

**Drug Shortage in Ireland: An In-depth Analysis of
Current Situation, Causing factors, Impact and
Future Recommendations.**



Griffith College

A research dissertation submitted to Griffith College Dublin, in partial fulfilment of the requirements for the degree of MSc in pharmaceutical business and technology (QQI).

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MAY 2024



ACKNOWLEDGEMENTS AND DEDICATION

I am thankful to the grace of God for the precious gift of life and for granting me the opportunity to experience the most enriching phase of my life, filled with wisdom and strength throughout this journey and successfully accomplishing this research work.

I extend my heartfelt gratitude to my father **Mr. Paul N P**, my mother **Mrs. Suja**, my sister **Richa Paul**, my friend **Mr. Trevor Matthews**, and **Mrs. Jacqueline Matthews** for their unwavering support and belief in my capabilities. Their constant encouragement has been my rock-solid foundation during this journey. Additionally, I am immensely thankful for the incredible opportunity to pursue my aspirations in one of the finest institutions.

I would like to express my appreciation to my supervisor, **Susanna Coghlan**, for her support and expert guidance throughout the dissertation process. Her continuous encouragement and insightful feedback have propelled me to excel and achieve the objectives of this dissertation.

To all the respondents who generously spared their time from their busy schedules to participate in my survey and interviews, I am deeply grateful. This dissertation would not have reached its completion without your invaluable inputs.

I want to thank all the writers and researchers who worked hard and laid the groundwork for my thesis. Their important contributions are the basis for my own ideas.

Also, I'm grateful to Inno pharma Education and Griffith College for their commitment and the support they've given to the program. Their efforts made my master's studies enlightening and rewarding.

With warm gratitude,

Riya Paul



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LIST OF ABBREVIATION

QQI - Quality and Qualification of Ireland

GSK – GlaxoSmithKline

IPU – Irish Pharmacy Union

MSI – Medicine Shortage Index

HPRA – Health Products Regulatory Authority

MFI – Medicines for Ireland

IMT – Irish Medical Times

WHO – World Health Organization

ASHP – The American Society of Health System Pharmacists

ISMP - The Institute for Safe Medication Practices

RSV – Respiratory Syncytial Virus

FIP – International Pharmaceutical Federation

EMPs – Exempt Medicinal Products

EMVS - European Medicines Verification System

GIRP - European Healthcare Distribution Association

FDA – Food and Drug Administration

A4R - Accountability for Reasonableness

R&D -Research and Development

EPMs -Essential Prescription Medications

OTC - Over-The-Counter

GDPR -General Data Protection Regulation

ABSTRACT

Medicine shortages in Ireland strain the pharmaceutical industry and pharmacists. Pharmacists face increased workload and patient distress, leading to burnout risk. Solving medicine shortages is crucial to ensure continuous patient care and maintain the health sector's efficiency. It reduces the pressure on pharmacists, improves patient satisfaction, and stabilizes the pharmaceutical industry. Therefore, it's essential to address this issue promptly and effectively.

This research work, titled "Drug Shortage in Ireland: An In-depth Analysis of Current Situation, Causing Factors, Impact, and Future Recommendations," aims to provide a comprehensive understanding of the ongoing drug shortage in Ireland, a country known as a hub for the pharmaceutical industry. Despite its significant role in global pharmaceutical production, Ireland grapples with the challenge of maintaining a steady supply of certain essential medicines. This study is steered by four primary objectives. Firstly, it aims to investigate the root causes of medicine shortages in Ireland. Secondly, it assesses the impact of these shortages on the healthcare sector and pharmaceutical industries. Thirdly, it identifies gaps and areas for improvement in the current approach towards managing and preventing shortages. Lastly, it proposes future recommendations and strategies for mitigating these medicine shortages. By addressing these objectives, the study hopes to offer insights that could guide policy decisions and contribute to ensuring a reliable supply of essential medicines for the Irish population.

The research employed both quantitative and qualitative research approaches. It utilized an online survey questionnaire and phone call interviews to gather information from participants. The survey targeted healthcare professionals, primarily pharmacists, with an estimated sample size of 100. Of these, 74 responded, resulting in a response rate of 64%. Among the respondents, 53 were retail pharmacists, and 11 were clinical pharmacists across Ireland. The estimated sample size for the phone call interview was 6. Two of retail pharmacist responded and recorded the data.

Additionally, the study's findings not only identified strategies to enhance supply chain resilience and improve patient access to essential medications but also offered insights to healthcare policymakers, administrators, and pharmacists to improve the current quality care. By examining causes, impact, and potential solutions, the study provides valuable guidance for improving the quality of care provided to patients.

CHAPTER 1: INTRODUCTION

1:0 OVERVIEW AND BACKGROUND

The author embarked on a search for a dissertation topic, a requirement for the partial fulfilment of the MSc degree in Pharmaceutical Business and Technology (QQI). After careful consideration, the author chose to explore challenges related to the pharmaceutical supply chain in Ireland. During this research process, the author discovered numerous complex factors affecting the pharma supply chain. To narrow the focus, the author decided to investigate a single challenge that significantly impacts both the supply chain and the health system.

The central issue identified was medicine shortages, a critical crisis faced by Ireland in recent years. This scarcity disrupts the delicate balance of the healthcare system, which is particularly intriguing given Ireland's reputation as a pharmaceutical hub. The question arises: Why are there shortages of over 200 medicines in Ireland?(Ryan, 2023) Armed with this insight, the author resolved to delve into the topic further, resulting in the research project titled "Drug Shortage in Ireland: An In-depth Analysis of the Current Situation, Causal Factors, Impact, and Future Recommendations."

Ireland has become a top spot for big pharma companies to invest in manufacturing and research. Companies like Eli Lilly, AstraZeneca, and Pfizer are pouring billions into expanding their operations there. This surge in investment is thanks to Ireland's history as a manufacturing hub and a long-term strategy by the government. Ireland's success in attracting these companies is built on several factors. Firstly, it has a rich history in manufacturing, dating back to the 1950s(Ben Hargreaves, 2023). Companies like Novartis and GSK have been there for years, and investments like Wyeth Pharmaceuticals' billion-dollar biologics site have boosted its reputation. The Irish government has also played a crucial role. It has offered incentives like low corporate taxes and access to land since the 1960s(Ben Hargreaves, 2023). The COVID-19 pandemic has further solidified Ireland's position as a biopharma hub, as companies seek to diversify their supply chains. Even Brexit has directed more investment towards Ireland, especially in regulated industries like pharma(Ben Hargreaves, 2023).

All pharmacies in Ireland have been affected by the increasing issue of medicine shortages in recent months, as reported by a survey conducted by the Irish Pharmacy Union (IPU)(Dominic Coyle, 2024). Additionally, more than four out of five pharmacists anticipate that these shortages will escalate over the next year. The Medicine Shortage Index (MSI), based on data

from (the Health Products Regulatory Authority (HPRA)(HPRA, 2023b), highlights major shortages in over-the-counter cough syrups, aspirin, and paracetamol, among others. Even antibiotics like Penicillin and Amoxicillin are unavailable. Crucial drugs for pain, pneumonia, and respiratory infections are also unavailable. Reasons vary from regulatory issues to manufacturing delays. Currently, Medicines for Ireland (MFI) members(IPU, 2023) are really worried about how complicated the healthcare system is. This is causing a big problem with not having enough medicines available. The pricing rules make things worse by always lowering medicine prices, which makes only a few big companies control the market. This leads to shortages of important medicines and makes us rely too much on certain types of medicine. This makes it harder for pharmacists to find alternative medicines for patients(IMT, 2023).

1.1 STUDY PURPOSE

The research study titled " Drug Shortage in Ireland: An In-depth Analysis of Current Situation, causing factors, Impact and Future Recommendations " aims to thoroughly investigate the issue of drug shortages in the Irish healthcare system. By examining the current state, the study aims to uncover the reasons behind these shortages, whether they're due to regulations, supply chain issues, or other systemic problems. Additionally, the research seeks to understand how these shortages affect patients, healthcare professionals, and the overall healthcare system. Through careful analysis, the study plans to provide practical insights and evidence-based suggestions to reduce the impact of drug shortages in Ireland. The goal is to ensure that people can still access the medications they need and improve how healthcare is delivered. Ultimately, the study hopes to inform policies and practices that strengthen the Irish healthcare system's ability to handle challenges in drug supply.

1.2 SIGNIFICANCE OF STUDY

Solving medicine shortages is really important for many reasons. It keeps patients safe and healthy by making sure they have the medicines they need on time. It ensures that people can get the medicines they need to manage their illnesses and feel better. Third, it helps prevent big health problems in communities by making sure vaccines and antibiotics are available. Solving medicine shortage helps hospitals and doctors work more efficiently, saving time and money. It stops people from spending too much money on alternative treatments. Lastly, it keeps the drug-making companies stable and able to keep making medicines for everyone who needs them. Overall, fixing medicine shortages helps keep everyone healthy, saves money, and keeps the healthcare system working well.

The research aims to understand why there aren't enough medicines sometimes and how it affects healthcare and drug companies. Firstly, it wants to find out why there are shortages of medicines, so that people who make decisions about healthcare can figure out how to fix it. Secondly, it looks at how these shortages affect both the healthcare system and the companies that make medicines, which helps us see how it affects patients and the economy. Thirdly, it finds out where the current plans to deal with shortages are lacking, so that decision-makers can make them better. Lastly, it suggests new ideas and plans to handle shortages better. Overall, this study helps us understand medicine shortages and gives ideas to make sure everyone can get the medicines they need, making healthcare stronger and more prepared.

1.3 RESEARCH QUESTIONS

1. What are the primary root causes of medicine shortages in Ireland?
2. How do drug shortages impact both the healthcare sector and pharmaceutical industries?
3. What gaps exist in the current approach to managing and preventing medicine shortages in Ireland?
4. What recommendations and strategies can be proposed for mitigating medicine shortages in Ireland, considering both short-term measures and long-term sustainable solutions?

1.4 RESEARCH OBJECTIVES

1. Investigate the root causes of medicine shortages in Ireland.
2. Assess the impact of drug shortage on healthcare sector and pharmaceutical industries.
3. Identify gaps and areas for improvement in the current approach towards managing and Preventing shortages.
4. Propose future recommendations and strategies for mitigating medicine shortages.

1.6 STRUCTURE OF THE STUDY

This dissertation titled " Drug Shortage in Ireland: An In-depth Analysis of Current Situation, causing factors, Impact and Future Recommendations" is organized into five chapters as outlined below:

Chapter 1: Introduction

This section introduces the chosen topic, outlining its main objectives and significance. It explains the purpose of the study and its relevance in contemporary context.

Chapter 2: Literature Review

Here, a thorough investigation is conducted into previously published articles related to the research subject. The information is organized under different headings based on the research objectives. This review enhances understanding of the research questions and identifies any gaps for further investigation.

Chapter 3: Methodology and Research Design

This chapter offers a thorough explanation of the process used to conduct the study, including the underlying philosophical principles that influenced the research. It discusses various elements such as the size of the sample group, the methods employed to gather data, the techniques used to analyse the data, and the conceptual framework that formed the basis of the study's design and interpretation.

Chapter 4: Discussion and Analysis

This chapter being referred to discusses the data collected from research. It utilizes visual aids such as graphs and tables to present the data. The findings are then analysed and interpreted, offering clear explanations for each research question and addressing all relevant aspects. Essentially, it suggests that the chapter thoroughly examines the research data, providing comprehensive explanations and insights.

Chapter 5: Conclusion and Recommendations

This section primarily focuses on summarizing the research results and drawing conclusions. It also addresses the limitations of the study and provides recommendations for future research in this area.

CHAPTER 2: LITERATURE REVIEW

2.0 OVERVIEW

The World Health Organization (WHO) (Fox *et al.*, 2014) considers drug shortages a significant global health issue, attributing them to factors like raw material shortages, regulatory influences, manufacturing difficulties, increased demands. The American Society of Health System Pharmacists (ASHP) (ASHP, 2020) reports that there are hundreds of active drug shortages each year. The COVID-19 pandemic has worsened these problems due to increased demand and supply-side challenges. Drug shortages have significant financial, logistical, and ethical consequences, costing millions of dollars each year due to expenses related to labour, alternative medications, and grey market distribution. Grey market distribution, also known as parallel importation or trading, is when genuine products are imported and sold through unauthorized channels. While the products may be the same, this can cause problems for manufacturers, authorized distributors, and consumers. Manufacturers may lose control over pricing and quality, consumers may face issues with warranties or services, and authorized distributors may see a negative impact on their profitability. Such events pose risks of medication errors and adverse patient outcomes(Chen *et al.*, 2021).

Drug shortages can have serious consequences for patients, leading to treatment delays, substitution with less effective medications, or even the inability to receive necessary treatment altogether. This can prolong suffering, worsen disease progression, and increase the likelihood of other health problems. For example, if a preferred medication isn't available, patients may have to settle for less effective alternatives, potentially compromising their care. A significant number of hospitals have had to alter patient care or delay therapy due to these shortages, highlighting the widespread impact. According to a survey conducted by the Institute for Safe Medication Practices (ISMP) (ISMP, 2018), a majority of pharmacy professionals have experienced difficulties providing recommended treatments due to shortages, with many patients consequently receiving fewer effective medications or experiencing delays in their treatment. Such shortages can also lead to increased pain or discomfort during medical procedures due to the unavailability of necessary drugs. Overall, drug shortages pose significant risks to patient well-being and health outcomes(Research, 2020).

2.1 WHY ARE BASIC MEDICINES SCARCE IN PHARMA-RICH IRELAND?

The pharmaceutical industry in Ireland has made significant progress, moving up the value chain from synthesizing pharmaceutical ingredients to manufacturing advanced therapeutics. The country has established itself as a global hub for biopharmaceutical manufacturing, known

for operational excellence, compliance, and supply security. In the last five years, there has been a notable increase in approvals for advanced therapeutics and vaccines, such as cell-based and gene-based therapies. This emerging category is expected to drive future growth in the biopharmaceutical sector, with estimated global revenues ranging from \$10 billion to \$60 billion by 2026(Irish Times, 2023). Ireland sees additional opportunities in advancing towards drug discovery and development, making use of its strong research capabilities in various fields, including biotechnologies, microbiome science, advanced materials, drug delivery, data analytics, and modelling (Irish Times, 2023).

People in Ireland might be curious about why many basic medicines are not available, despite the country having many pharmaceutical companies. In Ireland, a significant shortage of over 200 medicines, including over-the-counter treatments for respiratory illnesses and bacterial infections, has been reported. The Medicine Shortage Index reveals a lack of essential items such as cough syrups, sore throat sprays, dissolvable paracetamol powder, and soluble aspirin(Ryan, 2023). The shortage is exacerbated by the surge in Covid-19, respiratory syncytial virus (RSV), and flu cases. Medicines for various health issues, including respiratory and bacterial infections, strep throat, pneumonia, pain relief, and blood pressure, are affected. Common antibiotics like Amoxicillin and Penicillin, along with Cefalexin for respiratory infections, are currently unavailable from any source. The scarcity of Clarithromycin, crucial for strep throat and pneumonia, adds pressure as the major suppliers are out of stock. The index highlights that 40% of the unavailable medicines have only one supplier, leaving pharmacists with limited alternatives. Experts caution that Ireland's shortage level exceeds the EU average, and 11 critical medicines listed by the World Medical Organisation are among the affected drugs(Ryan, 2023).

