of response, participant 6 noted that there is mixed responsibility in this area between functions with their respective company '' This is carried out by the engineering function as part of the review process and shared with commercial teams for decision making''.

4.3.2 Objective 2: Internal influences on commercial decision making with regards to sustainability

The second key objective of this study investigates what internal factors are influencing commercial decision makers within this industry. This objective fundamentally was answered by question 9 of the survey which asked '' How do you perceive the expectations of internal stakeholders (e.g., country leadership, global/corporate leadership) regarding sustainability in the pharmaceutical industry?''

In analyses of responses 7 responders noted that the expectations of internal stakeholders was either a growing, a necessity, high priority, to extremely high. Respondent 8 noted that expectations of internal stakeholders was ''low''. Thematically more felt this was a senior leadership responsibility and that employees should be encouraged by leadership to take more sustainable approaches. There was an overall recognition of the ever increasing importance of sustainability, but competing priorities are hindering this influence. The balance between immediate business priorities with sustainability commitments remains challenging. The prevailing perception amongst responders noted that sustainability is shifting from a should do to a must do attitude and sustainability is becoming a must do in terms of compliance and related standards.

Analysis here underscores the significant complexity of integrating sustainable practices into corporate decision-making processes. There is a varying mix of perspectives, which range from endorsements and commitment to sustainability to the challenges such integration would present in the short term.

4.3.3 Objective 3: External influences on commercial decision making with regard to sustainability.

The third core objective of this study focused around external influences and the respondents key perceptions of this influence. Questions within the survey concerned with this aspect were question 8, 14, and 15. Analysis of these three questions is below:

4.3.3.1 Perceived expectations of external stakeholders

This question asked specifically around how participants perceived the expectations of external stakeholders (e.g., investors customers, regulators) regarding sustainability in an Irish pharma context. In response to this question participants in the majority saw this as an issue of some importance. Participant 2 '' I would say it's becoming more of an issue but again the potential health benefits of any discovery would have to be weighed against any concerns around sustainability'' with participant 9 responding similarly noting that '' sustainability is a consideration, however access to product/shortages higher on the radar'' with participant 7 responding '' With regards to national reimbursement is it considered even less unless there is the potential for wastage. This is because Innovation, price, unmet need etc takes precedent in my opinion''.

Commonality between the respondents saw shareholders / investors as a predominant influence who expect suitable practice as a foundation of pharmaceuticals. Across a number of respondants it was observed that expect sustainable practices within the industry as standard,

4.3.3.2 Perceptions to company collaboration with external partners to advance sustainability goals

Predominantly question 14 withing the survey dealt with this area of research asking to what extent does your company collaborate with external partners (e.g., suppliers, research institutions, NGOs) to advance sustainability goals in the Irish pharmaceutical industry?

Six of nine responses were either unsure or not exposed to this within their role. This suggests certain roles within the companies represented did not engage in external collaborations related to sustainability. Recurrently participants noted that responsibility for this rested with supply chain and manufacturing arms of the company.

Of the remaining 3 respondents answers patient advocacy groups, industry representative bodies and supply chain bodies were of note.

4.3.3.3 Partnerships with other stakeholders influence commercial decision making

Of the 9 respondents 4 were unaware or unsure as to the extent partnerships and stakeholders influence commercial decision making regarding sustainability. 1 respondent placed the responsibility with manufacturing sites, while the remaining respondents noted that stakeholders such as supply chain and logistics partners should be aligned and influence sustainability in commercial decision making from that aspect.

4.3.4 Objective 4: Performance indicators, barriers and challenges of sustainability within an Irish context

The last core objective within this research asked participants about performance indicators, barriers and challenges surrounding sustainability

4.3.4.1 Challenges & Barriers

Question 10 asked participants, What are the main challenges or barriers to implementing sustainable practices in pharmaceutical commercial decision-making? A number of key concepts were observed in responses from the answers provided. The main concept which surfaced was financial implications, with participant 1, 5, 7, and 10 referencing this theme. For example

participant 6 response was as follows '' The cost benefit of increasing sustainability. Lack of incentives of increasing sustainability within the business''. Further themes emerged to a lesser extent with regards to the influence of external influences creating barriers investors and the potential short to medium term decrease in revenues associated with the transition towards sustainability.

