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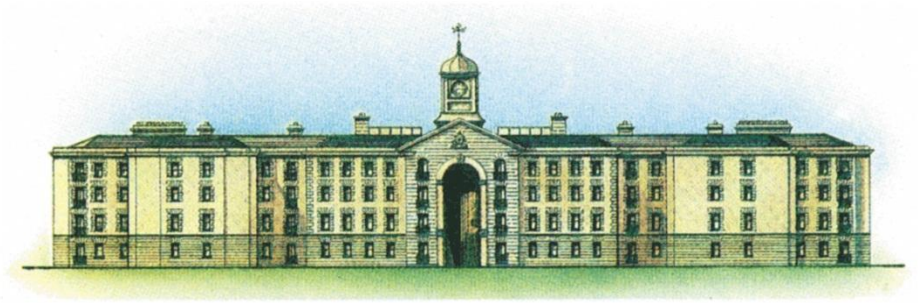

Griffith College

"COMPARATIVE ANALYSIS OF OVER THE COUNTER (OTC) PAIN RELIEVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA"

Research dissertation presented in partial fulfilment of the requirements for the degree of MSc in Pharmaceutical Business and Technology, Inno pharma Faculty of Pharmaceutical Science, Griffith College

DISSERTATION SUPERVISOR: - GANIRU PRISCILLA UGWU

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MAY 2025

CANDIDATE DECLARATION

I hereby declare that the dissertation entitled "COMPARATIVE ANALYSIS OF OVER THE COUNTER (OTC) PAIN RELIEVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA" is submitted in partial fulfilment of MSc in Pharmaceutical Business and Technology is my original piece of work and due acknowledgment is given, where the reference is made to others work. I also affirm that I have not plagiarised anybody else's work, either partially or entirely, including other students.

Candidate Name: ALEENA MANOJ Date: 11/05/2025

Candidate signature:

Supervisor Name: GANIRU PRISCILLA UGWU Date:

Supervisor Signature:

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LIST OF ABBREVATIONS

OTC	Over-the-counter
HPRA	Health Products Regulatory Authority
CDSCO	Central Drugs Standard Control Organisation
EU	European Union
EMA	European Medicines Agency
FDA	Food and Drug Administration
ICH	International council for Harmonisation
GMP	Good Manufacturing Practices
API	Active Pharmaceutical Ingredient
IP	Indian Pharmacopeia
AI	Artificial Intelligence
IMB	Irish Medicines Board

ABSTRACT

COMPARATIVE ANALYSIS OF OVER THE COUNTER (OTC) PAIN RELIEVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA

ALEENA MANOJ

This study examined the differences in recall practices for over- the counter (OTC) pain relievers in Ireland and India, focusing on quality related issues, regulatory enforcement and recall outcomes. With increasing reliance on OTC medications such as paracetamol and ibuprofen for self-medication, ensuring drug quality and safety is paramount. The study explores the differences between Ireland's centralised, EU-aligned regulatory model governed by the Health Products Regulatory Authority (HPRA) and India's decentralised recall system under the Central Drugs Standard Control Organisation (CDSCO).

Using a mixed-methods approach, recall data from the past 2 years were analysed alongside expert interviews to categorise recall causes and evaluate the effectiveness of recall systems. It was shown that Ireland's centralised, Eu aligned recall framework enables quicker and more transparent recall execution compared to India's decentralised and inconsistently enforced system. Contamination and mislabelling were identified as the leading causes of recalls, with India exhibiting a higher frequency of such events due to weaker post-marketing surveillance and inadequate regulatory infrastructure.

The findings revealed significant gaps in recall tracking and consumer notification in India, while Ireland faced challenges related to Eu coordination delays. The analysis highlighted that despite regulatory progress in both countries, key gaps persist in recall traceability, communication and stakeholder compliance. India's fragmented recall structure hampers timely action while Ireland reliance on EU coordination can create inter-agency delays. The conclusions drawn from these findings suggest that regulatory efficiency, digital traceability and public communication are critical in safeguarding patient safety.

This dissertation concludes that effective recall management requires strategic reforms tailored to each country's regulatory landscape. enforcement consistency and public communication. Strategic recommendations were proposed, including the implementation of centralised recall database in India, adoption of digital traceability systems, greater consumer education efforts and greater alignment with global best practices. These measures are essential for reducing the occurrence and impact of substandard OTC pain relievers and tom restore public trust in pharmaceutical quality control. The study underscores the need for harmonised international best practices to improve drug safety and protect public health.

CHAPTER 1: INTRODUCTION

Over the counter pain relievers are widely used medications that provide relief from pain and fever and are sold directly to the people without a prescription.(Kennedy, 1996; NIH, 2017) These medications include paracetamol, ibuprofen , aspirin which are essential in both developed and developing nations due to their accessibility and effectiveness. Ensuring high quality standards is crucial, as millions of people relay on that for health management as any defects or contamination can lead to serious health risks.(Kalidindi *et al.*, 2024) Despite regulatory efforts, recalls continue to pose challenges due to inconsistencies in enforcement, affecting the patient safety, consumer trust and pharmaceutical industry's reputation. This study focuses on OTC pain reliever recalls in Ireland and India, two different countries with distinct regulatory frameworks and enforcement strategies by comparing the recall management systems, regulatory enforcements and recall trends in Ireland and India.

1.1. BACKGROUND OF THE STUDY

As OTC being a non-prescription drug, they are widely sold across pharmacies, super markets and online platforms making them a key component of self-medication practices. India and Ireland offer a contrasting landscape of pharmaceutical regulations and recall management systems. Ireland, as part of the European Union (EU) adheres to strict quality control measures under the HPRA and the European Medicines Agency (EMA). The centralised regulatory structures ensure standardised enforcement, efficient recall execution and high transparency public safety communication. India, on the other hand has a rapidly growing pharmaceutical industry, being one of the world's largest producers of generic drugs.(Jadaun *et al.*, 2023) However, the country's recall management systems are decentralised, with enforcement varying across different states under the supervision of Central Drugs Standard Control Organisation (CDSCO). This decentralised approach often leads to delay in recall execution and enforce challenges in tracking defective medications. The recall process significantly affects multiple stakeholders including consumers, healthcare providers, pharmaceutical manufactures and regulatory authorities. For consumers it can affect the health and quality of life while for pharmaceutical companies, recall impose financial loss, supply chain disruptions and reputational damage.

Despite the importance of pharmaceutical recall management, existing research on recall practices remains fragmented, with most studies focusing on highly regulated markets such as United States Food and Drug Administration (FDA). There is limited comparative research on how different

regulatory guidelines affect recall efficiency, particularly in emerging markets like India. Additionally, while studies explore pharmaceutical recalls in general, fewer focus specifically on OTC pain relievers despite their widespread used and its role in public health. This research aims to bridge these knowledge gaps by analysing recall trends, regulatory enforcement and recall management efficiency in Ireland and India. The findings will provide valuable insights for regulatory authorities, pharmaceutical manufacturers policy makers and healthcare professionals.

1.2. RESEARCH AIM

The aim of the study is to conduct a comprehensive comparative analysis of OTC pain reliever recalls in Ireland and India. This research seeks to evaluate the trends and regulatory responses to these recalls while examining their impact on patient safety and pharmaceutical business. Furthermore, this research will quantify and categorise the types of quality issues leading to recalls over a two-year period and explore best practices to enhance recall management in Ireland and India.

1.3. RESEARCH OBJECTIVES

1. To analyse recall trends of OTC pain relievers in Ireland and India.
2. To compare the regulatory frameworks and recall strategies employed in Ireland and India.
3. To evaluate the impact of OTC pain reliever recalls on patient safety in Ireland and India
4. To assess the economic and business impact of OTC pain reliever recalls on pharmaceutical companies in Ireland and India
5. To quantity and categorise the types of quality issues leading to recalls in India and Ireland over a period of 2 years.
6. To explore the best practices and propose strategic recommendations based on findings for improving OTC recall management.