2.2 MEDICINES SHORT SUPPLY IN IRELAND: HPRA REPORT ANALYSIS

In Ireland, the Health Products Regulatory Authority (HPRA) maintains a list of over 300 medicine shortages. Recognized as a global problem by the World Health Organization, medicine shortages result from a complex interplay of causes. The supply chain relies heavily on a few countries for key ingredients, posing risks to stability. The International Pharmaceutical Federation proposed recommendations in 2020(FIP, 2020), emphasizing transparency, global collaboration, active procurement, regulatory consistency, and evidence-based risk mitigation.

The HPRA acknowledges that medicine shortages have diverse causes, including manufacturing delays, quality issues, and unexpected demand. The HPRA oversees a

framework involving various stakeholders to prevent and mitigate shortages, including industry participants, healthcare professionals, and patient groups. In conclusion, the complex pharmaceutical supply chain necessitates ongoing efforts to enhance visibility, collaboration, and resilience. Encouraging the production of generics, investing in research and development, and embracing artificial intelligence are crucial for providing access to medicines globally.

Shortages are not unique to the UK and Ireland, as a European survey (Boffey, 2024), reveals 95% of hospital pharmacists across Europe are experiencing the same issue. Factors contributing to the problem include the impact of the war in Ukraine, regulatory challenges post-Brexit, and the declining value of the pound. The continuous geopolitical tensions, such as the ongoing war in Ukraine, have the potential to interfere with or disturb supply chains. In this specific case, the war in Ukraine is cited as an example, explaining that it has impacted the accessibility of essential medicines in certain areas or regions. The idea is that conflicts and geopolitical issues can have a direct impact on the smooth functioning of supply chains, affecting the distribution and availability of important goods, including critical medicines (Boffey, 2024).

In European law, pharmaceutical companies and wholesalers are obligated to guarantee a consistent and adequate supply of the medicines they market. Specifically in Ireland, these entities must notify the Health Products Regulatory Authority (HPRA) of any shortages or potential shortages affecting the market. The HPRA, in turn, publishes and updates a comprehensive list of medicines in short supply, aiming to keep both patients and healthcare professionals well-informed about ongoing and resolved shortages. Acknowledging the challenges posed by medicine shortages, the HPRA emphasizes that many medicines in Ireland have multiple variations, such as different strengths, forms, pack sizes, or brands from various suppliers. In the event of an unavailable medicine, healthcare providers can often offer alternative options to ensure the uninterrupted continuity of treatment. Additional resources are provided by the HPRA to guide patients and healthcare professionals in preventing, managing, and reporting shortages effectively (HPRA, 2023b).

Few shortage medicines from HPRa medicine shortage list 2023 are given below: -

Product name	Active ingredient	Therapeutic alternative	Reason	Date of shortage	Expected return date	Additional information	Last updated
Rasilez 300mg Film-coated tablet EU/1/07/405/032 Noden Pharma DAC	Aliskiren	Similar alternative medicine authorised	Manufacturing Issues	2024/01/19	2025/01/31		2024/02/28
Abilify 7.5mg/ml Solution for Injection EU/1/04/276/036 Otsuka Pharmaceutical Netherlands B.V	Aripiprazole	Appropriate alternative medicine authorised	Quality issue (multiple countries affected)	2024/02/27	2024/03/20		2024/02/13
Abstral 200 microgram sublingual tablets PA2288/004/003 Kyowa Kirin Holdings B.V.	Fentanyl	Similar alternative medicine authorised	Unexpected increase in demand	2024/03/03	2024/03/29		2024/02/26
Aciclovir 25mg/ml Concentrate for Solution for Infusion PA0822/215/001 Pfizer Healthcare Ireland	Aciclovir	Appropriate alternative medicine authorised	Unexpected increase in demand	2023/12/08	2024/02/29	HCP letter	2023/12/22
Aciclovir Azevedos 250mg Powder for Solution for Infusion PA1852/003/001 Laboratórios Azevedos - Indústria Farmacêutica S.A	Aciclovir	Appropriate alternative medicine authorised	Regulatory Issues	2024/01/09	2024/02/29		2024/01/12
Actilyse Cathflo 2mg Powder for Solution for Injection and Infusion PA0775/011/004 Boehringer Ingelheim International GmbH	Alteplase	Similar alternative medicine authorised	Unexpected increase in demand (multiple countries affected)	2023/09/13	2024/07/30		2024/02/06
Actos 30 mg Tablet EU/1/00/150/004 CHEPLAPHARM Arzneimittel GmbH	Pioglitazone	Appropriate alternative medicine authorised	Unexpected increase in demand	2023/12/04	2023/02/28		2024/02/14

Figure 1: HPRa medicine shortage list 2023, Ireland.

2.4 MEDICATION SHORTAGES PROMPT DISPENSING OF UNLICENSED DRUGS

The pharmacists in Ireland are facing a growing problem of medication shortages, leading to an increase in the dispensing of unlicensed medicines known as Exempt Medicinal Products (EMPs). Exempt Medicinal Products (EMPs) are pharmaceuticals that can be legally supplied without the need for marketing authorization in certain situations, varying by country. They're used for unique medical needs, such as unlicensed medicines for individual patients, manufacturing specials tailored to specific patients, emergency use during health crises, medications used in clinical trials, and as temporary measures during shortages of licensed medicines to ensure continued patient treatment. These exemptions are granted under specific regulatory frameworks and conditions to balance patient needs with safety considerations. These EMPs are not authorized in Ireland but can be prescribed to meet special patient needs. However, there are concerns about their safety, as some have been recalled due to potential harm to patients (Shauna Bowers, 2023). Despite this, pharmacists report a rise in the use of EMPs due to shortages of licensed medicines. There's also worry about EMPs sourced from the EU, as they pose higher risks due to unfamiliar language and packaging (Shauna Bowers, 2023). The Department of Health states that while EMPs can be supplied, they are not assessed for quality, safety, or efficacy by regulatory authorities. Meanwhile, there are plans to extend prescription validity to help address medication supply issues.

In 2022, Ireland spent around €25 million on unlicensed exempt medicinal products, which are medications not officially approved but allowed in certain cases. This is €7 million more than what was budgeted for innovative high-priced medicines in 2023, which was only €18 million (Irish Times, 2023). It's estimated that over three million packs of these unlicensed medicines were given out in Ireland last year. Most of them were used because licensed medicines weren't available. While it's important to have these unlicensed medicines available when needed, they should only be used in special cases, not as a regular solution (The Irish Times, 2023)

The regulatory framework for EMPs is designed to balance patient safety with the need for access to essential medicines in situations where licensed alternatives are not available. Healthcare providers and pharmacists usually follow strict guidelines when prescribing or dispensing EMPs to ensure that their use is justified and monitored appropriately.

2.5 CAUSE OF MEDICINE SHORTAGE.

The shortage of medicines is a complex issue influenced by various factors that can impact the availability of essential drugs. One primary cause is the disruption in the supply chain, often due to manufacturing issues, natural disasters, or geopolitical conflicts in regions where

pharmaceuticals are produced. Additionally, increased demand for certain medications, such as during a pandemic, can strain the supply chain and lead to shortages. Regulatory challenges, like delays in approvals or changes in production standards, can also contribute to the problem. Understanding the causes behind medicine shortages is crucial for developing effective strategies to ensure a consistent and reliable supply of essential medications.

2.5.1 DISTRIBUTION PROBLEMS

Supply chain issues can have a significant impact on drug shortages. The pharmaceutical supply chain is a complex network that involves the production, distribution, and delivery of drugs to healthcare providers and ultimately to patients. Various factors within this chain can contribute to shortages when disrupted. Here are some ways in which supply chain issues can affect drug shortages. That includes manufacturing issues, unavailability of raw materials, business issues and logistical problems within the supply chain (Shukar *et al.*, 2021).

2.5.2 MANUFACTURING ISSUES

More than 60% of medicine shortages in Europe are attributed to manufacturing problems, according to the European Healthcare Distribution Association (GIRP) (Clews, 2019). The GIRP expressed concern over the intolerable impact on patients and proposed solutions, including holding buffer stocks of essential medicines in all EU countries. The association ruled out using the European Medicines Verification System (EMVS) for monitoring shortages. The Department of Health and Social Care in the UK has banned 32 medicines from parallel export to address shortages (Clews, 2019). The GIRP advocates for national buffer stocks, an early warning system, and acknowledges the need for significant investment to use the EMVS effectively. Martin Sawyer from the Healthcare Distribution Association emphasizes the importance of all parts of the drug supply chain providing information on shortages. Additionally, it was reported that half of safety warnings issued by drug regulators in Europe and the United States are directed at manufacturers in India and China due to the concentration of pharmaceutical production in these countries.

Manufacturing issues encompass quality problems and competing priorities. Drug shortages happen for various reasons. One major cause is problems with the quality of manufacturing. Delays in making drugs can also occur if companies face issues getting raw materials from suppliers. Sometimes, drug shortages happen because companies decide to stop making certain drugs. The FDA can't force a company to keep making a drug it wants to discontinue. This is common when companies choose to stop older drugs to focus on newer and more profitable ones. For example, drugs like Total Parental Nutrition products, which are older sterile

injectables, face shortages because only a few companies make them, and there are limitations in production capacity(Research, 2023). When one company has an issue or stops making the drug, it's hard for others to increase production quickly, leading to shortages.

2.5.3 INSUFFICIENT GENERICS

Manufacturers may hesitate to invest in or produce medicines with low profitability, like generic drugs and injectables, because these products compete for resources such as raw materials, manufacturing lines, and markets. The stricter quality requirements for manufacturing generics and injectables further reduce the motivation for production, as seen in the in Brazil for injectables(Acosta *et al.*, 2019).

2.5.4 UNAVAILABILITY OF RAW MATERIALS

Shortages of medicines can happen when there's a problem in getting the raw materials needed to make them. These materials include active ingredients, additives, and packaging items. Countries like India and China are major suppliers of these materials. Reasons for shortages can include political issues, conflicts, diseases in animals, trade problems, environmental issues, damage during transport, or low production from source countries. Having only one supplier for the materials of a medicine can led to shortages if there's a problem with that supplier. So, it's usually better to have at least three suppliers for the materials (Fink, 2023)

2.5.5 ECONOMIC FACTORS

Problems in the pharmaceutical business can cause a shortage of medicines. Economic Factors like low profit margin, having a small market, and needing costly upgrades in facilities make it difficult for companies. In wealthy countries, there's often a shortage of generic drugs because they are sold at low prices, and companies struggle to compete while maintaining quality. Some companies leave the market, closing their plants. Following quality regulations is also expensive for generic drug makers. If factories aren't properly maintained, production becomes less efficient. When companies join together, it limits the flexibility in delivering drugs, increasing the chance of shortages (Emmett, 2019). Drugs with small markets, like rare ones, are more likely to run out because companies may not want to produce them. In less wealthy countries, problems in the process of buying drugs, like delays and poor coordination, lead to higher costs and financial problems.

2.5.6 LOGISTIC ISSUES

Logistic issues, including transportation problems and supply chain management incompetency, can also contribute to drug shortages. Transportation problems, encompassing bad weather, traffic delays, and natural disasters, pose significant threats to the pharmaceutical

supply chain. This intricate process involves manufacturing, packaging, and distributing drugs to various destinations, such as hospitals and pharmacies. Severe weather conditions, like storms and heavy snowfall, render roads and ports inaccessible, disrupting timely deliveries. Traffic delays caused by accidents or congestion can lead to breakdowns in supply chain schedules. Natural disasters, such as earthquakes or floods, devastate infrastructure, impeding the movement of pharmaceuticals. In the pharmaceutical industry, where timely delivery is paramount for patient care, these disruptions can result in shortages, jeopardizing patient outcomes and potentially risking lives (Shukar *et al.*, 2021).

2.5.7 INCREASED DEMAND ISSUES

Demand issues, such as increased marketing, and unpredictable events like outbreaks or natural disasters, play a role in exacerbating drug shortages. The issues affecting medication supply are diverse, encompassing both predictable and unpredictable factors. Just-in-time inventory, a common cost-saving strategy, involves purchasing drugs based on immediate needs without maintaining backup stock, leading to a higher risk of shortages, particularly in high-income countries. Increased marketing efforts, whether predictable or not, can create a demand surge, with unethical practices in low-income countries exacerbating the problem (Emmett, 2019). Unforeseen events like outbreaks, disasters, and accidents can cause an abrupt spike in demand, disrupting the drug supply chain due to longer manufacturing lead times and complexities. Seasonal fluctuations in demand for specific medicines, such as those for respiratory conditions during winter, pose another risk. Additionally, in low and middle-income countries, factors like irrational drug use, lack of patient education, and prescription adherence contribute to wastage and increased demand. The tendering system, specifically in the United States and EU, has also led to drug shortages, as awarding tenders to a single supplier and low pricing forced some manufacturers out of the market, reducing competition and causing price hikes. Addressing these multifaceted issues is crucial for ensuring a stable and reliable drug supply chain (Shukar *et al.*, 2021).

2.5.8 REGULATORY CHALLENGES

Regulatory causes, stemming from inflexible processes, lack of policies, and poor communication among stakeholders, contribute to drug shortages, with safety and efficacy standards sometimes hindering new manufacturers' entry into the market. Overall, these supply issues have profound impacts on the healthcare system and public health (Shukar *et al.*, 2021). After a drug is approved by the FDA and is on the market, if a manufacturer wants to increase production using different suppliers or manufacturing sites, they have to get approval from the

FDA again. Many drug companies that supply the US also supply other places worldwide. Making changes to how drugs are made usually means getting approval from regulators in all those places. This can take a long time because each country has its own rules, and they don't review changes at the same time. So, drug companies often have to keep running the old way until everyone agrees to the new way, which can make it hard to upgrade equipment and prevent shortages.

If there's a shortage of a drug, getting approval to make more of it can be slow and expensive. It might cost millions of dollars and take several years to get approval from the FDA (Research, 2020). Sometimes, if a shortage is serious, the FDA can speed up the approval process for certain applications. However, the task force doesn't think that the speed or cost of getting approval is the main reason for shortages. They found that many approved drugs aren't actually being sold, and this could be because drug companies choose not to sell them. Shortages are mainly caused by decisions made by drug companies and others involved in the supply chain, influenced by FDA rules and reimbursement policies from programs like Medicare and Medicaid (Research, 2020).

2.6 DRUG AVAILABILITY: LONG TERM IMPACT OF COVID 19

In late 2019, a new strain of coronavirus, known as SARS-CoV-2, emerged, causing a severe respiratory illness termed COVID-19, leading to a global pandemic. In response, countries implemented measures to reduce the strain on healthcare systems, including restricting international trade (Badreldin and Atallah, 2021). However, these actions might be giving rise to another issue: global drug shortages. During events like COVID-19 pandemic, there were global shortages of raw materials for making medicines. Countries that usually supply these materials, like India and China, stopped providing them to others, causing a worldwide shortage. The pandemic also brought challenges like a lack of packaging materials, transportation issues, delayed shipping, and restrictions on importing and exporting medicines.

The COVID-19 pandemic, alongside unprecedented global economic disruptions, raises concerns about prolonged and severe impacts on the global drug supply, potentially affecting patient care. Delays in approvals for non-COVID pharmaceutical products are occurring worldwide as countries prioritize pandemic response, impacting decision-making processes and exacerbating delays, particularly evident in Iran due to economic challenges and regulatory agency closures (Ayati *et al.*, 2020). Additionally, reliance on India and China for essential pharmaceutical ingredients and generics has prompted worries about shortages during crises, leading governments to consider self-sufficiency measures and implement regulations to

safeguard pharmaceutical production (Thacker, 2020). For instance, the European Commission's guidelines on foreign investments in the health market aim to assess risks and prevent negative impacts on the EU's healthcare capabilities (FDI screening regulations, 2020).