4.3.4.2 Perceptions of Regulatory considerations to do with sustainability

In a highly regulated industry such as pharma to gain insights into the area of regulation and its ability to impact sustainability question 11 asked, How do regulatory requirements impact the integration of sustainability considerations into commercial decisions? A clear divergence in responses gathered was evident with 3 participants either ''unsure'' or ''unknown'' about this topic. Thematically a number of respondents noted that regulations would ''slow down procedures'', 'with participant 2 responding '' Regulatory requirements are onerous at the best of times and integration of sustainability considerations could slow development further''. Regulatory requirements in this context were perceived as potentially delaying for procedures related to ensuring compliance for Sustainability. New sustainable practices were viewed as an additional burden. This suggests a tension between the need for sustainability integration and the bureaucratic nature of regulatory compliance.

In conclusion the thematic analysis underscores the complex interplay between regulatory requirements and sustainability integration in commercial decision-making, highlighting challenges, and uncertainties surrounding this issue.

4.3.4.3 Key Performance Indicators (KPI's)

Question 12 asked participants: What key performance indicators (KPIs) or metrics does your company use to measure the sustainability of its operations and products? Or does this occur?

Of note was the awareness and exposure discrepancy amongst the surveyed persons. The majority expressed a lack of direct involvement or knowledge of any sustainability metrics or practices. A gap in knowledge is evident and some participants referred back to manufacturing as the gatekeepers of such metrics. Participant 2 noted '' unsure but those in manufacturing would have insights here''.

Some participants had a far greater understanding of science based targets noting that AbbVie utilizes science based targets based on ISO 50001 guidelines. Furthermore in depth understanding was provided from participant 9 who showed an in depth understanding of corporate level sustainability reporting noting their organisations annual report.

A significant variance in the knowledge of participants was evident

5 Discussion

The pharmaceutical industry as a whole is facing an increasingly stiffening pressure from both internal and external stakeholders to integrate sustainability and truly demonstrate a circular economy in its day to day practices. The heightened operation awareness of environmental and social impacts are the fundamental drivers of this. This paper utilised a inductive analyses approach through qualitative research to explore the integration of sustainability considerations in decision-making processes within the Irish pharmaceutical industry, focusing on perspectives from various management and executive level stakeholders.

5.1 Themes

Key themes become apparent during the course of analysing the data received

Awareness and perception within the cohort studied revealed a significant spectrum of familiarity with sustainability practices among respondents. Of note was the rift between those with high to expert levels of knowledge to those who had little knowledge. It was noted that some surveyed viewed sustainability as a secondary concern. A diverse landscape of attitudes exists within the industry and data yielded little uniformity in approach. Those who had a good to excellent knowledge of the area showed their knowledge of the three key areas of sustainability, CSR, Environmental and economic sustainability. For those who reported ‘’unknown’’ and ‘’unsure’’ to questions, these responders other answers correlated in general to speaking only to environmental sustainability.

The majority of data received pointed towards a general acceptance of the importance of integrating sustainability into decision making, with particular emphasis on regulatory compliance and commercialisation strategies. What was evident is the challenges of balancing sustainability goals with competing business interests such as financial and compliance considerations.

Integration of sustainability into corporate culture evidently varies amongst companies due to the diverse company background of participants. Evidenced in the data gathered during the survey period was the divergence in thinking of prioritizing sustainability as a core value and others treating it as a peripheral consideration. Corporate culture and strategy appeared divergent amongst responders.

Regulation was to the fore when analysing the data gathered during this survey. Despite the challenges, there is recognition of the critical importance of regulatory compliance in driving key business decisions. Participants acknowledge the potential financial and reputational risks associated with non-compliance, underscoring the influence of regulatory requirements on commercial operations with regards to sustainability.

Key performance indicators and the measurement and assessment of sustainability are utilised in this sector. Data gathered noted a general knowledge of sustainability of operations, carbon emissions, energy consumption and waste management. The economic viability of sustainability initiatives is also a factor in decision-making, this highlighting the importance of balancing environmental goals with financial considerations throughout the results obtained.

Gaps in knowledge, awareness and exposure discrepancy is evident from a commercial perspective. The fall back of participants throughout appears was that they acknowledged that participants in manufacturing roles would or may have insights into the specific areas asked about,

Conflicts are evident in both the data gathered and the research that as the industry is a financial and profit driven business sustainability and regulations surrounding its implementation pose risks and challenges.