1.4. RESEARCH PURPOSE

The purpose of the study is to conduct the comparative analysis of OTC pain reliever recalls in Ireland and India, focusing on regulatory frameworks and impact on patient safety and pharmaceutical business. This research identifies the gaps in existing recall management systems, assess the effectiveness of regulatory oversight and analyse recall trends over a two-year period to provide an evidence- based evaluation of the key challenges faced by both countries. Additionally, this study seeks to quantify and categorize the primary quality-related issues leading to recalls, offering insights into the most prevalent manufacturing and compliance failures. By evaluating the economic consequences of recalls on pharmaceutical companies, this research highlights the financial risk, and

operational disruptions caused by substandard products. Furthermore, the study explores best practices in recall process by proposing strategic recommendations for enhancing recall management. As a result, this research contributes in improving pharmaceutical regulatory policies, strengthening quality control measures and ensure better protection for consumers in both Ireland and India.

1.5. SIGNIFICANCE OF THE STUDY

By analysing the recall trends of OTC pain relievers in Ireland and India, this research will provide valuable insights for policy makers, regulatory authorities and pharmaceutical manufacturers. This research provides a deeper understanding of the challenges posed by quality-related recalls and effectiveness of existing regulatory frameworks in managing them. It will also highlight gaps and inefficiencies in recall management systems, helping regulatory authorities such as HPRA and CDSCO to refine their recall polices. For pharmaceutical companies, this research provides an idea about the key reasons for recalls and the financial and reputational risks associated with them. Understanding of common quality failures will enable manufacturers to enhance their production and quality assurance processes, thereby reducing the likelihood of recalls and ensuring compliance with international standards. Furthermore, by examining the economic impact of recalls, businesses can develop proactive strategies to mitigate financial loss and strengthen their market position.

Healthcare professionals will benefit from this study by gaining awareness of the risks associated with substandard OTC pain relievers and learning how recalls affect patient safety. This can aid in better patient counselling, ensuring that recalled medications should not reach the patients. Policymakers can use the findings to design more stringent regulations and ensure stronger enforcement measures to prevent OTC pain reliever recalls. Ultimately the study provides evidence-based recommendations to enhance recall management, strengthen drug quality control and improve overall pharmaceutical safety in both Ireland and India. With India being the 12th major exporter of pharmaceuticals and Ireland being the key player in the EU pharmaceutical market, this study will provide a comparative perspective on overall recall practices and can help to introduce best practices (Jadaun *et al.*, 2023).

1.6. RESEARCH QUESTIONS

1. What are the major quality issues leading to OTC pain reliever recalls in Ireland and India?
2. How do regulatory frameworks differ in handling recalls in Ireland and India?
3. What role does regulatory authorities play in OTC drug reliever recall management?
4. How do OTC pain reliever recalls affect patient health, consumer confidence and medication adherence?

5. What challenges do pharmaceutical companies face in maintaining quality standards in Ireland and India?
6. What are the key gaps and inefficiencies in the current recall management systems?
7. What recommendations can be proposed to enhance regulatory oversight and quality control in both Ireland and India?

1.7. RELEVANT MODULE

The relevant module for this study is The Regulatory Landscape of Pharmaceutical Business, which is highly important as it offers a comprehensive understanding of regulatory frameworks, compliance standards, and recall management. This module has prepared me with the essential knowledge to navigate global pharmaceutical regulations, making it especially valuable for analysing real-world case studies.

1.8. DISPOSITION OF THE STUDY

This dissertation is structured into five key chapters, each focusing on different aspects of the research on OTC pain reliever recalls in Ireland and India. Each chapter systematically builds upon the previous one to provide a comprehensive analysis of the research problem, methodology, findings and conclusions.

Chapter 1: Introduction

This chapter provides the foundation for the study by introducing the background, research aim, objectives and significance. It outlines the relevance of OTC pain reliever recalls, discusses the need for a comparative analysis between Ireland and India, and highlights the potential impact of the research on regulatory policies and pharmaceutical practices.

Chapter 2: Literature Review

This chapter presents an extensive review of existing literature related to pharmaceutical recalls, focusing on trends and regulatory frameworks in different countries. It explores the theoretical foundations of drug safety, previous studies on recall management, and the role of international regulatory bodies. The literature review helps identify gaps in existing research and justifies the need for this study.

Chapter 3: Research Methodology

This chapter details the research design, data collection methods and analytical approaches used in the study. It explains the mixed- methods approach involving both qualitative and quantitative data

sources, including regulatory reports, expert interview, surveys and case studies. Additionally, it discusses ethical considerations, data validation techniques and limitations of the study.

Chapter 4: Data analysis and Findings

This chapter presents the results of the study based on the collection data. It includes statistical analyses of recall trends, classification of quality related issues and thematic analysis of expert insights. The findings are discussed in relation to the research objectives, highlighting key differences and similarities in recall management between Ireland and India.

Chapter 5: Discussion and conclusion

The final chapter interprets the study's findings, linking them to existing literature and theoretical frameworks. It provides strategic recommendations for improving recall management, regulatory enforcement and pharmaceutical quality control. The chapter concludes with reflections on the study's contributions, practical implications and suggestion for future research.

CHAPTER 2: LITERATURE REVIEW

The chapter provides a comparative analysis of Ireland's and India's recall managements system, highlighting the key differences in regulatory guidelines, recall effectiveness and consumer awareness through literature review.

2.1. OVERVIEW OF OTC PAIN RELIEVER RECALLS

OTC pain reliever recalls are typically initiated due to various quality issues, including contamination, labelling errors stability problems, packaging defects and formulation inconsistencies. (Bond and Hannaford, 2003; Vvss *et al.*, 2020) Recent trends indicate a notable increase in OTC pain reliever recalls in both Ireland and India. In Ireland, the Health Products Regulatory Authority (HPRA) has reported a change from 124 medicines (2020)(HPRA, 2021) to 60 (2023)(HPRA, 2023) medicines that has been recalled by the organisation over the past 2 years. While, India has experienced a more substantial rise as from the 950 batches that has been recalled in 2019-2020 period where as it has changed into 1394 batches in 2023-2024 period by the CDSCO (The Economic times, 2024a; Patel, 2024). This upward trend highlights the need for improved quality control measures and more robust regulatory frameworks.

The reasons for recalls vary between the two countries, with contamination being more prevalent in Indian recalls, (Varshney *et al.*, 2024; Rapoza, 2025) while labelling errors are more common in Ireland(Roberts, 2025). These differences underscore the importance of tailored approaches to address recall issues in different regulatory environments. The impact of recalls on patient health and consumer trust cannot be understated. As per *Algabbani et al.*, the frequent recalls can lead to changes in consumer behaviour, including reluctance to use certain brands and increased concerns about medication quality (Algabbani *et al.*, 2023; Drugzone, 2024).

2.2. RECALL TRENDS IN INDIA AND IRELAND

Recall trends for over-the-counter pain relievers in Ireland and India have shown significant increases in recent years, reflecting growing concerns about product quality and safety in both countries. In Ireland, the HPRA has reported an increase in OTC pain reliever recalls over the past two years. (HPRA, 2025b; HPRA, 2025a) This trend indicates need for an extra vigilance in the Irish pharmaceutical regulatory system, with a focus on maintaining stringent quality control measures. The pharmaceutical recall process in Ireland is highly structured, aligning with the EMA regulations under the oversight of HPRA. Ireland follows a centralised recall system, ensuring that defective medications including OTC pain relievers, are swiftly identified, reported and removed from the

market(HPRA, 2017). The most common reasons for OTC pain reliever recall in Ireland include contamination (microbial, chemical or foreign particles), mislabelling (incorrect dosage or missing safety information) and potency inconsistencies (Vvss *et al.*, 2020; Ghijs *et al.*, 2024). The HPRA employs public databases, online recall alerts and direct communication with healthcare professionals to ensure that recalled medications are removed from the market as quickly as possible(HPRA, 2025d).Additionally, pharmaceutical companies in Ireland are required to adhere to Good Manufacturing Practices (GMP), minimizing the risk of widespread products defects. They key trend in Ireland is the integration of digital recall systems, where recalls are publicly announced in real time, ensuring transparency and consumer awareness(EMA, 2021; Gilija, 2024). However, one challenge in the Irish recall system is its dependence on the broader EU regulatory framework, which can sometimes lead to delays in multi-country recall execution when coordination is required across different authority(EU, 2004; HPRA, 2017).