The pharmaceutical industry faces potential growth slowdowns due to global economic downturns, particularly affecting emerging markets sensitive to economic fluctuations. Companies are reassessing and reprioritizing their portfolios amid ongoing economic challenges, leading to cautious strategic decisions and potentially hindering industry growth. Additionally, ethical concerns arise from increased clinical research during the pandemic, potentially resulting in the use of treatments without sufficient evidence of effectiveness, known as off-label use. To address this, healthcare providers are advised to exercise caution, thoroughly assessing potential long-term effects and making informed decisions based on robust evidence to ensure the safety and efficacy of medical interventions in clinical practice. (Shojaei and Salari, 2020).

The shift in consumption towards health-related products, influenced by telemedicine and changing habits, impacts drug shortages in several ways. Fluctuations in demand due to stockpiling and specific product demands can disrupt the supply chain. Forecasting challenges for pharmaceutical companies may affect production, leading to shortages. Regulatory adjustments might be needed to adapt to telemedicine and new consumption habits, affecting drug approval and supply chain regulations. Telemedicine could alter prescription distribution, while changing consumption trends may pose logistical hurdles in drug distribution efficiency. (Ayati et al., 2020).

2.7 IMPACTS OF MEDICINE SHORTAGE

2.7.1 IMPACT ON PATIENTS

Impact on Patients, shortages of essential medicines have serious consequences for patients. Treatment delays or cancellations are common when the necessary drugs are unavailable. Patients may receive less effective substitute medications, leading to substandard care. Medication shortages can have serious consequences for patients, affecting not only their health but also the healthcare system as a whole. It highlights that shortages impose financial burdens on the healthcare system, disrupt patient care, and result in dissatisfaction among patients. These shortages also contribute to increased out-of-pocket costs for patients and, most concerning, can lead to adverse events such as mortality, changes in treatment plans, suboptimal treatment, and medication errors (Phuong *et al.*, 2019). Patient safety is compromised due to the need for substitute drugs, potentially causing errors or unexpected side

effects. In some cases, deaths have been linked to drug shortages, emphasizing the life-threatening nature of the issue.

2.7.2 IMPACT ON ECONOMY

Economic Impact, Drug shortages result in increased costs for various stakeholders, particularly patients, across different economic levels. High-income countries are aware of shortages, and suppliers cope with raw material unavailability through additional operations. Retailers purchase short-supplied drugs at higher prices, hospitals incur extra costs managing shortages, and studies estimate significant expenses in the United States due to drug shortages (Phuong *et al.*, 2019). Medicine prices increase, especially for generics, leading to illegal practices in the grey market, where drugs are stocked in advance and sold at higher prices during shortages. This results in higher out-of-pocket costs for patients, who may resort to online purchasing from illegitimate vendors. Low and middle-income countries experience increased out-of-pocket expenses as the economic impact of drug shortages (Acosta *et al.*, 2019).

In high-income countries, healthcare systems vary, with some adopting models that relieve patients from out-of-pocket costs. However, in middle and low-income countries, the Out-of-Pocket Model prevails, burdening patients. Importing medicines during shortages can burden governments, especially in the EU where import/export criteria are not harmonized. Different countries have varying policies on importing and exporting medicines during shortages, leading to potential threats to medicine availability and severe economic impacts due to uncontrolled drug movements (Shukar *et al.*, 2021).

2.7.3 IMPACT ON MEDICAL CARE

doctors say that when they can't get the medicine, they want to use for treating patients, it can lead to problems. They might have to say no to some treatments or make patients wait. Sometimes, they may have to use other medicines that they think might not be as safe or effective. This is a big issue, especially for certain medical specialties like cancer treatment, anaesthesia, and emergency care. If the shortage of medicines continues for a long time, it could harm the quality of medical care. New doctors and healthcare workers who are trained when the preferred medicines are not available may not learn the best ways to treat patients (Research, 2020).

2.7.4 IMPACT ON HEALTHCARE PROVIDERS

Healthcare providers, including pharmacologists, pharmacists, and physicians, face challenges dealing with dwindling drug supplies. They spend additional time searching for alternatives

and assisting in the selection of substitute medications. Physicians must redirect their therapeutic efforts, leading to increased workload and challenges in providing optimal care (Shukar et al., 2021).

2.7.5 IMPACT ON HOSPITALS

Hospitals are facing challenges coping with drug shortages, leading to potential impacts on patient care. To manage shortages, hospitals may divert staff or hire additional personnel, increasing costs. Shortages require adjustments to electronic health records, IT systems, repackaging medications, and revising treatment protocols. When low-cost generic drugs are scarce, hospitals may incur higher expenses for alternatives. Additionally, obtaining medications from less-regulated sources like compounding facilities or the gray market poses risks. The Gray market refers to the distribution channels that lack authorization from manufacturers of prescription drugs. The Gray market exploits shortages by charging high prices for scarce drugs, prompting concerns and a call for further investigation (Research, 2020).

2.7.6 IMPACT ON RESEARCH

The shortage of chemotherapy drugs, vital for cancer treatment, is disrupting ongoing clinical trials. Almost half of all cancer trials are affected, hindering the determination of treatment efficacy and leaving future directions in cancer research uncertain. Lives are at stake as research trials are suspended, leading to both a loss of data and clinical evidence (Badreldin and Atallah, 2021).

2.8 SHORT TERM AND LONG-TERM SOLUTIONS FOR DRUG SHORTAGE

Managing drug shortages is critical for patient safety and healthcare access, with challenges varying depending on the medication and associated conditions. Immediate short-term strategies, alongside long-term planning, are vital. In hospitals, steps include informing doctors, suggesting alternatives, reaching out to suppliers, investigating supply restoration, considering medication substitution, and updating approved medication lists. Community pharmacies employ similar tactics, managing current supplies, contacting suppliers and other pharmacies, and suggesting alternatives (Shukar *et al.*, 2021). Strategies for optimizing available resources include stock restrictions involve imposing limits on medication usage to prioritize patients or conditions with urgent needs. Secondly, prioritizing patients through frameworks like A4R ensures fair allocation based on criteria such as Availability, Accessibility, Affordability, and Acceptability. Thirdly, utilizing products with minor defects enables the maximization of available resources by safely using medications that have minor

flaws. Fourthly, extending expiry dates involves rigorous testing to prolong the usability of medications nearing expiration, thereby extending their utility. Additionally, redistributing stock equitably ensures fair distribution among regions or institutions facing shortages. Establishing expert platforms facilitates proactive management by providing up-to-date information and reviewing alternatives, while minimizing wastage involves implementing measures to reduce medication waste, ultimately prioritizing patient care while optimizing resource allocation. These multifaceted approaches ensure efficient management, emphasizing patient safety and resource optimization(Panic *et al.*, 2020).

The reimagining the national stockpile of essential medications, advocating for a 3–6-month buffer maintained by the private sector or wholesalers to combat shortages effectively. This approach involves rotating inventory to prevent expiration and respond to demand surges or manufacturing issues swiftly. Emphasizing the negative impact of medicine shortages on patient care, concrete actions are urged over mere discussion. Collaboration among the pharmaceutical industry, supply chain partners, and government bodies is crucial. Utilizing data from national repositories, as per the Falsified Medicines Directive, offers insights into shortage causes. Combining this data with other sources could provide a clearer understanding. A practical example demonstrates how such data could be employed to prevent and manage shortages through coordinated efforts. Overall, proactive measures are deemed necessary to ensure uninterrupted access to medicines for patients(Bouvy and Rotaru, 2021).

Ireland plays a crucial role in global pharmaceutical supply, boasting major industry players like Novartis, Pfizer, and more. There is no quick fix or magic solution to providing access to medicines for all. However, ensuring access to medicines for all involves complex challenges. To address this, stakeholders must enhance supply chain visibility, foster collaboration, and embrace AI while encouraging generic production and R&D investment(Allen, 2023).

The Health Products Regulatory Authority (HPRA) in Ireland operates a comprehensive framework to prevent and manage human medicine shortages. It involves various stakeholders like manufacturers, distributors, and healthcare professionals, coordinated by HPRA. This framework focuses on early detection, communication, and prevention of shortages, excluding commercial aspects. HPRA's efforts aim to maintain a robust system for managing medicine shortages in Ireland(HPRA, 2023b; HPRA, 2023a).

Allocation models are frameworks used to distribute limited medical resources among pharmacies based on specific criteria. However, this system can lead to shortages and

misunderstandings when pharmacies run out of medications, as allocations may not always match actual needs. Challenges include inadequate supplies, communication gaps, and logistical difficulties in adjusting allocations to meet changing demand patterns. Understanding this model is crucial for effectively managing resources and improving communication about distribution constraints. Clear communication and efforts to find solutions are essential, especially for patients who are not regular medication users. For established patients with long-term treatment needs, pharmacists should minimize disruptions, even if it requires contacting the doctor in advance for alternatives (IPU, 2023).

The regulatory framework for Essential Prescription Medications (EPMs) refer to pharmaceutical products that are not required to have a marketing authorization and it aims to balance patient safety with access to necessary medicines when licensed alternatives are unavailable. Healthcare providers and pharmacists adhere to strict guidelines to justify and monitor the use of EPMs appropriately. Vulnerabilities in the global supply chain, intensified by geopolitical tensions, natural disasters, or pandemics, can disrupt medicine availability. Strategies like diversifying sourcing locations, establishing backup plans, and promoting domestic manufacturing can enhance supply chain resilience and mitigate these risks (IPU, 2023).

2.9 POLICY REFORMS TO ENHANCE DRUG AVAILABILITY.

The current procurement practices might prioritize cost-saving strategies, which could inadvertently limit the variety of suppliers a company works with. This could result in relying heavily on a small number of suppliers or even a single one. While this might save money in the short term, it can make the company vulnerable to disruptions, such as shortages in supplies if that sole or limited supplier encounters issues.

The recommendation is to adjust procurement processes to prioritize two factors: supplier resilience and diversity. By doing so, a company could reduce its vulnerability to shortages and other risks. Resilient suppliers are those who are able to withstand challenges and disruptions, while diversity in suppliers ensures that the company isn't overly reliant on any one source, thereby spreading out risk. Adjusting procurement processes to prioritize these aspects would involve seeking out a broader range of suppliers and evaluating them not just based on cost, but also on their ability to provide consistent supply and withstand disruptions (HPRA, 2023a).

The time-consuming nature of regulatory approval processes for new medications or for approving alternative suppliers of existing medications. These lengthy processes can result in

delays in accessing important drugs, which can be critical for patients in need. The suggestion here is to streamline these regulatory approval processes or to create expedited pathways specifically for essential medications. It refers to making the procedures for approving new medications or alternative suppliers more efficient and less time-consuming.

Implementing policies to promote generic competition or expedite the introduction of biosimilars could help increase the resilience of the medication supply. By fostering competition and facilitating the availability of cheaper alternatives, such policies could help mitigate issues related to medication shortages and affordability and revising reference pricing mechanisms to prioritize medicines with stable supplies or to incentivize the availability of alternatives could help mitigate shortages by encouraging the use of more readily available medications(IPU, 2023).

2.10 CONCLUSION

In summary, this literature review dives deep into the problem of medicine shortages in Ireland. It examines why these shortages happen, how they affect healthcare and pharmaceutical industries, and what methods are currently used to manage them. By looking at lots of different studies and reports, we found areas where the current strategies could be better. To tackle this issue, we need strong plans that deal with both short-term fixes and long-term solutions. Collaboration between healthcare providers, drug companies, regulators, and policymakers are crucial. This dissertation aims to help by suggesting practical ideas and strategies based on evidence to make sure everyone in Ireland can get the medicine they need.

CHAPTER 3: RESEARCH METHODOLOGY

3.0 OVERVIEW

Research methodology refers to a structured approach for tackling a problem. It involves the systematic study of how research is conducted, encompassing the methods used by researchers to describe, explain, and predict phenomena. Research methodology is also the examination of the techniques employed to acquire knowledge. Its primary objective is to outline the strategy for conducting research. Research methods try to solve research problems, while research methodology focuses on using the right steps to find those solutions(Goundar, 2012).

The main purpose of this study is to analysis the root causes, assess the impacts on healthcare, and propose recommendations for mitigating the current drug shortage while providing insights for future improvements in the pharmaceutical supply system. This chapter is all about explaining how the research was done. It goes into detail about why certain methods were chosen and how data was collected, including what tools were used. It also talks about any ethical issues and problems that came up during the research, as well as any limitations that affected the study's results.

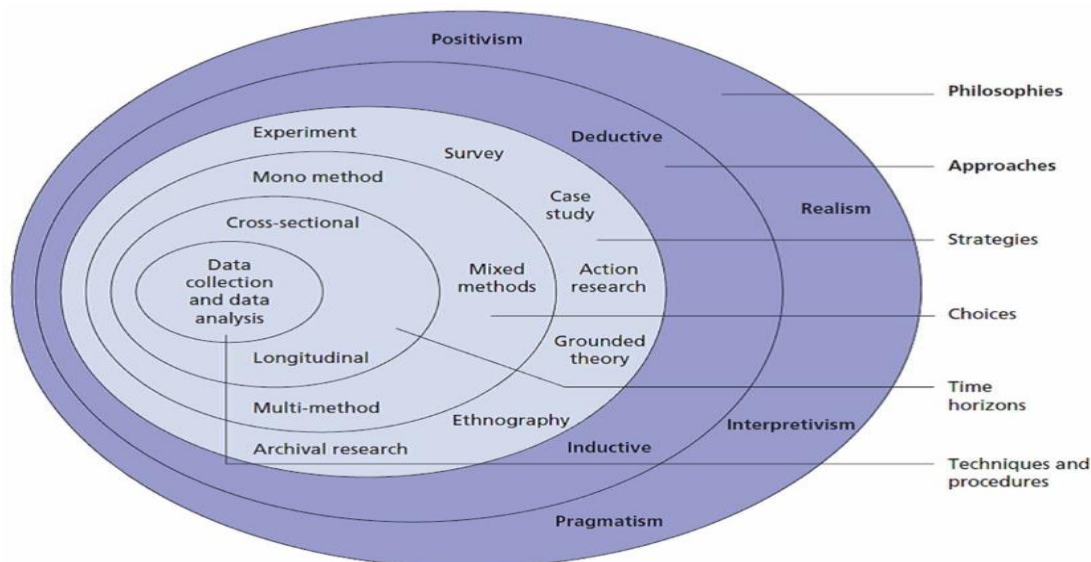


Figure 2: Research Onion (Saunders, 2009)

The research onion was like a roadmap for researchers, helping them navigate the complex journey of conducting research. Each layer represented a different aspect of the research process. Researcher first chose their research philosophy, deciding if they believed in an objective reality (positivism), understanding meanings (interpretivism), or a mix of both

(pragmatism). Researcher then picked a research approach, either starting with a theory (deductive) or observations (inductive). Next, they selected a research strategy, like case studies or surveys, followed by specific choices about data collection and sampling methods (Dissanayake, 2023). Researcher also considered the time horizon of the study and delved into practical techniques and procedures for data analysis. This onion helped to keep the research organized and thorough, ensuring that the choices were coherent, deep, and flexible to the needs. (Dissanayake, 2023).

PRIMARY DATA	DETAILS
Type of research design	Quantitative
Philosophy	Positivism
Approach	Deductive Approach
Strategy	Structured strategy- Survey
Choices	Mixed Methods -online survey includes both quantitative (e.g., multiple choice questions) and qualitative (e.g., open-ended questions) elements
Time Horizon	Cross – sectional
Techniques / tools & procedures	Online questionnaire- Microsoft form data collection and recorded phone call interview.
Participants	Retail /Clinical Pharmacists or Pharmacy Technician.