5.2 General Discussion

Described as Pharmaceuticals and personal care products (PPCPs) when considered from an environmental and sustainability perspective they have been subject to exponentially growing attention since the late 1990's.(Daughton and Ruhoy 2009) The industry has a massive carbon footprint from R&D through its full life cycle and has now well documented evidence of Active Pharmaceutical Ingredients (API's) evident in waste water and sewage. In 2008 Smith referenced the fact that pharmacutical '' companies must continually emphasize effort and investments in R&D in order to remain competitive in the global marketplace Economic and political constraints provide constant challenges for pharmaceutical companies to address and react to on top of internal organizational issues. These organizations must also take in account the ability to be socially responsible to the external stakeholders to address these constraints''. (Smith 2008) Such an all-encompassing problem requires the concerted effort of all involved, starting with those within the pharmaceutical industry. While this is well documented and investigated, this paper examined executive leadership within an Irish Pharmaceutical industries commercial divisions. Over the course of March to April 2024 surveys were taken from those in such roles to examine perceptions and knowledge of this issue and furthermore to examine how this influences commercial decision making. No literature was found to have investigated this specific topic. Considerable effort has been directed towards the content of corporate environmental reporting and accounting while little empirical investigation has been completed into the process of corporate eco change.(Blum-Kusterer and Hussain 2001) Interestingly Blum-Kusterer and Hussain found that the neo classical stereotype of pharmaceutical industry of profit driven stood up to their empirical analysis the sector is moving towards a more eco innovation approach.(Blum-Kusterer and Hussain 2001) This is in agreement with the thematic analysis of this study in terms of the disparity of response, with participants either somewhat aware of the issue or fully informed, no uniformity in any of the areas where data was gathered yielded uniformity. From the discussion surround themes above it is clear there is no consistent approach to such an issue from a commercial perspective. The beliefs of the majority of those interviewed placed the responsibility with the manufacturing and supply chain arms of this industry. Life cycle assessments and cradle to gate assessments impact assessments of pharmaceutical products are minimal with only certain products ascertaining the true impact on sustainability also adds to the issues discussed.(Jiménez-González and Overcash 2014)

When considering future approaches one could argue that this paper would benefit from a deductive approach to qualitative research by allowing this research to be re-examined, refined or refutation of the idea that was studied. The authors positionality as an employee within the pharmaceutical industry and as the researcher could have a potential impact on the interpretation of the data that was obtained. As the author works within the pharmaceutical industry, bias or inherent beliefs had the potential to interpret data collection. However when utilising inductive content analysis allows the author to identify concepts in his research to answer his research questions. As sustainability in commercial decision making is such a diverse topic such a research methodology coupled with the research onion concepts may offer meaningful insights.

When examining the literature many initiatives are described about manufacturing processes within the industry, however commercial decision making processes play a decisive role in the process. The circular economy principles of EFPIA encompass this where the association promote the ''transition to a circular economic by proactively innovating and expedite positive changes to embed circular

principles and remove regulatory blockers across the pharma value chain''. Moreover this is aligned with the European Commissions Circular Economy Action Plan. With regards to themes uncovered by this research external stakeholders such as supply chain, logistics and manufacturers of raw materials play a large part in making the circular economy of pharmaceuticals a reality and in turn should be involved in the commercial decision making process as part of an all encompassing coherent strategy to tackle sustainability. In general, the commercial leadership in those surveyed reported that the manufacturing arm had more of a role to play in sustainability whereas a large cohort of participants were unsure or not informed of their role as leaders as to where suitability plays a role in their decision making process. Milanesi, Runfola and Guercini in 2020 support the findings of this research where they note that during their systematic literature review which concluded that '' the literature review showed that even if management studies are permeable to the issue of sustainability of the pharmaceutical industry, the analysis mainly revealed the focus of such studies to be environmental sustainability, mainly in terms of cleaner production, green supply chain, green materials, and sustainable HRM. However, a certain level of fragmentation and lack of convergence towards major themes appears evident''. (Milanesi, Runfola et al. 2020)

As the survey was sent to participants within a number of different Irish based Pharmaceutical companies the author hypothesizes that sustainability is not a constant amongst Irish Pharmaceutical companies commercial units. It is hypothesised that sustainability is a key focus of some commercial units but not within others.