In India, the recall trend has been even more pronounced, with the CDSCO documenting a much greater rise in OTC pain reliever recalls (CDSCO, 2025). India does not have a centralised recall database, leading to delays in tracking and executing recalls across different states (Batham, 2013). The most common cause of OTC pain reliever recalls in India include contaminated products, counterfeit drugs, substandard active ingredients and incorrect labelling, which has been identified over the last 2 years (CDSCO, 2025). This difference underscores the need for enhanced manufacturing practices and quality control measures in the Indian pharmaceutical sector. Studies show that India has a higher frequency of pharmaceutical recalls compared to Ireland, primarily due to manufacturing inconsistencies, supply chain vulnerabilities and regulatory lapses (Bhalodiya *et al.*, 2023). In India even with various levels of recalls systems and recall alerts systems consumer awareness of recalls remains low, as public notifications are not widely distributed and patients may continue using recalled products unknowingly (Varshney *et al.*, 2024). The introduction of advanced quality control technologies, real time product traceability systems and strengthen enforcement measures could help bridge the gap between India and more regulated markets like Ireland (Vvss *et al.*, 2020; Dahiya, 2023).

2.3. REGULATORY FRAMEWORKS AND RECALL STRATEGIES

Different countries implement varied regulatory approaches to drug recalls, influenced by legal frameworks, healthcare need and enforcement capabilities (Vvss *et al.*, 2020). In Ireland and in EU, the recall process is centralised and strictly regulated under agencies like HPRA and EMA, ensuring uniformity and efficiency in recall execution (HPRA, 2017; EMA, 2021). In contrast, Indian's recall

management is decentralised, regulated by the CDSCO alongside state level drug control authorities, which creates inconsistencies in recall enforcement and execution speed (Dahiya, 2023).

The EMA and HPRA in Ireland classify recalls into three categories based on their severity and potential risk to public health. Class 1 recalls involve products that pose life threatening risk, requiring immediate action to remove them from the circulation. Class II recalls address moderate health risk, while Class II recalls involve products with minor defects that do not pose a direct health hazard. Once recall is initiated in Ireland, companies must notify regulatory authorities, healthcare providers and the public through structured channels, ensuring timely withdrawal of the affected drug. Ireland benefits from the EU -wide Rapid Alert system for drug recalls, allowing cross border collaboration in recalling defective medications (HPRA, 2017; Gilija, 2024). Conversely, India's CDSCO lacks a centralised recall tracking system, leading to delays in notifying consumers and ensuring recalled products are completely removed from circulation. Studies indicate that many recalled drugs in India continue to sell in pharmacies even after official recall announcements due to the lack of a proper recall laws. Along with this, the weak enforcement of laws, lack of consumer awareness and fragmented regulatory oversight can contribute to this issue (The Hindu, 2023). To address these gaps, India has introduced updated guidelines aimed at strengthening recall management, improving regulatory transparency and ensuring timely public notification. However, challenges such as interstate coordination, lack of recall monitoring databases and limited consumer education remain barriers to effective recall execution (Stubb and Kasiva, 2023).

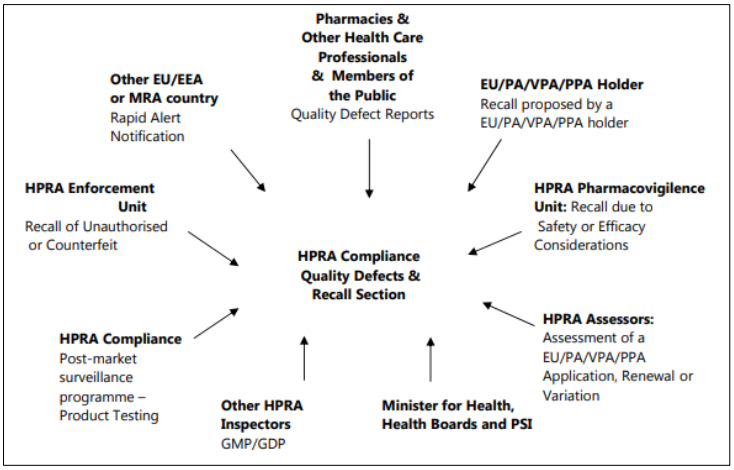

Figure 1:- Sources of product recall notifications received by HPRA (HPRA, 2017)

In addition to differences in regulatory structures, the strategies used to execute recalls in Ireland and India also very significantly. In Ireland, pharmaceutical recalls are supported by stringent pharmacovigilance policies, requiring continuous post marketing surveillance and adverse event

reporting to detect safety concerns early (HPRA, 2025c). The transparency of Ireland's recall system allows consumers to access real time recall alerts via public databases and government websites there by increases the awareness and compliance (IDA Ireland, 2025). In contrast, India's recall strategies relay heavily on voluntary compliance by manufacturers with no unified national recall databases to track recall execution across different states (Kalidindi *et al.*, 2024). Additionally, public recall announcements in India are often limited, leaving many consumers unaware that they are using recalled medications (Bhalodiya *et al.*, 2023; Varshney *et al.*, 2024).

Recall Classification	Class I	Class II	Class III	Caution in Use Notification
Notification Period**	Within 24hrs	Within 72hrs	Within 5 days	Within 5 days
Method of Notification	Phone & fax, Radio/TV (if necessary), press announcements followed by letter	Letter/Fax if necessary, followed by phone (if necessary)	Letter/Fax if necessary,	Letter
Extent of Notification	Wholesalers, pharmacies, other retailers, medical practitioners and patients,	Wholesalers, pharmacies, other retailers possibly medical practitioners	Wholesalers, possibly pharmacies and other retailers	Pharmacies, possibly medical practitioners possibly wholesalers.
Method of Retrieval of recalled stock	Direct uplift of stock	Via wholesaler	Via wholesaler	Not applicable

Figure 2:- Notification process for recall process by HPRA (HPRA, 2017)

The economic impact of drug recalls is another critical factor influencing regulatory enforcement and industry practices. In both Ireland and India, pharmaceutical companies bear significant financial losses due to product recalls, legal liabilities and reputational damage. However, Ireland's structured regulatory network reduces long term risk by ensuring that recalls are managed efficiently, minimising supply chain disruptions. In India, delays in recall execution often leads to increased legal issues, consumer distrust and long-term economic consequences for the pharmaceutical firms (Dutta, 2024). As per Miglani *et al.,* the companies with proactive quality control measures and strong regulatory compliance frameworks are less likely to experience large scale recalls, highlighting the importance of strict manufacturing oversight and preventive measures (Miglani *et al.*, 2022). Improving recall strategies in both countries will require ongoing collaboration between regulatory agencies, pharmaceutical companies and healthcare providers. Additionally, public awareness campaigns play a crucial role in educating consumers about recalled medications and encouraging proper compliance with recall notices (Joseph L. Fink III, 2012).