Table 1: Research Methodology Overview

3.1 RESEARCH PHILOSOPHY

The philosophical approach used in research was based on positivism on medicine shortage. The methodology philosophy employed in an online survey on medicine shortage typically aligns with quantitative research methods, utilizing a positivist approach. Positivism emphasizes objective data collection and statistical analysis to uncover patterns and trends within a defined population. The online survey would likely employ structured questionnaires with closed-ended questions and open ended questions allowing for efficient data collection and quantitative analysis of respondents' perceptions, experiences, and opinions regarding

medicine shortages (Alharahsheh and Pius, 2020). This approach facilitates the systematic examination of the prevalence, causes, and impacts of medicine shortages, enabling researchers to draw reliable conclusions and inform evidence-based interventions and policies to address this pressing issue in healthcare. The author has adopted a mixed-methods approach, that the online survey includes both quantitative (e.g., multiple choice questions) and qualitative (e.g., open-ended questions) elements (Alharahsheh and Pius, 2020).

3.2 RESEARCH DESIGN AND APPROACH

The research approach employed both deductive approaches to investigate the issue of drug shortages in Ireland. Drug shortages posed significant challenges to healthcare systems globally, and Ireland was no exception. The researcher starts with ideas and then checks if they're true using numbers. They ask lots of people questions through surveys to get data. This helps to see how big the medicine shortage is, find patterns, and understand how it affects people (Dissanayake, 2023). By doing this, the researcher wants to gather clear proof and understanding to help solve the problems caused by medicine shortages in healthcare. This study aimed to delve into the complexities surrounding drug shortages, incorporating a mixed methods research design to capture a multifaceted perspective in a cross-sectional timeline. The study utilized quantitative method strategies to gain a holistic understanding of the current situation, identify causing factors, assess the impact, and formulate future recommendations. The primary data collection methods that were research techniques included survey-based quantitative data, and in-depth qualitative insights.

A structured survey was distributed to healthcare professionals includes Pharmacy technicians, Retail pharmacists, clinical pharmacists, OTC pharmacy assistant across Ireland to gather quantitative data. Surveys such as list question surveys included closed-ended questions and open-ended questions to quantify the extent of the issue, categorize the types of drugs affected, and assess the economic impact on healthcare providers. All survey participants were told that any information collected during the research would be kept private and stored following the rules of the General Data Protection Regulation (GDPR). They had to answer a consent question before finishing the survey. Messages inviting individuals that clearly explained the purpose and importance of the research were composed. They clearly outlined how participants could contribute to the study through their Email, LinkedIn profiles.

3.3 TIME HORIZON

The time horizon in research is typically divided into two categories: cross-sectional and longitudinal. Cross-sectional studies involve a shorter time frame, limiting data collection and

analysis to a specific period. On the other hand, longitudinal studies entail observing subjects over an extended period(Goundar, 2012). In this research, a cross-sectional approach was chosen due to time constraints, allowing for data collection and analysis within a defined timeframe.

3.4 RESEARCH STRATEGY

The research strategy is outlined, focusing on evaluating the availability of medicines in Irish retail pharmacies. The aim was to identify any existing issues and propose improvements. The literature review highlighted drug shortage problems but lacked solutions tailored to Ireland's context. Importantly, all participants were informed about the purpose of the research, this suggests a collaborative approach and ensures transparency in the research process.

This research used both primary and secondary sources for collecting data, meaning they gathered information from different places. There are various methods for collecting data, like surveys, interviews, and experiments. In this study, they used surveys. Surveys focus on current events and use numbers to gather information, often in descriptive or exploratory research. The study used a quantitative approach, meaning it focused on numbers and measurements. These surveys have advantages like saving time and money, offering anonymity to participants, and being flexible. The open-ended questions in the survey allows for a deep exploration of people's experiences and perspectives, giving a fuller understanding of the topic.

3.5 RESEARCH TECHNIQUES /TOOLS AND PROCEDURES

Research techniques or tools are the different ways or tools researchers use to collect information during a study. They can be like surveys, interviews, experiments. Research procedures are the organized steps researchers follow when doing their study, from planning and collecting data to analysing and understanding it. These steps make sure the research is done properly and ethically, and that the results are trustworthy and meaningful.

The tool/technique that used in this research is online survey using Microsoft forms. The questionnaire was created using a Microsoft form and made easy and simple to answer by the author. The questionnaire was sent out to over 100 pharmacist participants/ pharmacy technician/OTC pharmacy assistants in Ireland.

	SURVEY
SAMPLE SIZE	100
PARTICIPATED	71

Table 2: Survey Sample Size.

3.6 SOURCES/PARTICIPANTS

The questionnaire was distributed via electronic devices and in person using platforms such as LinkedIn, Email, WhatsApp. The participants distributed to were Retail pharmacists/Clinical Pharmacy/Pharmacy technician/OTC pharmacy Assistant in Ireland. 71 pharmacists completed the survey.

Pharmacists are the ideal participants for the survey on drug shortages in Ireland due to their frontline experience in dispensing medications and managing inventory. Their expertise enables them to provide valuable insights into the causes, effects, and potential solutions to address drug shortages. Additionally, pharmacists' direct interaction with patients and healthcare providers positions them as key stakeholders in understanding the real-world impact of drug shortages on patient care.

Retail pharmacists primarily work in settings like drug stores or supermarkets, where they dispense medications prescribed by doctors and provide advice to customers on over-the-counter products. They ensure that prescriptions are filled accurately, counsel patients on medication usage, and may offer health screenings or immunizations. Clinical pharmacists, on the other hand, typically work in hospitals or healthcare facilities, collaborating with medical teams to optimize medication therapy for patients. They review prescriptions, monitor medication regimens, and provide specialized expertise in areas like oncology or critical care. Pharmacy technicians support pharmacists by preparing medications, managing inventory, and assisting with administrative tasks in both retail and clinical settings. They may also interact with customers, although their primary focus is on the behind-the-scenes work of pharmacy operations. OTC (over-the-counter) pharmacy assistants usually work in retail pharmacies, helping customers find non-prescription medications and providing information on their use. They may also handle cashier duties and assist with maintaining a clean and organized store environment. Each role plays a crucial part in ensuring safe and efficient medication management, but their responsibilities and areas of expertise vary based on the setting and scope of practice.

3.7 DATA COLLECTION

In this study, data collection involved both online questionnaires. The researcher utilized pie charts and bar charts to analyse the gathered data, aiming to reduce errors and biases for enhanced research reliability. The questionnaire comprised 14 multiple-choice queries, administered via Microsoft Forms, and the resulting data was transformed into visual representations for clarity. To ensure precision, we cross-referenced our findings with relevant literature. Systematic analysis of results, through categorization, draws meaningful conclusions. Integrating both primary and secondary data gives comprehensive understanding of our research outcomes.

3.8 QUANTITATIVE ANALYSIS

An online survey was conducted using Microsoft Forms and distributed to pharmacists via WhatsApp, email, and LinkedIn. The survey included both close-ended and open-ended questions. The questionnaire comprised five sections and a total of 14 questions, tailored for pharmacists and pharmacy technicians participating in the study. The introductory question was to give consent permitting the use of data obtained from the research after reading through the overview of the purpose and aim of the study. All participants via the survey were informed that all data obtained from the research are kept strictly confidential and stored in accordance with general data protection regulation (GDPR). The question to give consent was mandatory and had to be answered to complete the survey. Distribution of the questionnaires occurred electronically through various online platforms, with participants encouraged to complete the survey voluntarily.

Researchers can view and collect the responses from the Microsoft Forms site. A response result is well-published in the form. Research uses charts and Excel in Microsoft Word to analyse the collected response data and conducts the analysis under each section called cause analysis, impact analysis, gap analysis, and recommendation analysis. A pie chart is a circular graph that represents data by dividing the whole circle into smaller slices or sectors. Each slice corresponds to specific data, and the entire circle represents the total. It shows proportions or percentages of different categories within a whole, while a bar chart displays data using rectangular bars, either horizontally or vertically. Each bar represents an absolute value or proportion for a specific category.

Pie charts and bar charts give a visual presentation of the data, helping readers understand and evaluate the points that researchers are putting forward. The result summary from the survey

data, which includes primary research and data from secondary sources like literature reviews, is analysed and presented in the conclusion section of the paper.

Survey format	Question construction	Data Collection	Data visualization	Result representation
Online	Total 14 questions include, <ul style="list-style-type: none"> - Close end question – multiple choice - Ranking type - Open end question - descriptive sentences 	LinkedIn, emails, WhatsApp app	Pie charts, Bar charts tables	<ul style="list-style-type: none"> - Written summary - Tables - Figures
Tools			Tools	
Microsoft form			Excel, tableau, Microsoft word charts.	

Table 3: Quantitative Analysis Structure

3.9 ETHICAL CONSIDERATION

Ethical considerations in this research encompassed several key aspects such as obtaining informed consent, ensuring data protection and confidentiality, and addressing participant responses. It was crucial to transparently communicate the objective of the study to participants. Participants were informed that the research was a component of a master's degree program. The handling of sensitive data, including participant opinions and experiences, could potentially raise privacy and confidentiality concerns. Therefore, during data collection, efforts were made to avoid gathering sensitive or private information. All participants were told that any information collected during the research would be kept private and stored following the rules of the General Data Protection Regulation (GDPR). They had to answer a consent question before finishing the survey. The questionnaire design aligned with the study's goals and criteria, ensuring that it only requested necessary information without delving into overly personal details. This approach aimed to uphold ethical standards and prioritize the protection of participant privacy throughout the research process (Collis and Hussey, 2021).

3.10 CONCLUSION

The primary research involved a quantitative approach using questionnaires containing 14 questions and qualitative approach with 4 in-depth questions. The survey involved participants in the supply of medicines which were retail pharmacists/ pharmacy technicians. Interviews were carried out to further obtain qualitative results for the research. The data collected was organized and prepared to ensure there were no errors and all information was accurate and are

compared with secondary information to confirm causing factors of shortages and recommendation for improvement. Based on the data analysed, recommendations in relation to the research objectives is analysed.

CHAPTER 4: RESULT AND ANALYSIS

4:0: OVERVIEW

In the results and analysis section, the author presents and explains the findings of the study. This part typically includes visual aids such as graphs and tables to display the collected data. Here, the author discusses the significance of these findings, their implications, and how they relate to the original research questions. Moreover, there may be a comparison between these results and earlier studies or theories to provide a broader understanding.

This section analysis the questions asked to check how well retail or clinical pharmacists and pharmacy technicians or over-the-counter pharmacy assistants answered. The study also discusses the data gathered from participants, highlighting and emphasizing the alignment of these findings with the results from the questionnaire and the literature review on medicine shortages in Ireland.

4:2: QUANTITATIVE ANALYSIS: ANALYSIS OF PHARMACIST RESPONSE

The survey was given to healthcare practitioners (including retail/clinical/pharmacy technicians and over-the-counter pharmacy assistants) over a time period of 24 days, from March 20th to April 12th. 71 pharmacists participated, resulting in a response rate of 71 %. 71 pharmacists from Ireland responded to the survey out of 100 pharmacists who were asked to participate. The survey comprises six sections: the first section addresses participant consent, the second section gathers demographic information, the third section focuses on root cause analysis, the fourth section on impact analysis, the fifth section on gap analysis, and the sixth section on recommendation analysis.

The survey introduction also gave a short explanation of what the research aimed to achieve. Participants were told they could contact the author if they had any worries or questions. They were reminded that taking part in the survey was completely up to them, and they could stop participating whenever they wanted.

4:2:1: CONSENT AGREEMENT FOR PARTICIPATION

QUESTION 1: PARTICIPANT CONSENT

The first section addresses participant consent. Before the survey began, a question was included to ensure participants understood and agreed with the study's purpose. Except for one participant, the remaining 70 participants acknowledged that they had read and understood the

consent form and agreed to participate in the research study. Despite not acknowledging consent, this one participant proceeded to complete all sections of the survey.

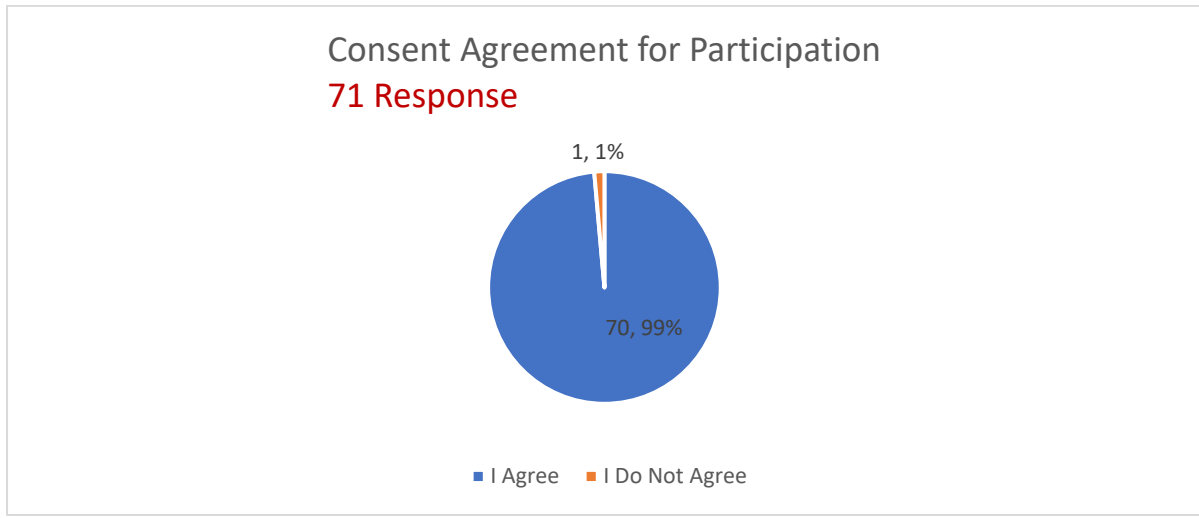


Figure 3: Pie chart representation with percentage of survey respondent's consent agreement for participation.

4:2:2: DEMOGRAPHIC INFORMATION ANALYSIS

QUESTION 2: AGE GROUP

Age Group allows you to tailor recommendations or interventions based on the specific needs or viewpoints of different age groups within the pharmacist community. While older pharmacists might offer more experience-based perspectives and they have finished their training long time ago. The survey results, with 48 respondents (68%) aged 20-30, 22 (31%) aged 31-50, and 1 (1%) aged 51-60, suggest a predominantly younger demographic among pharmacists engaging with the study. That is majority of pharmacists engaging with the study have completed their training relatively recently.