6 Conclusion & Recommendation

6.1 Conclusions

Commercial decision makers within the pharmaceutical industry have a critical role to play, to plan and achieve a truly sustainable industry. This is fundamentally because this industry plays a pivotal role in human health but in contradiction had the ability also to effect both humans and the environment. The principles of circularity must be balanced with regulation in this highly regulated industry, but should not be a deterrent for commercial leaders to take an active role in sustainability across the three main pillars of environmental, social, and economic sustainability. While the focus remains within manufacturing and how to increase innovation alongside reducing environmental risk, energy usage and raw material consumption, commercial decision making has a significant role to play in the overall sustainable pharmaceutical picture. To achieve a fully circular economy in the pharmaceutical industry within Ireland and globally requires definite action by all persons involved, not a single department such as manufacturing or supply chain should bear the brunt of this multifaceted issue.

Gaps remain in knowledge of both the literature with regards to the real consequences that climate change is causing due to a distinct lack of life cycle assessments on pharmaceutical products, which is reported as almost non-existent for over the counter medications and limited for prescription medications. Evident from this research is some leading executives within the Irish pharmaceutical commercial industry have large gaps in knowledge with regards to the three main pillars of sustainability and in turn have a reliance on the manufacturing arms of the business to enact sustainable practices. While there are a number of participants in this research who displayed a good to excellent level of knowledge of sustainability practices across commercial decision making the disparity of knowledge can only be assumed to aggravate the problem of integrating a fully sustainable circular economy in pharmaceuticals.

As this is an area of little research currently a qualitative research method was employed to allow this research to be presented in a way to be critiqued and opened up to analysis, critique, and / or adaptation.

6.2 Recommendations

More research with a larger sample size is required within this area. Due to the relatively small sample size available within Irish Pharmaceutical commercial divisions a larger study encompassing more countries of similar economic background may lead to more in-depth thematic analysis.

Furthermore, the author has hypothesised that large variations in the consideration of sustainability exists between pharmaceutical companies. Segmenting the research to examine pharmaceutical companies could lead to further analysis as to why this occurs.

Throughout this research it is evident there is little research at present with regards to social sustainability exists within the pharmaceutical sector. The author proposes that further research should take place on the theme of management practice and sustainability in the pharmaceutical sector within the European Union.

6.3 Declaration of competing interest

The author declares no financial or competing interests that could have influenced this research

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8 Appendices

Appendix I: Interview Questions

1. Informed consent:
   This research survey looks to discover how sustainability influences commercial decision making within the Irish Pharmaceutical Industry. This study looks to capture insights into current market dynamics and how internal and external factors influence your decision-making process within this context. This survey is completely anonymous, any answers given will not be traced back to any one individual. At any time during the survey, you may opt-out of the survey process, any incomplete surveys will not be used in the findings of the study. All information gathered in the survey will be securely stored by the researcher. The survey consists of sixteen questions and takes approximately 5-10 minutes to complete. Surveyor is contactable at [redacted] and or [redacted].
2. Gender
3. Age
4. Which of the following best describes your seniority level within the company?
5. How long have you been working in the Irish Pharmaceutical industry?
6. How familiar are you with sustainability within the pharmaceutical industry?
7. How are sustainability considerations integrated into the decision-making process for new drug development or commercialization strategies?
8. How do you perceive the expectations of external stakeholders (e.g., investors, customers, regulators) regarding sustainability in the Irish pharmaceutical industry?
9. How do you perceive the expectations of internal stakeholders (e.g., country leadership, global/corporate leadership) regarding sustainability in the pharmaceutical industry?
10. What are the main challenges or barriers to implementing sustainable practices in pharmaceutical commercial decision-making?
11. How do regulatory requirements impact the integration of sustainability considerations into commercial decisions?
12. What key performance indicators (KPIs) or metrics does your company use to measure the sustainability of its operations and products? Or does this occur?
13. How do you assess the economic viability of sustainability initiatives in pharmaceutical commercial decision-making? Or does this occur?
14. To what extent does your company collaborate with external partners (e.g., suppliers, research institutions, NGOs) to advance sustainability goals in the Irish pharmaceutical industry?
15. How do partnerships with other stakeholders influence commercial decision-making regarding sustainability?
16. On a scale of 1 to 10, how important do you believe sustainability is in commercial decision-making within pharmaceutical companies?
17.