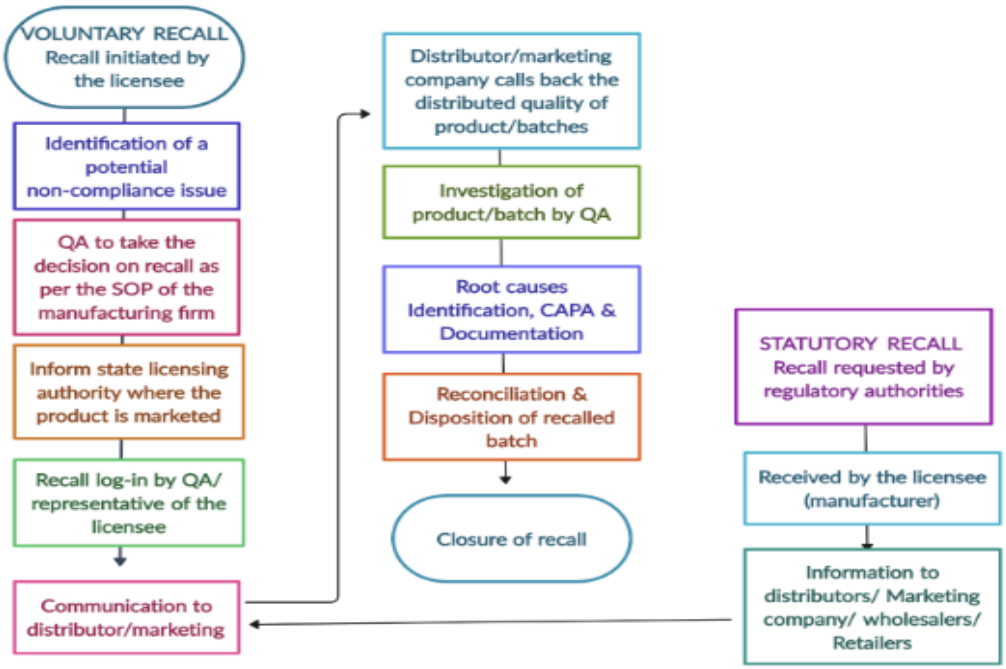

Figure 3:- Recall process by CDSCO(Kalidindi et al.*, 2024)*

2.4. IMPACT OF OTC PAIN RELIEVER RECALLS ON PATIENT SAFETY

The recall of OTC pain relievers due to quality issues presents significant challenges to patient health, particularly in terms of drug safety, accessibility and trust in healthcare systems (Cusack *et al.*, 2021). One of the most immediate concerns is the direct health impact on patients who have already consumed defective products. Contaminated or substandard pain relievers can lead to adverse reactions ranging from mild discomfort such as gastro intestinal issues, and severe consequences including organ toxicity, allergic reactions or even fatalities (Cavany *et al.*, 2023; WHO, 2024). The presence of microbial contamination a frequent cause of recalls can be particularly dangerous for immunocompromised individuals, leading to life threatening infections (Salami *et al.*, 2023). Underdosing may result in ineffective pain management, causing prolonged suffering and increased reliance on additional medications, which in turn raises the risk of polypharmacy and drug interactions(Tariq *et al.*, 2024). Overdosing on the other hand, can lead to toxicity, particularly in drugs like paracetamol, where exceeding the recommended dose may cause liver failure. (Rasool *et al.*, 2020). Moreover, recalls often cause uncertainty regarding alternative medication options, especially when patients rely on a particular brand or formulation. This is especially concerning for those with chronic pain conditions who require consistent pain relief medications. Patients who lose access to their regular medication may experience worsened symptoms, increased stress and a

diminished quality of life (Drugzone, 2024). The search for alternative pain relief options can be daunting and time-consuming process, often involving multiple doctor visits, trial and error with different medications and the potential for increased healthcare costs (Lin and Hertig, 2023). Ireland has come up solutions for this issues as they in accordance with EMA publish interchangeable drug list which can be effectively used for finding the best alternative for recalled medication (HPRA, 2025a). The lack of immediate access to accurate recall information, particularly in regions where regulatory communication is slow, further exacerbates the risks for patients who may unknowingly continue using recalled products. Public health campaigns are then needed to restore trust and promote adherence to prescribed treatment plans (Varshney *et al.*, 2024).

Beyond immediate health concerns, the long-term impact of recalls on patient behaviour and trust in healthcare systems is profound. Patients who repeatedly experience recalls of widely used medications may develop scepticism toward pharmaceutical manufacturers, regulatory authorities, even medical professionals. This erosion of trust can discourage patients from adhering to prescribed treatments, increasing the likelihood of self-medication or reliance on unregulated sources, which may be dangerous (Kalidindi *et al.*, 2024). In Ireland, patients are better informed and take prompt action to discontinue the use of recalled drugs (HPRA, 2017). However, in India delays in public notifications, mainly in rural areas, where access to healthcare professionals and up to date information is limited (Dahiya, 2023). Additionally, the financial strain of purchasing new medications, coupled with potential medical expense arising from adverse drug reactions, place additional stress on affected individuals. While multinational pharmaceutical companies operating in Ireland may offer replacement medications or refunds, many Indian patients, particularly those in rural areas may struggle to afford alternative treatment options (Honeywell, 2024; Drugzone, 2024).

2.5. IMPACT OF OVER-THE-COUNTER PAIN RELIEVER RECALL ON PHARMACEUTICAL INDUSTRY

Financial losses incurred due to recalls are mixed expenses, from direct and indirect costs that can significantly affect a company's profitability and long-term sustainability (Miglani *et al.*, 2022). Direct costs include the expenses associated with retrieving recalled products, conducting investigations to determine the root cause regulatory compliance penalties and compensating affected consumers. These expenditures are substantial, especially when a recall involves a widely distributed product, requiring extensive coordination across multiple retail chains, pharmacies and distributors (Daga, 2018; Drug.Card, 2023). Furthermore, large scale recalls often necessitate production halts or manufacturing plant shutdowns for quality audits and process corrections, further exacerbating

revenue losses. Beyond these immediate costs, indirect financial losses include damage to brand reputation and consumer trust, which has everlasting effects on the sales (Nagaich and Sadhna, 2015). As per Miglani *et al.*, Consumers who associate a brand with frequent recalls may switch to competitors, leading to declining market share and lower future revenue projections (Miglani *et al.*, 2022).

Unlike larger firms with diversified product portfolios, smaller manufactures often rely heavily on a limited range of drugs, making a recall of a high demand OTC pain reliever an existential threat. Insurance premiums for pharmaceutical companies also rise in response to frequent recalls, adding another financial burden (Chawla *et al.*, 2016). Companies with a history of recalls may struggle to secure investments or partnership, as stakeholders become wary of potential future liabilities (Daga, 2018). The need for extensive legal representation, consumer settlements and potential class actions lawsuits further compounds financial strain, with litigation costs sometimes exceeding the initial recall expenses. Additionally, companies exporting from India to regulated markets such as EU and the US face heightened scrutiny from agencies like EMA and FDA which can impose import bans or additional regulatory requirements, making market re-entry more difficult (Vvss *et al.*, 2020; Wassel *et al.*, 2023). The impact on stock prices is another financial consideration, as publicly traded pharmaceutical firms often experience sharp declines in share value following high profile recalls. Rebuilding investor confidence requires substantial effort, including transparency in recall handling, investment in quality assurance measures and proactive engagement with regulatory agencies (Gopinath *et al.*, 2011; Miglani *et al.*, 2022).

The supply chain disruptions caused by the OTC pain reliever recalls present major challenges for pharmaceutical companies, affecting production timelines, distribution networks and market stability (Bilodeau, 2022). For companies that operate across multiple markets, such as those manufacturing in India for distribution in Ireland, recalls can lead to increased regulatory inspections, stricter import controls and greater difficulty in maintaining a steady supply of products. These disruptions often result in shortages of essential pain relievers, forcing pharmacies and retailers to seek alternative suppliers. This can permanently alter existing supplier- retailer relationships (Nagaich and Sadhna, 2015; Harrison, 2020). The loss of shelf space due to recalls is another critical issue, as major retailers and pharmacies may reluctant to stock recalled brands in the future. This shift can lead to a long-term decline in market penetration and revenue generation for affected companies (Pharmacy Business, 2023; Drugzone, 2024). Recalls also place a strain on contract manufacturing organisations (CMO) that produce OTC pain relievers for multiple pharmaceutical brands. A recall involving a CMO can be a ripple effect, impacting multiple companies relaying in the same facility. This can lead to loss of

business for the manufacturer and potential legal disputes over liability (Manufacturing Net, 2012; Sinha, 2016). In cases where contamination or quality failures originate from raw material suppliers, pharmaceutical companies may be forced to break supplier contracts that can led to supply shortages and production delays (Sinha, 2016; Miglani *et al.*, 2022).

Market stability is another concern, as recalls can lead to fluctuations in consumer demand, regulatory restrictions and increased competition. Companies experiencing frequent recalls may struggle to retain their market position, as competitors capitalise on their vulnerabilities to gain consumer trust. For instance, a well manged recall by a competitor – where transparency and swift action are prioritized – can create a perception of superior quality standards. This can lead to increased market share for the competitors (Fierce Pharma, 2012; Harrison, 2020). Companies that fail to recover effectively from recalls risk being permanently sidelined in favour of more reliable alternatives (Nagaich and Sadhna, 2015; Drug.Card, 2023). Companies that proactively implement strategic responses may not only reduce the risk of future recalls but also position themselves as industry leaders in quality and safety (Marcotte, 2021; Kalidindi *et al.*, 2024).