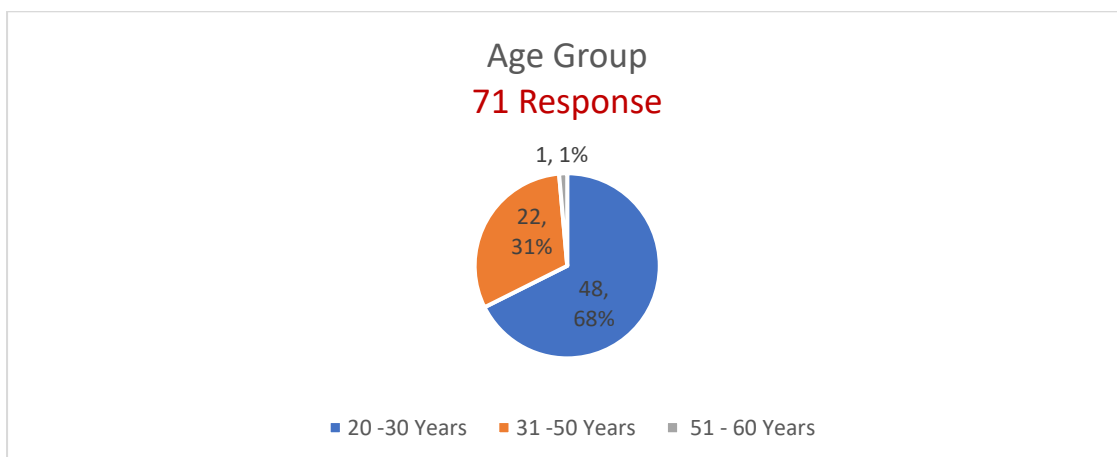


Figure 4: Pie chart representation with percentage of survey respondent's age group.

QUESTION 3: JOB TITLE

This question aims to determine the specific type of professional responding to the questionnaire, which targets four healthcare roles: Retail Pharmacists, Clinical Pharmacists, Pharmacy Technicians, and Over-the-Counter (OTC) Pharmacy Assistants.

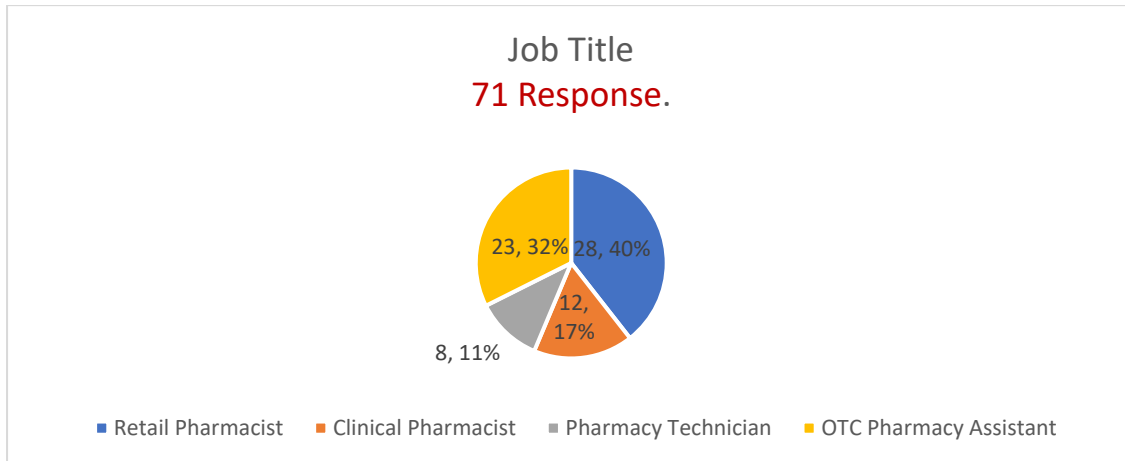


Figure 5: Pie chart representation with percentage of survey respondent's job title.

That the Pharmacists are highly suitable participants for a survey about drug shortages in Ireland because they have firsthand experience in both dispensing medications and overseeing inventory management. The pharmacist's direct engagement with patients and other healthcare professionals means they play a crucial role in grasping the practical effects of drug shortages on patient well-being and healthcare delivery. The Retail Pharmacists make up the largest proportion of respondents at 40%. OTC Pharmacy Assistants represent the second largest group at 32%, followed by Clinical Pharmacists at 17% and Pharmacy Technicians at 11%. Further analysis could explore the specific perspectives and experiences of each professional group regarding drug shortages to gain deeper insights into the problem and potential solutions.

QUESTION 4: EXPERIENCE LEVEL

The distribution of experience levels among respondents provides valuable insights. With 35 participants (49%) having 1-2 years of experience, 16 (22%) with 3-5 years, and 20 (28%) with over 5 years, this data sheds light on how different experience levels might perceive, understand, and potentially address drug shortages. Pharmacists with fewer years of experience may have completed their training recently, while those with more extensive experience might offer practical insights and historical context.



Figure 6: Pie chart representation with percentage of survey respondent's Experience Level.

4:2:3: ROOT CAUSE ANALYSIS

QUESTION 5: WHAT, IN YOUR OPINION, ARE THE PRIMARY FACTORS CONTRIBUTING TO THE SHORTAGE OF MEDICINES IN IRELAND?

The aim of the question "What, in your opinion, are the primary factors contributing to the shortage of medicines in Ireland?" is to gather qualitative insights and perspectives from respondents regarding the underlying causes of medicine shortages in the country. By asking for respondents' opinions, the question seeks to uncover a range of potential factors that may not be captured through quantitative data alone.

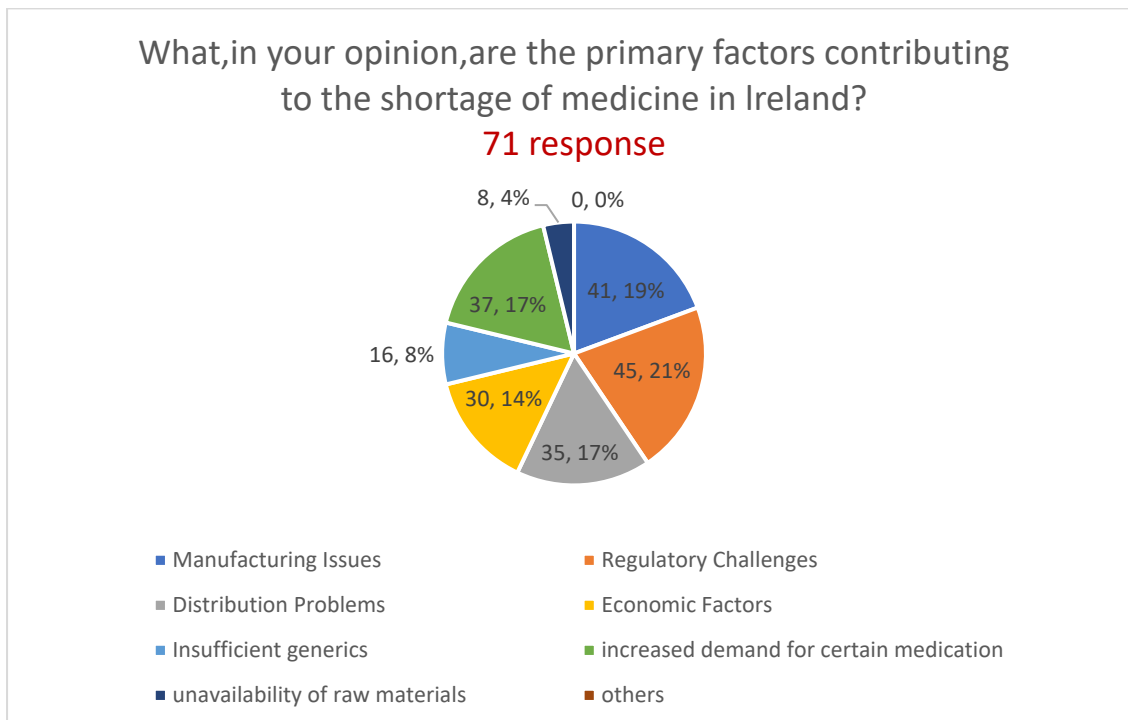


Figure 7: Pie chart representation with percentage of respondent's opinion on primary factors contributing to the shortage of medicine in Ireland.

Regulatory challenges emerged as a prominent concern, with 45 pharmacists highlighting hurdles like approval delays and stringent regulations as impediments to timely availability. Manufacturing issues followed closely, with 41 pharmacists citing factors such as production delays and quality control issues as significant contributors to shortages. Increased demand for the certain medication, noted by 37 pharmacists (approximately 17% of respondents), added another layer of complexity, encompassing issues like supply chain disruptions. Economic factors, insufficient generics, distribution problems, and unavailability of raw materials were also identified as contributing factors. In conclusion, addressing the medicine shortage in Ireland requires collaborative efforts across various stakeholders, including policymakers, regulatory agencies, pharmaceutical manufacturers, distributors, and healthcare providers.

QUESTION 6: IN YOUR EXPERIENCE, WHICH CATEGORY OF MEDICINES EXPERIENCES SHORTAGES MORE FREQUENTLY?

By asking respondents to reflect on their own experiences, the survey aims to gather qualitative data on which categories of medicines they perceive as experiencing shortages more frequently. This information can be valuable for understanding potential gaps or issues in the availability of medicines.

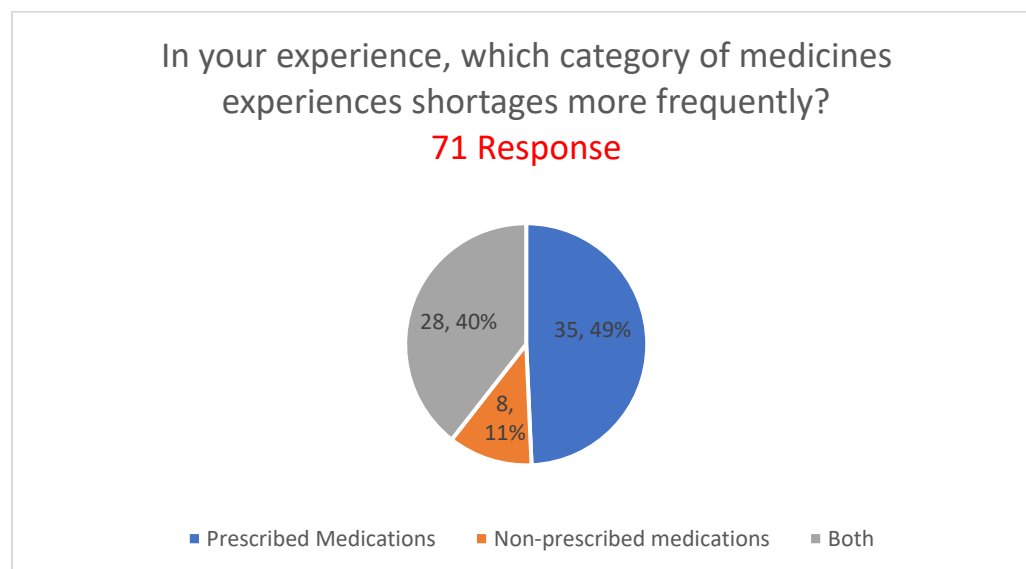


Figure 8: Pie chart, showing response on category of the medicines experiencing shortages frequently.

The significantly higher number of respondents (35, 49%) experiencing shortages in prescribed medications compared to non-prescribed medications (8, 11%) suggests that shortages in prescribed medicines are more prevalent or at least more noticeable among the respondents. The majority of retail pharmacists (20%) experienced shortages in prescribed medications, this

could be due to several factors, including the higher demand and reliance on prescribed medications for managing chronic conditions or serious illnesses, which makes shortages in this category more impactful and noticeable.

while the rest of the retail pharmacists, clinical pharmacists, pharmacy technician and 15% of OTC pharmacy assistants experienced shortages in both prescribed and non-prescribed medicines., that is 28 respondents (40%) who reported shortages in both prescribed and non-prescribed medications indicate that shortages are not limited to one category but can affect both types of medicines. This suggests a broader issue within the healthcare system or pharmaceutical supply chain that needs to be addressed comprehensively.

4:2:4: IMPACT ANALYSIS

QUESTION 7: HAVE YOU PERSONALLY EXPERIENCED OR OBSERVED THE EFFECTS OF DRUG SHORTAGES IN IRELAND?

The aim of the question "Have you personally experienced or observed the effects of drug shortages in Ireland?" is to gather firsthand accounts and observations from individuals regarding the impact of medicine shortages in the country. By asking respondents whether they have personally experienced or observed these shortages, the survey seeks to capture real-life experiences and perceptions of how medicine shortages affect individuals, communities, and healthcare systems in Ireland. This question is relevant in the survey as it provides qualitative insights into the tangible effects of drug shortages, which can complement quantitative data and help in understanding the severity, scope, and implications of medicine shortages on

patients, healthcare providers, and the overall healthcare landscape in Ireland.

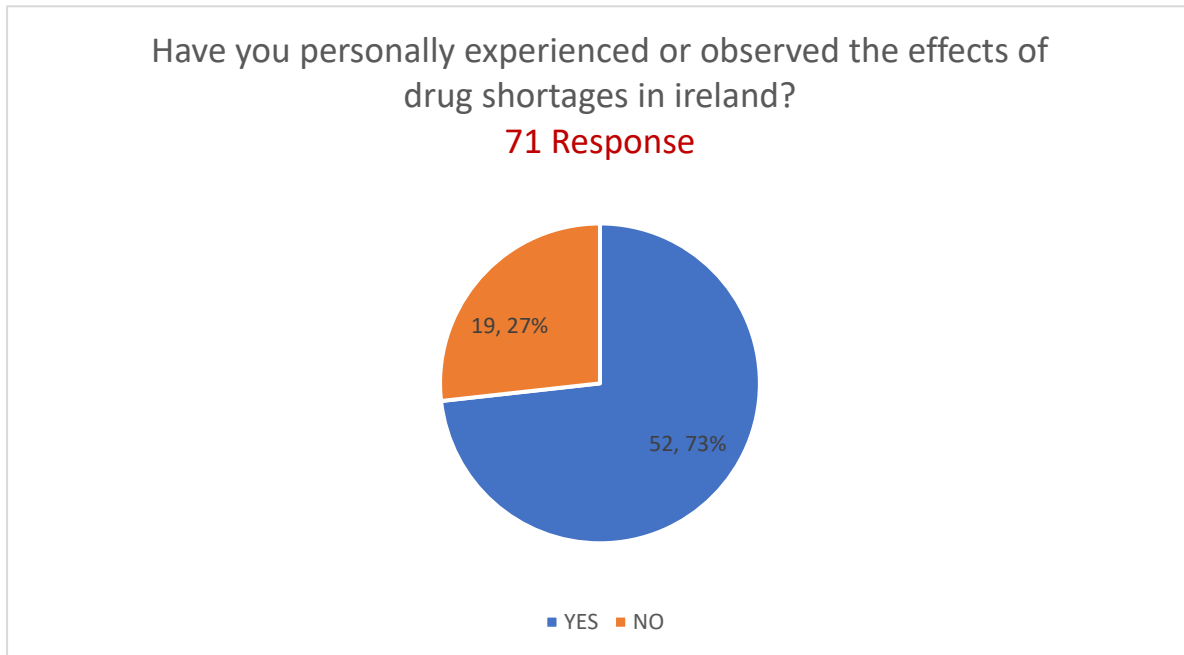


Figure 9: Pie Chart represents the responses from the respondents on whether they have experienced or observed the effect of drug shortage in Ireland.

A majority of respondents, 73% (52 individuals), have either personally experienced or observed the effects of drug shortages in Ireland. According to the response rate on personal experience on medicine shortage Many respondents reported experiencing medicine shortage issues are a common and real problem affecting many people, showing it has a wide impact on individuals, healthcare services, and the community. This suggests that Ireland is having trouble providing consistent access to essential medicines, which could harm patient care and public health. Solving these shortages is important to ensure people can get the medications they need on time.

QUESTION 8: SELECT TWO PROBLEMS THAT YOU HAVE EXPERIENCED ON HOW DO MEDICATION SHORTAGES IMPACT PATIENT SAFETY?

The aim of the question "Select two problems that you have experienced on how do medication shortages impact patient safety?" in the survey is to gather insights from respondents regarding specific challenges or issues they have encountered related to the impact of medication shortages on patient safety. By asking respondents to select two problems they have personally experienced or observed, the survey aims to identify common themes or concerns regarding how medication shortages affect patient safety.

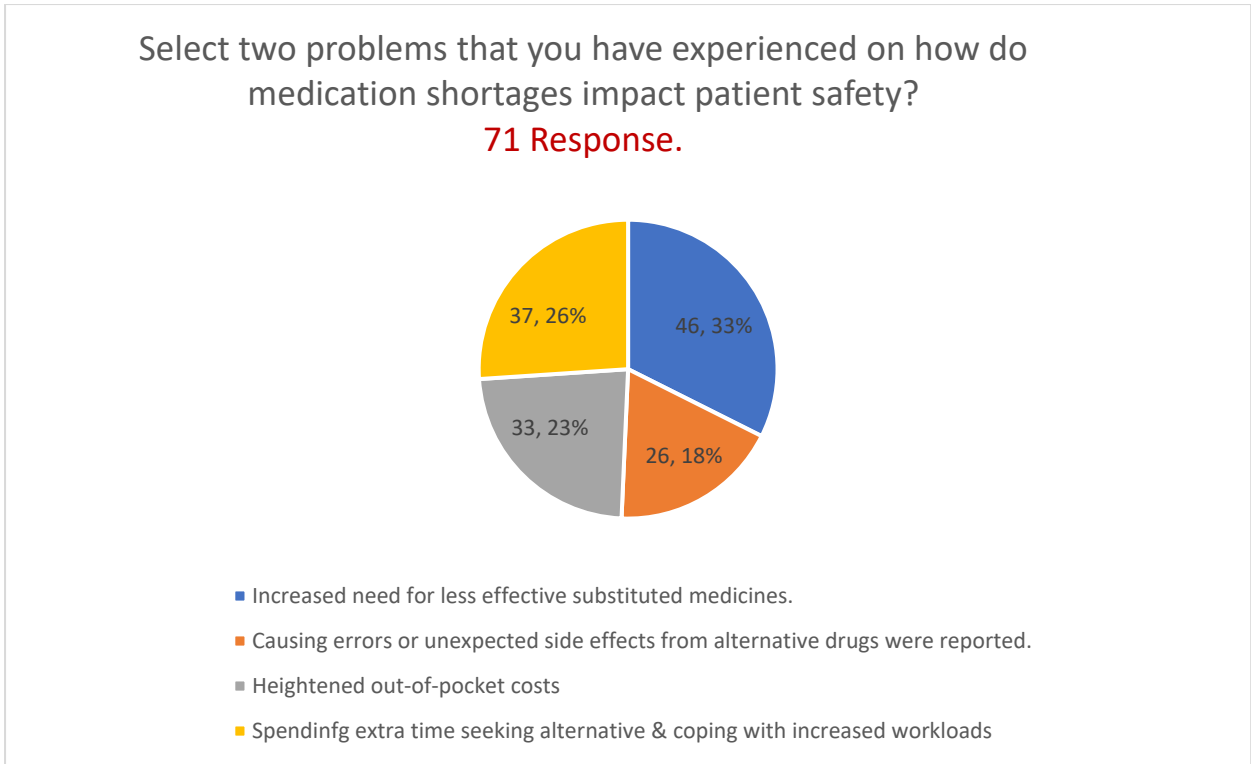


Figure 10: Pie Chart represents the frequency of responses on how do medication shortages impact patient safety.

The analysis of the survey data on how medication shortages impact patient safety in Ireland reveals several concerning trends. The most commonly experienced problem, reported by 33% of respondents, is the increased need for less effective substituted medicines. This suggests that during shortages, patients may not always receive the most suitable or effective treatments, potentially jeopardizing their health outcomes. Additionally, 26% of respondents reported spending extra time seeking alternatives and coping with increased workloads, indicating additional strain on healthcare providers. Moreover, 23% experienced heightened out-of-pocket costs, indicating financial burdens on patients due to medication shortages. Overall, these findings highlight the impacts faced by both patients and healthcare professionals in Ireland due to medication shortages, indicating a need for urgent measures to ensure patient safety, access to effective treatments, and alleviate financial burdens on patients.

4:2:5: GAP ANALYSIS

QUESTION 9: RANK THE FOLLOWING IDENTIFIED GAPS IN ORDER OF THEIR IMPACT ON DRUG SHORTAGES IN IRELAND, FROM MOST TO LEAST SIGNIFICANT?

By asking respondents to rank these identified gaps, the survey aims to gather valuable insights into which issues are considered most pressing and have the greatest impact on the occurrence

of drug shortages in the country. This information is crucial for policymakers, healthcare professionals, and pharmaceutical stakeholders to prioritize interventions and allocate resources effectively to address the most significant contributing factors to drug shortages in Ireland, ultimately aiming to improve the accessibility and availability of essential medications for the population.

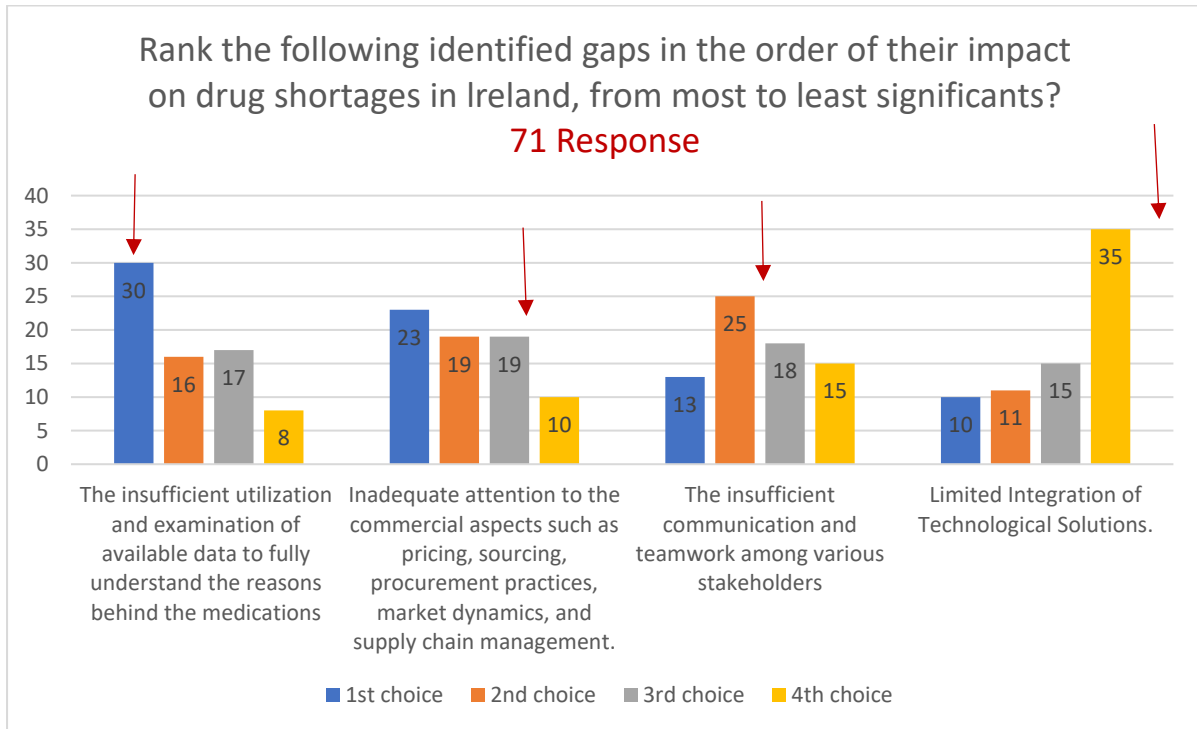


Figure 11: Bar Chart represents the responses on identified gaps in the order of their impact on drug shortages.

Firstly, all 30 participants agreed that inadequate use of available data is the primary issue, indicating a need for better analysis to understand the root causes of shortages. Secondly, 25 respondents emphasized the importance of improved communication and teamwork among stakeholders in the pharmaceutical supply chain, suggesting that better collaboration could lead to more proactive solutions. Thirdly, 19 participants highlighted commercial factors like pricing and procurement practices as significant contributors to shortages, signalling a need for attention in these areas. Lastly, 35 respondents noted the limited integration of technological solutions, suggesting that leveraging technology could streamline processes and enhance transparency in the supply chain to address shortages effectively. Overall, addressing these gaps is crucial for tackling drug shortages in Ireland and ensuring uninterrupted access to essential medications for patients.

QUESTION 10: SELECT ANY TWO KEY AREAS THAT NEED IMPROVEMENT MOSTLY IN THE CURRENT APPROACH TO MANAGING AND PREVENTING DRUG SHORTAGES?

The aim of this survey question seems to be to gather feedback on the key areas perceived to need improvement the most in the current approach to managing and preventing drug shortages. By allowing respondents to select two key areas, the question enables them to prioritize and provide insights into the most pressing issues within the context of drug shortage management and prevention.

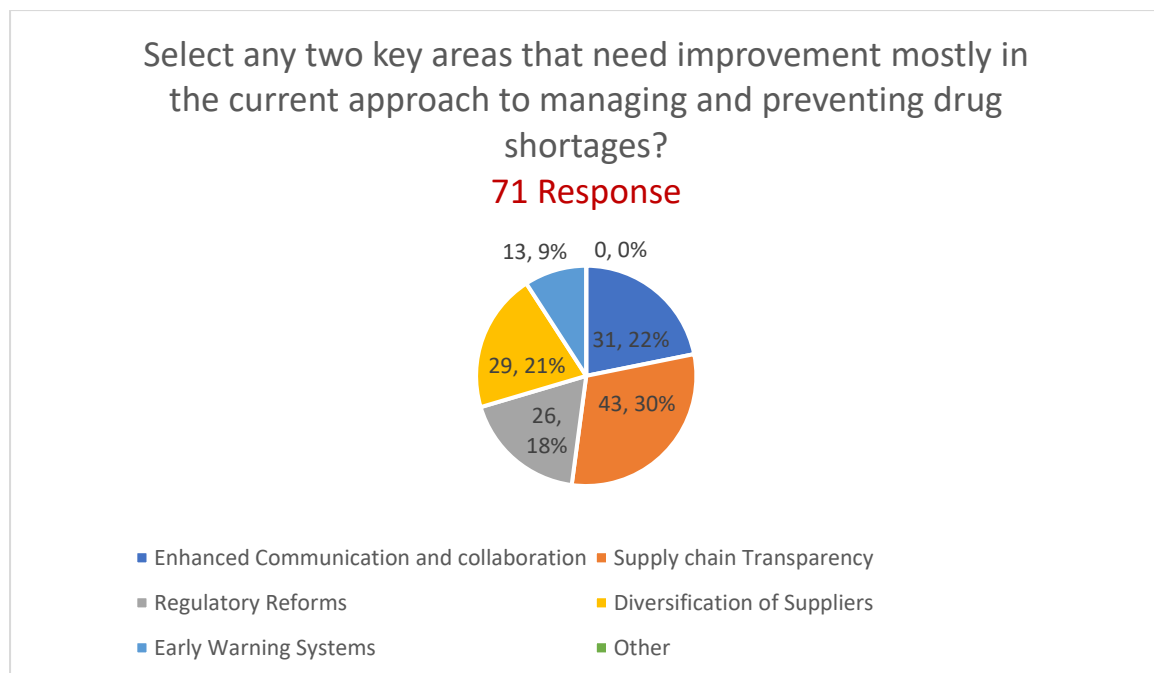


Figure 12: Pie chart represents the responses on areas that required improvement in current approach to manage and prevent drug shortage.

The survey asked people in Ireland about what could be done to tackle medicine shortages better. The answers show what they think is most important. The biggest concern, according to 43 people, is making the supply chain more transparent. This means they want to see and understand better how medicines move from where they're made to where they're needed. By knowing this, they believe it will be easier to spot problems that cause shortages.

Next on the list, with 31 responses, is the need for better communication and teamwork among everyone involved in providing medicines. This means people think it's crucial for drugmakers, suppliers, doctors, and regulators to work closely together to manage shortages more effectively. They believe that by sharing information and working as a team, they can respond to shortages faster.

Other important points raised include the need to have more suppliers (29 responses) and to change regulations (26 responses) to prevent shortages. Having more suppliers means not relying too much on just a few companies to make medicines. Changing regulations can help

fix deeper issues that lead to shortages. Surprisingly, fewer people (only 13 responses) mentioned the idea of early warning systems to predict and prevent shortages. This might suggest that while some see its potential, most think other approaches are more urgent.

Overall, the survey results underline the importance of making the supply chain clearer and more open to everyone involved. This means efforts should focus on improving communication, changing regulations, and having more options for where medicines come from. While early warning systems are seen as useful, they might not be the top priority right now according to the people surveyed.

QUESTION 11: HOW WOULD YOU RATE THE CURRENT STRATEGIES IN PLACE FOR MANAGING AND PREVENTING MEDICINE SHORTAGES IN IRELAND?

This survey question aims to find out what people think about how well Ireland is managing and preventing medicine shortages. It wants to know if people think the strategies currently used are good enough or if they need to be better.

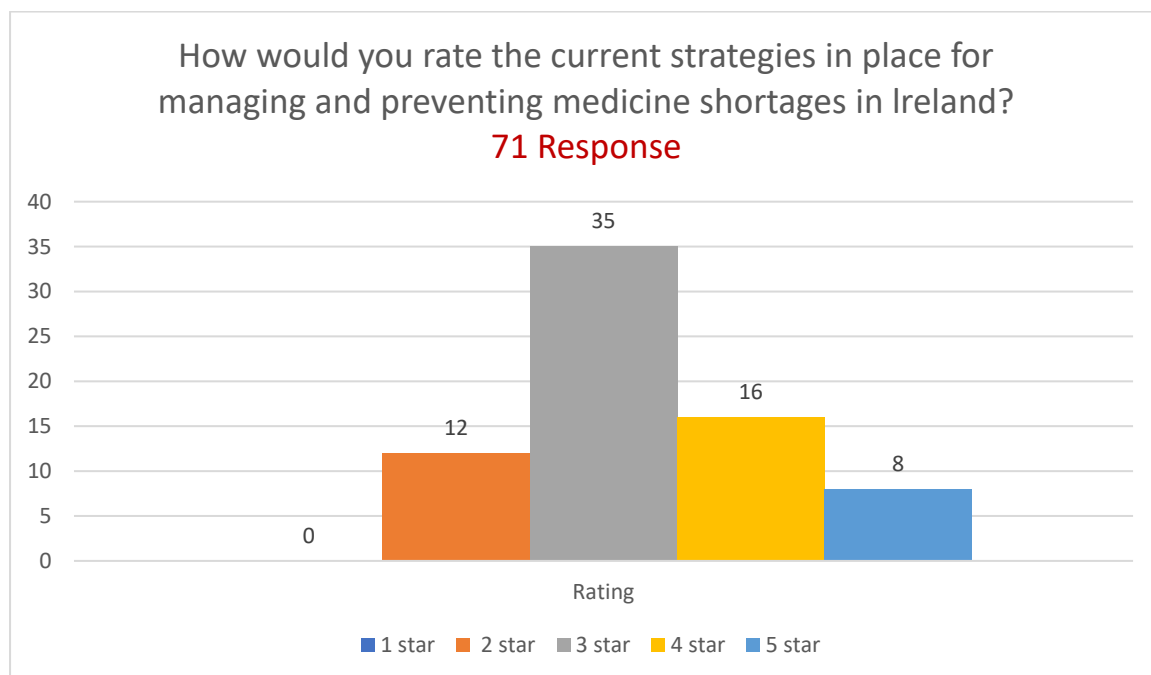


Figure 13: Bar chart representation of respondents rating on current strategies in place for managing and preventing medicine shortage in Ireland.