2.6. QUALITY ISSUES LEADING TO OTC PAIN RELIEVER RECALLS

Quality issues leading to the recall of over-the-counter (OTC) pain relievers are multifaceted, ranging from contamination and mislabelling to formulation inconsistencies and stability failures (Neupane *et al.*, 2022). Microbial contamination, particularly in liquid pain relievers has been a recurring issue, leading to drug recalls in both Ireland and India. The presence of harmful bacteria, fungi or endotoxins in pharmaceutical formulations can cause serious infections. Contamination often occurs due to lapses in Good Manufacturing Practices (GMP), such as inadequate sterilisation process, raw materials used insufficient quality control testing or environmental exposure during production (Buntz, 2023). Another significant quality issue is the presence of toxic impurities, which can result from chemical degradation, residual solvents or cross contamination during manufacturing. For example, the detection of carcinogenic nitrosamine impurities in some OTC medications like ranitidine, has led to global recalls in recent years. Such impurities can form due to improper chemical synthesis, inadequate purification process or storage under suboptimal conditions (Pharmtech, 2019; Rosenfeld, 2019; White, 2020). Furthermore, recalls have been triggered by the presence of foreign particles which may enter drug formulations due to faulty equipment, inadequate filtration systems or poor handling procedures. These physical contaminants pose a serious risk, as they can cause internal injuries, gastrointestinal issues, or toxicity if ingested (Tawde, 2015; MHRA, 2023; Liu and Hutchinson, 2024). In India, where pharmaceutical regulations are inconsistently enforced across

different states, contamination risk are further heightened due to variability in GMP compliance among manufacturing facilities (Buntz, 2023). In contrast, Ireland's pharmaceutical sector operates under strict regulatory oversight, yet contamination related recalls still occur, particularly due to unexpected failures in adherence with cGMP (Kavanagh *et al.*, 2024).

Another major factor contributing to OTC pain reliever recalls is mislabelling and packaging errors, which can lead to incorrect dosing, potential overdoses and unintended side effects. Labelling errors encompass a range of issues, including incorrect dosage instructions, missing or inaccurate warnings and misprinted expiration dates. Such errors can have life threatening consequences, especially for medications with narrow therapeutic index, such as paracetamol, where even a slight overdose can lead to liver failure(Pharma news, 2024; Roberts, 2025). Packaging defects, such as compromised blister packs, leaking bottles or faulty child resistant caps also contribute to product recalls, as they affect integrity and safety of the medication (Law, 2023; Keenan, 2023). Stability failures are another prominent issue, where the API degrades over time making the medication ineffective or harmful (Vvss *et al.*, 2020; Bhalodiya *et al.*, 2023). In Ireland, regulatory bodies, like HPRA enforce stringent stability testing requirements to ensure that medications maintain efficacy throughout their shelf life. However, stability related recalls still occur when unexpected degradation products are identified during post market surveillance (Kavanagh *et al.*, 2024; IDA Ireland, 2025). In India, where supply chain infrastructure varies significantly stability issues are more common. Mainly in rural areas where medication may be stored under suboptimal conditions (Stubb and Kasiva, 2023; Varshney *et al.*, 2024).

2.7. GAPS AND INEFFICIENCIES IN CURRENT RECALL MANAGEMENT SYSTEMS

Despite the existence of regulatory frameworks governing the recall of OTC pain relievers in both Ireland and India, significant gaps and inefficiencies continue to hinder the effectiveness of these recall management systems. One of the most pressing concerns is the lack of a centralised and transparent recall database, particularly in India. In India, the recall notifications are scattered across different regulatory authorities which makes it difficult for the consumers, healthcare providers and supply chain stakeholders to track recalled products (Stubb and Kasiva, 2023). Unlike Ireland, where the HPRA maintains a publicly accessible recall databases aligned with EMA standards India lacks a national recall registry. This absence of centralised tracking systems increases the risk of defective OTC pain relievers remaining in the circulation especially in rural and semi urban areas where regulatory oversight is weaker (Batham, 2013). Additionally delayed recall execution is a significant

challenge in both countries. In India, recalls are often executed at a state level rather than a national level, resulting in fragmented enforcement and varying response times (Dahiya, 2023). While, Ireland's recall management system is more structured and aligned with EU regulatory frameworks, challenges still persist. The recall process, while effective in theory, can face delays due to complex procedural requirements, supply chain logistics and the need for multi- stakeholder coordination. Furthermore, Ireland's system largely relies on voluntary compliance from manufacturers and distributors, meaning the recall s may not be implemented as swiftly as required, particularly if a company downplays the severity of the issue to avoid financial and reputational damage (HPRA, 2017; Kavanagh *et al.*, 2024).

The reliance on self-reporting mechanism by pharmaceutical companies also poses a challenge as some manufactures may delay reporting quality defects to regulatory authorities due to concerns over litigation, market penalties or loss of consumer trust (Gopinath *et al.*, 2011). The lack of proactive monitoring and post marketing surveillance mechanism in India further exacerbates the inefficiencies in recall management. Unlike in Ireland, where regulatory authorities frequently conduct post market inspections and pharmacovigilance assessments (HPRA, 2025b). The absence of a robust adverse monitoring system in India means that consumer complaints and quality concerns may not always trigger immediate regulatory action, allowing substandard pain relievers to remain in market longer (Batham, 2013).

Another, critical inefficiency in recall management systems is the limited public awareness and inadequate risk communication strategies, which hinder consumer responsiveness to recall notices (Corbae, 2023). In Ireland, while regulatory agencies issue official recall notices through public databases, healthcare providers and pharmacies the public get required information (HPRA, 2017). But there is still a limited direct engagement with consumers particularly those who purchase OTC pain relievers without consulting pharmacists or medical professionals. This issue is even more pronounced in India, where recall notifications often do not reach consumers effectively, especially in rural and remote areas where access to digital platforms, healthcare providers and regulatory announcements are limited. The lack of widespread public education campaigns and direct consumer alerts means that many people continue using defective pain relievers, unaware of the associated health risks (Raju *et al.*, 2024; Kalidindi *et al.*, 2024). Additionally, Ireland benefits from EU-wide pharmaceutical safety alerts, recall communication primarily relies on healthcare institutions, regulatory websites and news releases, which may not reach all affected consumers promptly (Miglani *et al.*, 2022).

Another major gap in recall management systems is the absence of effective product retrieval mechanisms, which results in incomplete recalls and the continued presence of defective pain relievers in the market (Pulparambil and Shanthakumar, 2020). In Ireland, although manufactures and distributors are required to remove recalled products from pharmacies and retail stores, there is no standardised mechanism tracking whether all affected batches have been successfully removed (Marcotte, 2021). Similarly, in India where the pharmaceutical supply chain is highly fragmented, retrieving recalled products from small retailers, informal markets is a hectic process. Many recalled products, especially counterfeit or substandard pain relievers, often re-enter the supply chain through parallel markets, further undermining the effectiveness of recalls (CDSCO, 2017). The absence of strict penalties for noncompliance with recall orders in India also discourages swift action from the manufacturers and distributors, leading to prolonged consumer exposure to recalled medications (Krishnan and John, 2025). In Ireland, while pharmaceutical companies and regulators have begun exploring digital serialisation technologies, implementation remains inconsistent across different categories. In India, where supply chain digitalisation is still in its early stages, tracking recalled pain relievers from manufactures to end consumers is even more challenging (Vvss *et al.*, 2020). Ultimately improving recall frameworks in both will require stronger regulatory enforcement, technology integration and consumer awareness.