It's worth mentioning that none of the participants gave the lowest rating to the strategies. This shows that they acknowledged that strategies are there, but they might not all work equally well. The majority of respondents, 35 out of 71, rated the strategies with three stars, reflecting a neutral stance, suggesting a perceived lack of consistency or comprehensiveness in the

existing strategies. On the positive side, 16 respondents rated the strategies with four stars, indicating a belief in their effectiveness to a significant extent, while 12 respondents gave two stars, signalling a perception of inadequacy. Additionally, eight respondents rated the strategies with five stars, showing a highly positive perception. This mixed perception underscores the need for further exploration into specific shortcomings and areas for improvement in Ireland's medicine supply chain management.

Overall, the data analysis reveals different perspective on the effectiveness of current strategies, highlighting both strengths and areas requiring attention. This suggests potential room for enhancement in the strategies employed to manage and prevent medicine shortages in Ireland.

4:2:5: RECOMMENDATION ANALYSIS

QUESTION 12: RANK THE FOLLOWING BASED ON HOW YOU DECIDE TO GIVE ORDER OF SUPPLYING MEDICINES TO PATIENTS WHEN THERE IS A SHORTAGE, FROM MOST TO LEAST SIGNIFICANT?

By asking respondents to rank the criteria from most to least significant, the researcher aims to gain insights into the decision-making process and identify the factors that are considered most important in such situations.

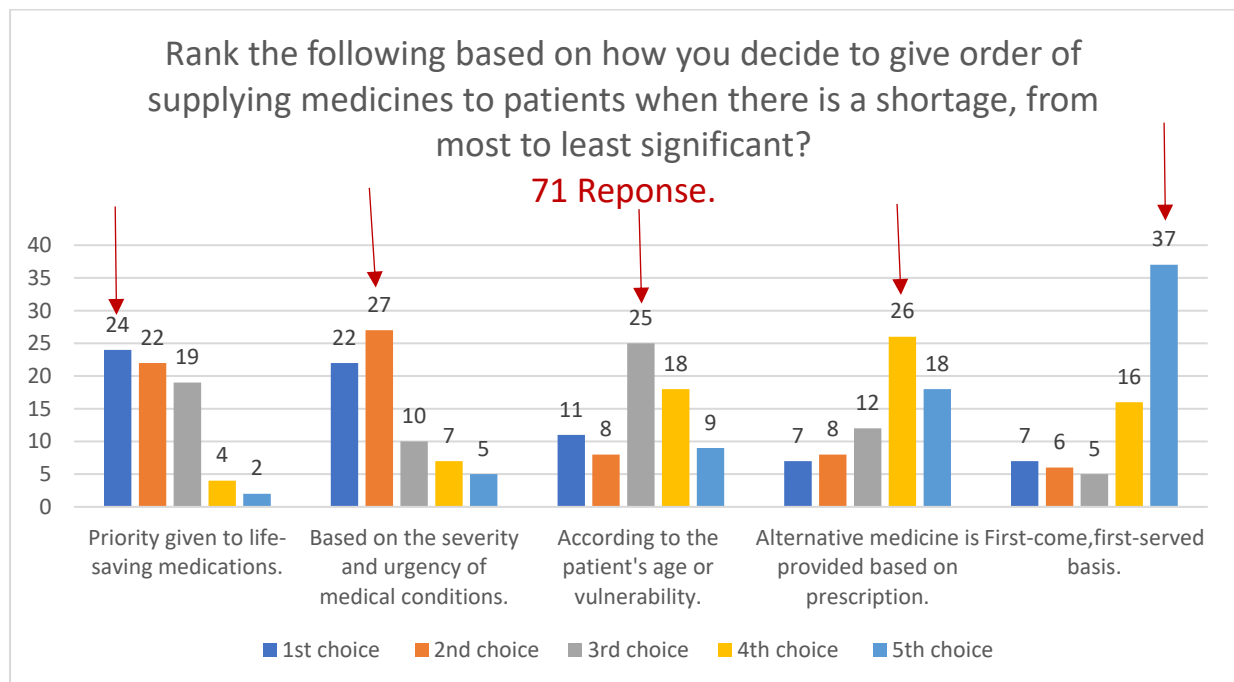


Figure 14: Bar chart representation of responses on how they decide to give order of supplying medicines to patients during the shortage.

It's evident that the majority of respondents, advocate for prioritizing life-saving medications as their 1st choice. This suggests a strong emphasis on saving lives and prioritizing the treatment of critical conditions over other considerations. It underscores a moral imperative to ensure that those in dire need receive essential medications promptly. Following closely behind, 27 respondents (27%) support a criterion based on the severity and urgency of medical conditions. This approach acknowledges the importance of assessing patients' conditions and allocating medications accordingly. Interestingly, age or vulnerability as a criterion for prioritization ranks third, with 25 respondents (25%) supporting it. The fourth-ranked criterion, supported by 26 respondents (26%), involves providing alternative medicines based on prescription. Lastly, the criterion of a first-come, first-served basis is supported by the largest number of respondents as their 5th choice.

This shows that we need to think carefully about who gets what medicine, making sure it's fair and everyone gets what they need. Overall, it's clear that deciding who gets medicine during shortages is tricky, but by considering different factors like urgency, fairness, and vulnerability, we can make sure everyone gets the care they need.

QUESTION 13: BASED ON YOUR EXPERIENCE AND INSIGHTS, WHAT SPECIFIC RECOMMENDATIONS WOULD YOU PROPOSE FOR MITIGATING MEDICINE SHORTAGES IN IRELAND IN THE FUTURE?

This question serves two main purposes. First, it gathers insights from people involved in the issue to find new solutions. Second, it gives respondents a chance to influence future decisions and policies. 71 people shared their ideas in a survey about how to deal with medicine shortages in Ireland.

Notably, about 19% of the people who responded to the survey said that it's really important for regulations to be put in place or needed some changes to help solve the problem of medicine shortages. Furthermore, the analysis of the data highlights several key themes including the importance of oversight on manufacturers, optimization of production processes, strengthening the supply chain, exploration of alternative medicine options, promotion of local manufacturing endeavours, implementation of strategic stockpiling measures, and fostering collaborative relationships with suppliers. These insights collectively offer valuable guidance for policymakers and stakeholders in devising effective strategies to combat medicine shortages and ensure the resilience of Ireland's healthcare system.

QUESTION 14: ARE THERE ANY ADDITIONAL STRATEGIES OR APPROACHES NOT COVERED IN THIS SURVEY THAT YOU BELIEVE WOULD BE EFFECTIVE IN ADDRESSING MEDICINE SHORTAGES?

The aim of the question is to encourage respondents to think creatively and expansively about potential solutions beyond those already considered in the survey. Its importance lies in fostering innovation and inclusivity in problem-solving, as it allows participants to contribute unique insights or overlooked ideas that could be valuable in tackling medicine shortages effectively. By inviting diverse perspectives and alternative approaches, this question enhances the comprehensiveness and effectiveness of the overall strategy for addressing medicine shortages.

41 participants offered valuable insights. Among the key themes identified from their responses were the integration of advanced analytics, incentives for overproduction, enhanced demand forecasting, predictive analytics, and the streamlining of alternative medicines protocol approval processes. The consensus among participants underscores the importance of leveraging technological advancements and data-driven approaches to better anticipate and mitigate shortages. Integrating advanced analytics and predictive modelling can provide healthcare providers and policymakers with timely insights into potential shortages, enabling proactive measures to address them before they escalate. Furthermore, the suggestion for incentives aimed at stimulating overproduction aligns with the need to ensure a robust supply chain capable of meeting fluctuating demands. Additionally, optimizing alternative medicines protocol approval processes could offer a strategic solution for diversifying treatment options and alleviating pressure on commonly scarce medications. Overall, these suggested strategies, as highlighted by the survey participants, present promising avenues for bolstering Ireland's healthcare system against the challenges posed by medicine shortages.

4.3 SUMMARY/DISCUSSION OF RESULTS

The summary and discussion of survey results presented below encapsulate the valuable insights obtained from our thorough analysis. These insights offer valuable perspectives for policymakers, healthcare professionals are dedicated to addressing and resolving this urgent issue. The survey from Microsoft was expected to reach 100 pharmacists, but only 71 took part. They answered questions, and Microsoft's tool analysed their responses. The results revealed that among the 71 participants, there were 28 retail pharmacists, 12 clinical pharmacists, 8 pharmacy technicians, and 23 over-the-counter (OTC) pharmacy assistants. The majority of

respondents (49%) have 1-2 years of experience as pharmacists. This suggests that the survey audience might consist of relatively new or early-career pharmacists.

The evaluation provides a comprehensive examination of the reasons behind medicine shortages in Ireland, highlighting regulatory challenges, manufacturing issues, and increased demand as key factors contributing to the problem. The impact analysis section reveals the widespread effects of drug shortages, with a significant percentage of respondents personally experiencing or witnessing these repercussions. Patients and healthcare professionals face challenges such as increased reliance on less effective substitutes, additional time spent seeking alternatives, and heightened out-of-pocket costs during shortages, underscoring the urgent need for measures to ensure patient safety and access to effective treatments. The gap analysis section identifies crucial areas for improvement, emphasizing the importance of better use of available data, enhanced communication and teamwork among stakeholders, and transparency in the supply chain. Moreover, the recommendation analysis offers valuable insights into addressing medication shortages, advocating for prioritizing life-saving medications and implementing strategies to enhance supply chain resilience, and streamline regulatory processes,

The survey results highlight the complex nature of medicine shortages in Ireland and the recommendations from the study say we should focus on keeping patients safe, working better together, and making sure rules are in place to prevent shortages in the future. These suggestions help policymakers, doctors, and others come up with strong plans to fight medicine shortages and make sure Ireland's healthcare system stays strong. By dealing with the main reasons behind shortages, improving how we communicate, and taking action early, Ireland can tackle the problem of medicine shortages and make sure everyone gets the medicines they need on time.

The following section will discuss into additional conclusions and offer suggestions for future research.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

In the conclusion section of the dissertation, we will evaluate whether the research objectives have been adequately addressed through both primary and secondary research data on drug shortages. We will discuss whether the findings from the primary data obtained through the survey align with those from the secondary data gathered through the literature review.

1. Investigate the root causes of medicine shortages in Ireland.

According to the survey, root cause analysis section results highlight three root causes for drug shortages in Ireland include regulatory challenges, manufacturing issues, and increased demand for certain medications. Approximately 21% of pharmacists agree that regulatory challenges significantly impact medicine availability due to approval delays and stringent regulations. Similarly, 19% acknowledge that manufacturing issues contribute to shortages, with production delays and quality control problems being key factors. Additionally, 17% attribute shortages to unexpected demand, often arising from unanticipated increases in prescribing specific medications or higher-than-expected levels of seasonal illnesses.

The literature highlights several critical factors contributing to medicine shortages. A significant portion, over 60%, stems from manufacturing issues such as quality problems and competing priorities. Delays in drug production are often caused by challenges in obtaining raw materials or addressing quality-related concerns. Demand factors like just-in-time inventory practices, aggressive marketing, and unpredictable events such as outbreaks or natural disasters further disrupt supply. Regulatory challenges also play a significant role in drug shortages. Inflexible processes, inadequate policies, and poor communication among stakeholders contribute to supply issues. The post-approval, any changes in drug production necessitate additional FDA approval, which can be time-consuming due to varying international regulations. Obtaining approval to ramp up production during shortages can be slow and costly. These regulatory hurdles, significantly impact healthcare systems and public health. Addressing these complex challenges is essential for maintaining a stable and reliable drug supply chain.

2. Assess the impact of drug shortage on healthcare sector and pharmaceutical industries.

The impact analysis section of the survey results highlights the widespread effects of drug shortages in Ireland, with 73% of respondents personally experiencing or witnessing this

problem. Further analysis of the survey data sheds light on how medication shortages impact patient safety in Ireland, revealing several troubling trends. The most commonly reported problem, cited by 33% of respondents, is the increased reliance on less effective substituted medicines during shortages. This indicates that patients may not always receive the most suitable or optimal treatments, potentially compromising their health outcomes. Additionally, 26% of respondents reported spending extra time seeking alternatives strain on healthcare providers. Moreover, 23% experienced heightened out-of-pocket costs, signalling financial burdens on patients due to medication shortages. These findings underscore the significant impacts faced by both patients and healthcare professionals in Ireland as a result of medication shortages, emphasizing the urgent need for measures to ensure patient safety, access to effective treatments, and alleviate financial burdens on patients.

The literature underscores the profound impact of essential medicine shortages on patients. When necessary, drugs are unavailable, patients often face treatment delays or cancellations and may receive fewer effective substitutes, leading to substandard care. These shortages impose significant financial burdens on healthcare systems, disrupt patient care, and increase patient dissatisfaction. They also result in higher out-of-pocket costs and can lead to adverse events such as mortality, changes in treatment plans, suboptimal treatment, and medication errors. Healthcare providers, including pharmacologists, pharmacists, and physicians, experience increased workloads as they search for alternatives and assist in selecting substitute medications., complicating their efforts to provide optimal care.

3. Identify gaps and areas for improvement in the current approach towards managing and preventing shortages.

The gap analysis section of the survey results from the dissertation on medicine shortage in Ireland sheds light on key areas needing improvement. Participants unanimously agreed that better use of available data is essential to understand the root causes of shortages. Improved communication and teamwork among stakeholders in the pharmaceutical supply chain were highlighted by 25 respondents as crucial for finding proactive solutions. The survey also asked people in Ireland about solutions to tackle medicine shortages. The majority of responses focused on making the supply chain more transparent, emphasizing the importance of communication and teamwork among stakeholders, and the need for more diverse suppliers and regulatory changes. The responses also reflected a mixed perception of the effectiveness

of current strategies, indicating room for improvement in Ireland's medicine supply chain management.

The literature review highlighting both immediate and long-term strategies. Key strategies include stock restrictions to prioritize urgent needs, frameworks like A4R for fair allocation, using products with minor defects, extending expiry dates, and redistributing stock equitably. Establishing expert platforms and minimizing wastage are also crucial. The HPRA's comprehensive framework in Ireland focuses on early detection and prevention of shortages, involving multiple stakeholders. Effective allocation models and regulatory frameworks are essential to balance patient safety and medicine access, with strategies to enhance supply chain resilience.

4. Propose future recommendations and strategies for mitigating medicine shortages.

The recommendation analysis from the survey reveals important insights into addressing the challenges posed by medication shortages. The majority of respondents advocate for prioritizing life-saving medications as their first choice, emphasizing the moral imperative to save lives and treat critical conditions promptly. This highlights the need for fair and equitable allocation of medications during shortages, considering factors like urgency, severity of medical conditions, age, vulnerability, and prescription-based alternatives. Moreover, respondents emphasize the importance of regulations to address medicine shortages, highlighting themes such as oversight on manufacturers, optimization of production processes, and strengthening the supply chain. Recommendations include enhancing supply chain transparency and resilience, streamlining regulatory processes, promoting domestic manufacturing, and increasing stockpiling of essential medicines. Additionally, comprehensive education and training programs for healthcare professionals, fostering collaboration among stakeholders, and improving monitoring and reporting mechanisms are suggested strategies to mitigate future shortages. These recommendations offer valuable guidance for policymakers and stakeholders to devise effective strategies and ensure the resilience of Ireland's healthcare system against medicine shortages.