2.8. MAJOR OTC PAIN RELIEVER RECALLS IN INDIA AND IRELAND

Both India and Ireland have faced notable cases of OTC medications recalls, each serving as a reminder of the vulnerabilities that persist within pharmaceutical supply chains and regulatory systems (Vvss *et al.*, 2020). In Ireland, one of the most high-profile OTC drug recalls occurred in August 2011 when packs of Nurofen plus, an analgesic commonly used to manage pain, were found to be compromised. Consumers and pharmacist discovered that some packs contained other medications, including antipsychotic drug Seroquel XL (quetiapine) and the anticonvulsant Neurontin (gabapentin). These were found either in place of or alongside the actual intended drug. The Irish medicines board (IMB) which has since become HPRA, issues an immediate recall and advised consumers to return any suspicious packs. Pharmacists were instructed to inspect all stocks thoroughly (Orr, 2011). Although the issue was initially reported in the United Kingdom, where the suspected sabotage took place, Ireland's proactive response highlighted the importance of swift regulatory intervention in ensuring public safety. The manufacturer, Reckitt Benckiser, temporarily suspended distribution of Nurofen plus and launched an investigation in collaboration with regulatory authorities. This recall was significant not only because of the severity of the potential consequences

but also because it exposed potential lapses in packaging system, distribution practices and detection mechanisms within the European pharmaceutical supply chain (McLysaght, 2011).

A more recent and widely publicized OTC pain reliever recall in India occurred in October 2024, when Dr. Reddy's laboratory voluntarily recalled more than 3000 bottles of Ibuprofen from the US market. The product, manufactured at Dr. Reddy's Indian facility, failed to meet the specifications to pass the quality test. FDA had reported it as a class III recall, which is that the product exposure is not likely to produce any adverse effects. These deviations raised concerns regarding the formulation, quality assurance, and potentially toxic degradation products. This recall creates the need for real-time surveillance, robust consumer feedback process and the continuous training of personnel in Good Manufacturing Practices (GMP) (FDA, 2024; Qaderi, 2024). Another recall that raised alarm occurred on June 2024, when the Indian regulators flagged 3 major brands (Alekm laboratories, Glenmark pharmaceuticals and Sun pharmaceutical industries) Over-the Counter medications and are categorised as not of standard quality. They flagged around 53 medications that contain paracetamol, a widely used OTC pain reliever across the world (Sadam, 2024). Apart from this, on September 2024, 92 medications including a paediatric paracetamol were recalled as the CDSCO found some deficiencies in the product. The identified medication failed to pass the assay test for paracetamol. Along with that it failed the description of suspension form, as the pink coloured medication forms a cake sedimentation at the bottles that cannot be redispersed by shaking (Didyala, 2024). This incident emphasized that even seemingly minor issues can have significant public health consequences when they involve high-consumption medications such as paracetamol.

Furthermore, there have been instances in India where pain-relieving medications were recalled due to the presence of unapproved excipients or microbial contamination. Sanofi, a popular manufacturer has recalled combiflam suspension from the market due to contamination found in some batches. Combiflam is a medication used for reducing fever or pain and it is a combination of ibuprofen and paracetamol. As the microbial contamination prompted a recall and temporary suspension of production all over India (The Economic times, 2024b; Sharma, 2024). In contrast to the relatively frequent but less-publicized Indian recalls, Ireland has seen fewer but more high-profile cases related to OTC painkillers, reflecting its more consolidated regulatory infrastructure and smaller pharmaceutical market size. The Nurofen Plus case remains the most cited example due to the seriousness of the medication mix-up. However, there have been other recalls involving OTC ibuprofen and paracetamol products in Ireland, primarily driven by stability concerns and packaging defects. In 2019, certain batches of ibuprofen suspension intended for paediatric use were recalled

due to the overdosing of Ibuprofen, which could alter the intended dosage and pharmacokinetics. The HPRA acted quickly, working with pharmacists to identify and isolate affected batches and providing public advisories to ensure safe disposal and substitution. The high dose of ibuprofen can create an NSAID induced renal injury. No cases were reported after recall (EPR, 2019; Lascala, 2019). These examples reinforce that even in high-regulation environments, quality lapses can occur, especially when products are manufactured in bulk for rapid distribution. Collectively, these cases from India and Ireland underscore the critical importance of robust regulatory frameworks, vigilant post-marketing surveillance, and international cooperation in ensuring the safety and efficacy of OTC medications.

2.9. RESEARCH GAPS AND FUTURE RESEARCH DIRECTIONS

Despite extensive literature on OTC pain reliever recalls, significant research gaps remain, particularly in comparing Ireland and India. A key gap is the lack of data on recall execution efficiency and post-recall monitoring. While Ireland's HPRA provides accessible data, little research evaluates the effectiveness of product removal. In India, this issue is compounded by the absence of a centralized recall database and inconsistent regulation across states. Most studies focus on individual cases rather than systematically analysing recall trends, root causes, and long-term public health impacts. Another gap is the limited exploration of supply chain vulnerabilities, such as poor-quality raw materials, counterfeit products, and quality control failures. The effect of logistical and financial constraints on recall execution remains under-researched.

Consumer awareness and response to recalls, especially in India, are also poorly understood. There is limited research on public trust in regulators and behavioural responses to recalls across demographics. Future studies should explore the role of digital technologies—like mobile apps, SMS alerts, and blockchain—for improving recall communication and product removal. Policy-focused research is needed to assess potential improvements, such as stricter recall timelines, public disclosure, and stronger penalties in Ireland, and centralized systems and better enforcement in India. Comparative studies of global best practices could guide enhancements in both countries. The economic impact of recalls is another underexplored area, particularly long-term effects on brand reputation, investor confidence, and consumer trust. Future research should also examine how AI and predictive analytics can identify risks early and improve recall management. Addressing these gaps can help build more effective, transparent, and consumer-focused recall systems in Ireland and India.

2.10. CONCLUSION

The comparative analysis of OTC pain reliever recalls in Ireland and India reveals key challenges in quality control, regulatory frameworks, and recall management. Despite Ireland's stringent regulations under the HPRA and evolving oversight in India through the CDSCO, recalls remain a significant risk due to contamination, mislabelling, potency failures, and supply chain issues. Regulatory differences influence recall processes, with Ireland benefiting from structured EU-aligned systems, while India's fragmented enforcement, lack of centralized databases, and inconsistent compliance lead to delays, incomplete removals, and prolonged consumer exposure. Pharmaceutical companies in both countries face financial, reputational, and legal consequences from recalls. The impact on consumers includes low awareness, poor communication, and continued use of defective medications, leading to adverse health outcomes and reduced trust in OTC drug safety. Addressing these issues requires regulatory reforms, improved tracking systems, better surveillance, and enhanced recall transparency.

CHAPTER 3: - RESEARCH METHODOLOGY

3.1. OVERVIEW

This chapter outlines the research methodology used to conduct a comparative analysis of OTC pain reliever recalls in Ireland and India due to quality- related issues. This chapter adopts a comparative study design focusing on the different regulatory environments, market structures and enforcement practices in Ireland ani India. Qualitative and quantitative data will be collected from regulatory experts, industry professionals and healthcare providers through interviews, surveys and recalled databases from HPRA and CDSCO. As the chapter progress, it provides a detailed explanation for participant selection, ethical procedures and the conceptual framework that guides the research.

3.2. RESEARCH PHILOSOPHY

This study adopts a pragmatic research philosophy, which is particularly suitable for addressing complex, real world issues like pharmaceutical product recalls. It is appropriate to adopt to this philosophy when both measurable outcomes and contextual understanding are crucial for achieving the research objectives. Pragmatism is not confined to a single system of thought or reality. Instead, it values both subjective and objective knowledge and allows the researcher to apply the most appropriate tools and techniques to investigate the research problem. It allows integration between objective recall data and subjective expert perspectives, offering deeper insights than a mono-method approach.

In this study, the pragmatic philosophy enables the integration of both quantitative and qualitative methods. On one hand, pragmatic reasoning justifies the integration of quantitative data- derived from the analysis of publicly available recall data from Ireland's HPRA and India's CDSCO provides structured, numerical evidence about recall trends. On the other hand, qualitative interviews with regulatory professionals, health care providers and pharmaceutical industry professionals offer deeper insights into the regulatory, operational and institutional factors that contribute to recall events. Along with this a structured mixed format survey, designed to collect quantitative and qualitative data through Likert scale and open-ended questions.

Pragmatism is particularly relevant in comparative research, where goal is not only to measure differences but also to understand the underlying causes and contextual influences. This approach aligns with the study's aim to compare two different national regulatory environments and explore the implications of their differences in recall frequency, causes and management practices. By embracing a pragmatic philosophy, this research avoids the limitations of relying solely on positivist

(quantitative) or interpretivist (qualitative) paradigms. It supports a flexible, problem centred approach, allowing the researcher to address both what is happening (e.g.: recall rates, causes) and why it is happening (e.g.: regulatory gaps, manufacturing issues), leading to a more comprehensive and actionable recommendations.

3.4. RESEARCH APPROACH

This study employs a mixed- methods approach, combining both qualitative and quantitative strategies to comprehensively examine the nature and causes of OTC pain reliever recalls in Ireland and India. This dual approach enhances the depth of the analysis, supporting integration of data sources and increasing the credibility of the findings.

3.4.1. QUALITATIVE APPROACH: INTERVIEWS

The qualitative component involves semi structured interviews with key stakeholders in the pharmaceutical recall process, including:

- Regulatory officials from HPRA (Ireland) and CDSCO (India)
- Healthcare providers such as pharmacists, doctors and nurses
- Pharmaceutical industry professionals, who have a knowledge about OTC pain reliever recalls.

These interviews aim to explore the perspectives of experts directly involved in drug safety, quality management and regulatory enforcement. It is designed to provides insights in the systematic and operational causes of product recalls, effectiveness and challenges of recall mechanism and regulatory gaps and best practices in each country. Participants for the study are selected through purposive sampling, ensuring those with direct experience in relevant areas are included.

3.4.2. QUANTITATIVE APPROACH: RECALL DATABASES

This involves the collection and analysis of publicly available data from official recall databases. This includes recall reports and notifications from the HPRA in Ireland and the CDSCO in India. This structured data will provide measurable insights into recall frequency, causes and trends over the 2-year period of 2023 to 2025. These databases act as a crucial step in comparison of Ireland and India and to help to identify systemic quality issues that they face.

3.4.3. QUANTITATIVE AND QUANTITATIVE APPROACH: SURVEYS

The quantitative approach will involve structured surveys distributed to a broader pool of professionals in the healthcare and pharmaceutical sectors in both countries. The surveys involve both Likert-scale (quantitative) and open-ended questions (qualitative) targeting pharmacists,

professionals in pharmaceutical companies and regulatory professionals. The survey will gather data on awareness of OTC recall events, recall management in each country, impact on patients and pharmaceutical business and recommendations for improvement in recall management. This mixed approach allows me to address both patterns of recalls along with deeper insights about dependent factors and stakeholder views and opinions on recalls.

3.5. RESEARCH STRATEGY

The research stagey adopted for this study is a comparative case study, which is particularly well-suited to examining differences and similarities in recall practices between two distinct regulatory environments – Ireland and India. The case study approach allows for in-depth exploration of contextual, structural and operational factors that influence the quality and recall of over-the counter (OTC) pain relievers in each country. A comparative strategy was selected because the study seeks to understand not only the patterns of regulatory frameworks, quality assurance practices, enforcement mechanism and post-market surveillance in both jurisdictions. By focusing on two contracting cases- a highly regulated, centralised EU system (Ireland) versus a complex, decentralised system (India) - the strategy enables a rich analysis of best practices, challenges and opportunities for improvement.

SL NO.	HEADING OF THE SECTION	NUMBER OF QUESTIONS
1	Introduction, participant consent and purpose of the study	2
2	General information	4
3	Recall Trends and causes	4
4	Regulatory framework and Recall strategies	8
5	Impact on Patient Safety	6
6	Impact on Pharmaceutical Business	4
7	Best practices and Recommendations	4

Table 1:- Representing the summary of survey questionnaire

SL NO.	HEADING OF THE SECTION	NUMBER OF QUESTIONS
1	General information	2
2	Recall Trends and causes	4
3	Regulatory framework and Recall strategies	5
4	Impact on Patient Safety	4
5	Impact on Pharmaceutical Business	3
6	Best practices and Recommendations	6

Table 2:- Representing the summary of interview questions

3.6. TIME HORIZON

This research adopts a cross-sectional horizon, which involves collecting data at a single point in time or within short, defined time frame. This approach is suitable for capturing a snapshot of current and recent trends in OTC pain reliever recalls, as well as stakeholder perceptions related to quality issues, regulatory practices and recall management. The cross-sectional design aligns with the practical constraints of the dissertation timeline and allows for efficient collection and comparison of both quantitative and qualitative data. Specifically, the study focuses on recall data from the last 2 years (2023-2025) to ensure relevance and analysis of the data. Surveys and interviews will be conducted within a defined 1-2 week allowing for timely synthesis of findings without compromising depth or validity. While a longitudinal study could offer insight into changes over time, the cross-sectional approach is more appropriate for the current research objectives, which are centered on identifying and comparing present-day recall patterns, causes and regulatory practice gaps in Ireland and India.

3.7. DATA COLLECTION

To effectively explore and compare OTC pain reliever recalls due to quality issues in Ireland and India, this study uses a mixed-methods data collection strategy incorporating both quantitative and qualitative techniques. Firstly, quantitative recall data are collected from the official websites of the HPRA in Ireland and the CDSCO in India. These datasets include recall notifications, alert bulletins and enforcement notices related to OTC pain relievers over a 2-year period (2023- 2025). The data will be systematically analysed to identify recall trends, common causes of quality failure and country level differences.

Secondly, semi-structured interviews are conducted to provide qualitative insights into the factors contributing to product recalls, the challenges faced by regulatory bodies and the effectiveness of current systems. Interviewees are selected through purposive sampling and include regulatory officials, professionals in pharmaceutical firms and healthcare providers such as pharmacists. Approximately 3 interviews (1 from Ireland and 2 from India) are be conducted through video conferencing (e.g. Zoom), depending on participant availability.

Thirdly, the survey is distributed to a broader sample of stakeholders in both countries. It consists of Likert-scale questions that measure perceptions of regulatory gaps, recall frequency and quality control practices as well as open-ended questions that allow participants to elaborate on their views and experiences. The survey is distributed electronically via professional networks, LinkedIn and academic referrals, targeting regulatory professionals, pharmaceutical industry professional and

healthcare providers. The survey has been disseminated online using platforms like google forms, ensuring accessibility and data privacy. An estimated sample size of 97 respondents is targeted, with balanced participation from Ireland and India.

3.8. PARTICIPANT SELECTION

To ensure meaningful and credible insights, this study adopts purposive sampling strategy for selecting participants for both the interviews and the survey. The aim is to gather data from individuals who are directly involved in or knowledgeable amount pharmaceutical recalls, regulatory compliance and quality assurance process in the contexts of Ireland and India.

3.8.1. INTERVIEW PARTICIPANTS

The participants for the semi-structured interviews will be selected based on their professional expertise and direct involvement in recall processes. This may include regulatory officials from HPRA (Ireland) and CDSCO (India), pharmaceutical industry professionals particularly working in regulatory affairs, quality assurance and manufacturing of OTC pain reliever recalls and healthcare providers such as pharmacists, who may deal with product recalls at the point of care. The selection criteria for interview participants include, a minimum of 3 years of relevant experience in pharmaceutical regulation, familiarity with recall procedures, quality issues or compliance challenges, willingness to participate and provide informed consent. Approximately 3 participants (1 from Ireland and 2 from India) will be interviewed to ensure a balanced comparative perspective.

3.8.2 SURVEY RESPONDENTS

The mixed-format survey will target a broader pool of stakeholders in both countries to ensure a statistically relevant and demographically diverse sample. Respondents include pharmaceutical manufacturing professionals, healthcare professionals (nurse, doctors and most importantly pharmacists) and regulatory officials. Survey participants will be selected through professional networks and academies contacts, healthcare institutions, direct invitation sent via email and LinkedIn. The goal is to obtain appropriately 97 survey response, with a relatively even distribution between Irish and Indian participants.

3.9. SAMPLE SIZE

The sample size was calculated using the formula:

$$\text{Sample size} = \frac{\frac{z^2 \times p\,(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p\,(1-p)}{e^2 N}\right)}$$

Figure 4: Sample size formula by survey monkey

Where,

N = population size

e = margin of error (10%)

z (z-score) 1.96 for confidence interval of 95%

p (standard deviation) = 0.5 to ensure sample size is large enough

There are nearly 10 million healthcare professionals and pharmaceutical professionals in India and in Ireland. So, sample size obtained using the formula is 97. The number of responses obtained from the online survey was 112.