The literature review highlights that prioritizing cost-saving strategies in procurement practices can inadvertently limit supplier diversity, increasing vulnerability to supply disruptions. To mitigate these risks, it recommends prioritizing supplier resilience and diversity by seeking a broader range of suppliers and evaluating them on their ability to provide consistent supply and withstand disruptions. Additionally, lengthy regulatory approval processes for new medications

and alternative suppliers cause delays in accessing essential drugs; streamlining these processes or creating expedited pathways is suggested to reduce delays. Promoting generic competition and expediting the introduction of biosimilars could enhance medication supply resilience by fostering competition and facilitating the availability of cheaper alternatives. Revising reference pricing mechanisms to prioritize medicines with stable supplies and incentivize the availability of alternatives is also recommended to address shortages.

5.2 RECOMMENDATION FROM THE STUDY

The study recommends enhancing supply chain transparency and resilience by improving communication among stakeholders and developing contingency plans. It suggests streamlining regulatory processes to expedite drug approvals, promoting domestic manufacturing to reduce reliance on international suppliers, and increasing the stockpiling of essential medicines. The study also calls for comprehensive education and training programs for healthcare professionals, fostering multi-stakeholder collaboration, and improving monitoring and reporting mechanisms for medicine shortages. Raising public and professional awareness about the impacts and causes of shortages, strengthening financial support and reimbursement policies, and encouraging research and innovation in supply chain management and pharmaceutical production are also key strategies proposed to mitigate future shortages.

5.3 LIMITATIONS OF THE RESEARCH

The research provides valuable insights, there are several important limitations to consider. Firstly, the study used a cross-sectional design, data were collected at only one point in time. This limits the study's ability to track changes and trends over time, which could provide a more complete picture. Secondly, most of the participants were pharmacists with less than five years of experience. Their limited experience might have influenced their responses, making their perspectives different from those with more experience, which could affect the overall findings.

Additionally, the study focused only on pharmacists in Ireland and did not include other important groups such as wholesalers, doctors, nurses, and drug manufacturers. Including these stakeholders could have provided a more well-rounded understanding of the issue. Lastly, the research faced difficulties in finding detailed secondary data on strategies to overcome medicine shortages and manage the current situation. While there were many news articles and

radio interviews discussing the problem, there was a lack of in-depth articles offering concrete solutions. Overall, these limitations mean that the research findings should be interpreted carefully, considering the context and recognizing the need for further studies to fill in these gaps.

5.4 CONTRIBUTION OF THE RESEARCH

This research makes a significant contribution by thoroughly investigating the root causes of medicine shortages in Ireland and examining their impact on the healthcare sector and pharmaceutical industries. It identifies gaps and areas for improvement in current management and prevention approaches, providing a clear understanding of the issues. Additionally, the study offers practical recommendations and strategies to help policymakers, healthcare professionals, and industry stakeholders develop more effective solutions to mitigate future medicine shortages.

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APPENDICES

APPENDIX I: ETHICAL APPLICATION AND DECLARATION FORM



Ethics Application & Declaration Form

DISSERTATION TITLE: **Drug Shortage in Ireland: An In-depth Analysis of Current Situation, Causing factors, Impact and Future Recommendations.**

RESEARCHER'S NAME: **Riya Paul**

PROGRAMME OF STUDY: **Masters in Pharmaceutical Business and Technology – Full Time**

SUPERVISOR'S NAME: **Susanna Coghlan**

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: Riya

DATE: 28-03-2024

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required:

Yes

No

SUPERVISOR SIGNATURE:

Susanna Cofla

For Ethics Committee (if required):

Ethics Committee Approval Given:

Yes

No

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research:

The research topic is more like investigating and exploring on the subject rather than trying to prove a hypothesis. The shortage of drugs in Ireland is influenced by a combination of factors, including supply chain disruptions, regulatory challenges, and increased demand. This dissertation aims to uncover the root causes, assess the impacts on healthcare, and propose recommendations for mitigating the current drug shortage while providing insights for future improvements in the pharmaceutical supply system. According to the Health Products Regulatory Authority (HPRA) reports a record level of shortages, exceeding 300 medicines by mid -December, have been observed in 2023, showing a 30% increase compared to 2022. Drug shortages can have serious consequences for patients, leading to treatment delays, substitution with less effective medications, or even the inability to receive necessary treatment altogether. This can prolong suffering, worsen disease progression, and increase the likelihood of other health problems

Research Objectives:

- Investigate the root causes of medicine shortages in Ireland.
- Assess the impact of drug shortage on healthcare sector and pharmaceutical industries.
- Identify gaps and areas for improvement in the current approach towards managing and Preventing shortages.
- Propose future recommendations and strategies for mitigating medicine shortages

1.2 Research methodology:

The research approach employs both deductive and inductive approach to investigate the issue of drug shortages in Ireland. Drug shortages pose significant challenges to healthcare systems globally, and Ireland is no exception. This study aims to delve into the complexities surrounding drug shortages, incorporating a mixed methods research design to capture a multifaceted perspective in cross sectional timeline. The study utilizes both quantitative and qualitative research method strategy gain a holistic understanding of the current situation, identify causing factors, assess the impact, and formulate future recommendations. The primary data collection methods that is research technique include face-to-face interviews and Zoom meetings, case study, integrating survey-based quantitative data and in-depth qualitative insights.

A cross-sectional timeline survey that is collecting information about drug shortages by asking people questions at one specific moment in time. This helps researchers understand how common and what types of drug shortages are happening at that particular point. A structured survey is distributed to pharmacy technician, retail pharmacists, across Ireland to gather quantitative data. Surveys such as list question surveys include closed -ended questions to quantify the extent of the issue, categorize the types of drugs affected, and assess the economic impact on healthcare providers. All survey participants will be told that any information collected during the research will be kept private and stored following the rules of the General Data Protection Regulation (GDPR). They must answer a consent question before finishing the survey.

Qualitative research technique such as Face-to-face interviews, with Retail pharmacists, pharmacy technician and case study on type of drug that is affected are conducted to explore the root causes of drug shortages. online meetings using Zoom or phone call interview are set up to allow people from different locations to have discussions. This ensures that a variety of viewpoints and opinions are considered. Compose a message inviting individuals that clearly explains the purpose and importance of the research. Clearly outline how participants can contribute to the study through their LinkedIn and Indeed profiles.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential

No

Research into politically and/or racially/ethnically and/or commercially sensitive areas No
Sensitive, personal, professional or corporate issues No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants No
Research that may negatively affect the reputation of Griffith College/Innopharma No
Use of personal records without consent No
Use of company data without consent No
The offer of any inducements to participate No
Audio or visual recording without consent No
Using a language other than English No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English No
Does your research group include any of the following vulnerable groups No
(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control/influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

- 3.1. If your ethics relates to **Subject Matter**, outline your action plan to work around any sensitive issues.
- 3.2. If your ethics relates to **Research Procedures**, outline your action plan to deal with possible ethical issues in your research procedures.
- 3.3. If your ethics relates to **Participants**, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

- 4.1. Outline your participant profile and why you have chosen them for this study.

The study will involve retail pharmacists and pharmacy technicians in Ireland due to their direct involvement in managing drug shortages and their expertise in pharmaceuticals and supply chain management. Their firsthand experience and access to real-time information will offer valuable insights into the causes and impacts of drug shortages, facilitating the development of effective recommendations. As frontline healthcare providers, they represent a crucial stakeholder group affected by these shortages, ensuring a comprehensive understanding of the issue and enabling targeted solutions to be formulated. Overall, their participation will enrich the study's findings and contribute to evidence-based strategies for addressing drug shortages in Ireland.

- 4.2 How do you plan to gain access to/contact/approach your participant(s).

The study aims to recruit participants via email and social media platforms like Facebook and LinkedIn, targeting R&D professionals in contracted study companies and pharmaceutical firms in Ireland. Individualized invitations emphasizing

participants' expertise and the value of their insights will be sent, along with clear explanations of the research's goals. Participation is voluntary, with transparent information provided to aid decision-making. An online questionnaire will be distributed using tools like Google Forms. Assurances of anonymity and ethical principles will be maintained to ensure participant privacy and safety. Qualitative research techniques including face-to-face interviews with pharmacists on drug shortages will be employed. Online meetings via Zoom or phone calls will be arranged to accommodate diverse perspectives. A message inviting individuals will highlight the research's purpose and significance, guiding them on how to contribute through their LinkedIn and Indeed profiles.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 Participant Information Letter (PIL) for participants

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarizing and explaining the purpose of the research at the

beginning of the survey. In all other research e.g. interviews, phone calls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 Informed Consent Form (ICF) for participants

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phone calls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on Moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/GDPR-and-health-research/>].

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on Moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Data will be collected and stored securely with password protection, following General Data Protection Regulation (GDPR) and national data protection laws. Information provided by participants will be stored according to Griffith College Dublin/Innopharma Education policies and GDPR regulations. Raw data, including consent forms and audio recordings, will be kept confidentially until the end of the research and dissertation results confirmation, stored in an appropriate folder on Moodle. Limited personnel, including myself, my supervisor, a second reader, or an external examiner, will have access during the retention period. Transcripts of interviews with personal identifying information removed will be accessible to supervisors or examiners. Personal data will be anonymized at the earliest opportunity, and sharing will require consent. Results will be included in the final dissertation, stored with encryption in college

databases accessible only to authorized faculty for result purposes. Anonymity of participants will be maintained and updated.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 Non-Disclosure Agreement (NDA)

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non - Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 Student consent

If a Non-Disclosure Agreement (NDA) is not required, does the student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 Viva Recording

The Dissertation viva will be recorded. This recording maybe used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programmed. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

- | | |
|--|-----|
| 9.1 Participant Information Letter (PIL) for participant | Yes |
| 9.2 Informed Consent Form (ICF) for participant | N/A |
| 9.3 Questions/surveyfor interviewees/focus groups etc. (<i>can be in draft form</i>) | Yes |
| 9.4 Any other documents e.g. Non-Disclosure Agreement | N/A |

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: Riya

DATE :28-03-2023

APPENDIX II: QUESTIONNAIRE AS CREATED ON MICROSOFT FORMS

Available at : <https://forms.office.com/Pages/ResponsePage.aspx?id=KfrvH2Tm0S-yNHPh7DGxycEAj3eQJOlgJ4xdKPGBhUNTBWQzZHMDdFukVJSVY2VU1WMzhJRjlcRC4u>.

Survey Questionnaire for pharmacists

Drug Shortage in Ireland: An In-depth Analysis of Current Situation, Causing factors, Impact and Future Recommendations.

Dear Participants,

I am writing to introduce myself as Riya Paul, a current Master's degree student in Pharmaceutical Business and Technology at Griffith College, Dublin. In the final semester of my program, I am undertaking a dissertation project centred around the An In-depth Analysis of Current Situation, Causing factors, Impact and Future Recommendations. The primary objective of this dissertation is to comprehensively examine the root causes of medicine shortages in Ireland, evaluate their impact on the healthcare sector and pharmaceutical industries, identify existing gaps in the current management and prevention approaches, and propose future recommendations and strategies to effectively mitigate medicine shortages.

In this research endeavour, I prioritize safeguarding the strict confidentiality and anonymity of all participants. Your participation in the survey carries no risk, as all your input will be handled with the utmost confidentiality. Be assured that no personally identifiable details, like your name or email address, will be gathered. To ensure your privacy, the questionnaire has been carefully crafted to avoid any personal identifying information. The outcomes of this study will be utilized exclusively for academic purposes.

We sincerely appreciate your valuable participation in this research. Thank you in advance.

Sincerely,

Riya Paul



DRUG SHORTAGE IN IRELAND

Welcome to my survey on dissertation topic '**The Drug Shortage in Ireland: An In-depth Analysis of Current Situation, Causing factors, Impact and Future Recommendations.**'

Dear Participant,

Prior to taking this survey, we kindly request you to carefully review the following details. This survey is being conducted for specific purposes such as academic research or market analysis. Your participation is entirely voluntary, and you retain the option to decline or withdraw at any stage without repercussions.

Rest assured, all your responses will be treated with utmost confidentiality and solely utilized for the intended survey objectives. Collected data will be securely stored and will not be disclosed to any third parties. Furthermore, this survey ensures anonymity, with no collection of personally identifiable information unless explicitly stated.

The survey is estimated to take approximately 10 minutes to complete. By proceeding, you confirm that you have thoroughly read and comprehended the provided information and consent to participate in this study.

Thank you for your participation!

For any questions or further information, please do not hesitate to contact me through the email address below.

riyapaul032001@gmail.com

* Required

Consent Agreement for Participation

1. By selecting "I Agree" below, you acknowledge that you have read and understood this consent form and agree to participate in this research study. If you do not agree to participate, you may select "I Do Not Agree" and will not be included in the study.

*

I Agree

I Do Not Agree

Demographic details

2. What is your age? *

20 - 30 years

31- 50 years

51 - 60 years

3. Job title *

Retail Pharmacist

Clinical Pharmacist

Pharmacy technician

OTC Pharmacy Assistant

Other

4. Experience Level *

1 -2 years

3- 5 years

Over 5 years

Root cause analysis

5. What, in your opinion, are the primary factors contributing to the shortage of medicines in Ireland? *

Please select 3 options.

- Manufacturing Issues
- Regulatory Challenges
- Distribution Problems
- Economic Factors
- Insufficient generics
- Increased demand for certain medication
- Unavailability of raw materials
- Other _____

6. In your experience, which category of medicines experiences shortages more frequently? *

- Prescribed medications
- Non-prescribed medications
- Both

Impact Analysis

7. Have you personally experienced or observed the effects of drug shortages in Ireland? *

Yes

No

8. Select two problems that you have experienced on how do medication shortages impact patient safety? *

Please select 2 options.

Increased need for less effective substituted medicines.

Causing errors or unexpected side effects from alternative drugs were reported.

Heightened out-of-pocket costs.

Spending extra time seeking alternative & coping with increased workloads.

Gap Analysis

9. Rank the following identified gaps in order of their impact on drug shortages in Ireland, from most to least significant? *

The insufficient utilization and examination of available data to fully understand the reasons behind medication shortages.

The insufficient communication and teamwork among various stakeholders.

Inadequate attention to the commercial aspects such as pricing, sourcing, procurement practices, market dynamics, and supply chain management.

Limited Integration of Technological Solutions.

10. Select any two key areas that need improvement mostly in the current approach to managing and preventing drug shortages? *

Please select 2 options.

Enhanced Communication and collaboration

Supply Chain Transparency

Regulatory Reforms

Diversification of Suppliers

Early Warning Systems

Other

11. How would you rate the current strategies in place for managing and preventing medicine shortages in Ireland? *



Recommendation Analysis

12. Rank the following based on how you decide to give order of supplying medicines to patients when there is a shortage, from most to least significant? *

Priority given to life-saving medications.

Based on the severity and urgency of medical conditions.

According to the patient's age or vulnerability.

Alternative medicine is provided based on prescription.

First-come, first-served basis.

13. Based on your experience and insights, what specific recommendations would you propose for mitigating medicine shortages in Ireland in the future? *

14. Are there any additional strategies or approaches not covered in this survey that you believe would be effective in addressing medicine shortages?

End of the Survey

We sincerely welcome any additional comments or insights you may have regarding the Drug shortage in Ireland. Your valuable input will contribute significantly to the depth and comprehensiveness of our research. Please feel free to share your thoughts, experiences, or any relevant information that you believe could enhance our understanding of this critical subject.

For any questions or further information, please do not hesitate to contact me through the email address below.

riyapaul032001@gmail.com

Your participation is highly appreciated, and we thank you for your time and contribution to our study.

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