3.10. DATA ANALYSIS

The data collected for this study were analysed using a descriptive and thematic approach, in line with the mixed-methods design. Since the aim of the study is to understand and compare the recall of OTC pain relievers in Ireland and India, the analysis is focused on identifying patterns, trends, and insights rather than conducting statistical testing. For the quantitative data, recall records obtained from regulatory agencies—namely the HPRA in Ireland and the CDSCO in India—were reviewed manually and compiled to identify key trends in recall frequency, types of quality issues (e.g., contamination, mislabelling), and affected products over a 2-year period. This data was organised using simple tables and visual summaries to highlight differences and similarities between the two countries. The analysis was purely descriptive, aiming to compare recall characteristics based on publicly available information.

The survey responses, which included both closed and open-ended questions, were also reviewed descriptively. For the closed-ended questions (such as Likert-scale items), the responses were summarised to observe general tendencies and perceptions related to recall procedures, regulatory

efficiency, and quality assurance practices. No complex statistical tools were used; instead, results were reported based on the overall frequency of responses and commonly observed patterns. For the qualitative data, which included open-ended survey responses and semi-structured interview transcripts, a manual thematic analysis was conducted.

3.11. CONCEPTUAL FRAMEWORK

The conceptual framework underpinning this study is designed to guide the methodological approach in exploring the recall of OTC pain relievers due to quality issues in Ireland and India. It integrates both Quality risk management (ICH Q9) and Regulatory compliance theory to examine how regulatory structures, manufacturing standards, and institutional practices influence recall frequency and effectiveness. These theoretical foundations support the selection of a mixed-methods approach, allowing the combination of quantitative recall data and qualitative stakeholder perspectives to provide a comprehensive analysis. The quantitative component—comprising public recall data from HPRA and CDSCO and structured survey responses—helps identify measurable trends and patterns, while the qualitative component—based on semi-structured interviews and open-ended survey responses—offers insight into the contextual and institutional dynamics behind those trends. This framework ensures that the research captures both the technical and regulatory dimensions of product recalls, while remaining sensitive to the operational realities in each national setting.

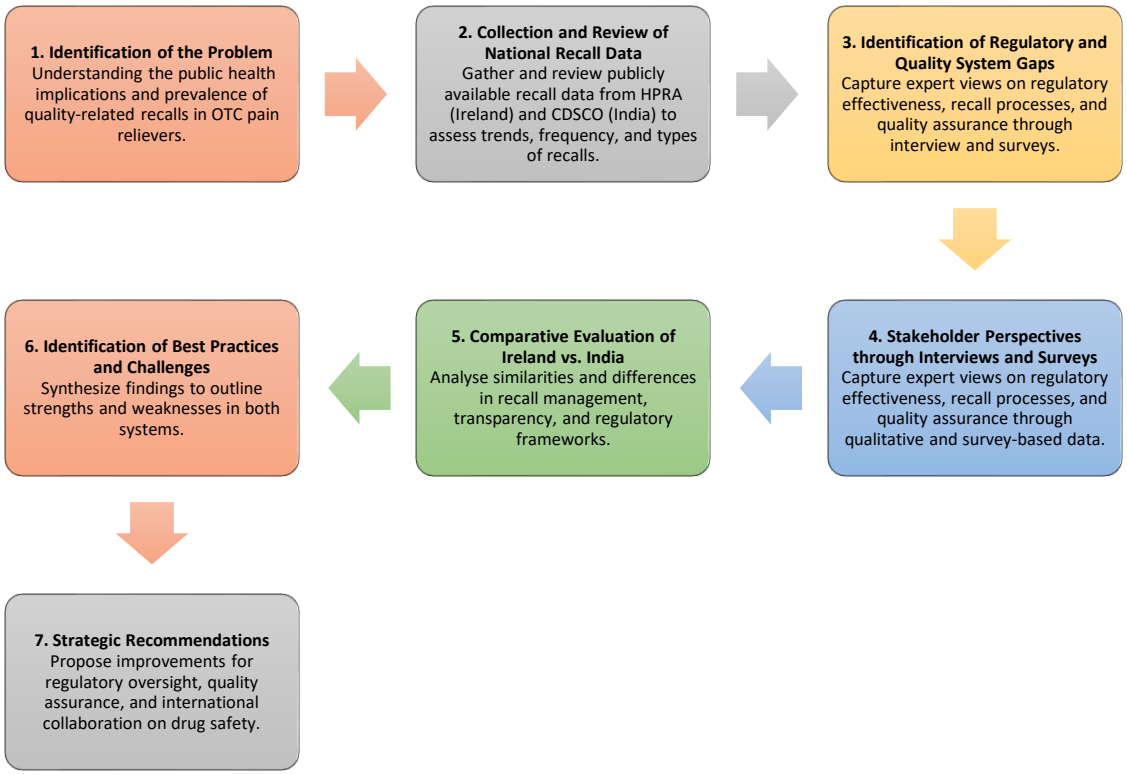

Figure 5:- Conceptual framework of the research

3.12. ETHICAL CONSIDERATION

This study fully adheres to established ethical research standards to ensure the protection, privacy, and autonomy of all participants involved. Informed consent was obtained from all participants prior to their involvement in the study, and they were clearly informed of the purpose, procedures, and voluntary nature of their participation. Participants were made aware that they could withdraw from the study at any point without any consequences. To maintain privacy and integrity, all participant data were anonymised and handled confidentially. Responses from both surveys and interviews were stored securely on encrypted, password-protected devices accessible only to the researcher and academic supervisor. Ethical approval for the research was obtained from the relevant institutional ethics review board. Furthermore, the study strictly complies with data protection regulations, including the General Data Protection Regulation (GDPR) in Ireland and the applicable data privacy laws in India. These measures ensured that ethical responsibilities were upheld throughout the entire research process.

3.13. LIMITATIONS OF METHODOLOGY

This study has several methodological limitations. The availability and consistency of recall data differed between Ireland and India, with India's CDSCO records being less detailed and transparent than Ireland’s HPRA, potentially affecting data comparability. The sample size for both the survey and interviews was limited due to time and access constraints, which may have influenced the diversity of perspectives captured. As participation was voluntary, there is a risk of self-selection bias. Additionally, the study did not involve statistical analysis; instead, findings were based on descriptive and thematic interpretation, which may limit generalisability. Finally, qualitative analysis was conducted manually, which carries the potential for researcher bias despite efforts to maintain objectivity.

3.14. CONCLUSION

This chapter has outlined the comprehensive research design used to compare OTC pain reliever recalls in Ireland and India. The use of mixed methods within a pragmatic paradigm ensures balanced and practical insights into both empirical recall data and contextual industry realities. The next chapter will present the findings derived from both data streams and their implications for regulatory policy and quality assurance practices.

CHAPTER 4 : FINDINGS AND ANALYSIS

4.1. INTRODUCTION

This chapter critically analyse the findings derived from the data collected through three key sources: publicly available recall data from Ireland's HPRA and India's CDSCO, a mixed-methods survey distributed to regulatory professionals, pharmaceutical industry experts and healthcare providers and semi-structured interviews with selected stakeholders from both countries. The purpose of this chapter is to explore patterns, trends and perceptions regarding the quality related recalls of OTC pain relievers in the two entirely different regulatory environments. The analysis is structured around the key research objectives and uses a comparative style to highlight the similarities and differences between Ireland and India. By the integration of both qualitative and quantitative data, this chapter offers refined understanding the factors contributing to product quality failures, how of recall management happens in Ireland and India and the perspectives of those directly involved in ensuring drug safety and compliance.

4.2. QUANTITATIVE ANALYSIS

The quantitative analysis of the study is derived from two primary data resources, publicly available recall records from Ireland's HPRA and India's CDSCO and a structured survey responses collected from healthcare professionals, regulatory officials and pharmaceutical industry experts in both Ireland and India. The goal of the analysis is to identify and compare trends in OTC pain reliever recalls and assess stakeholder perceptions related to recall management, regulatory effectiveness and gaps.

4.2.1. TRENDS AND PATTERNS IN OTC PAINKILLER RECALL (2023-2025)

This section examines the trends and patterns in OTC pain reliever recalls in India and Ireland over a 2-year period (March 2023 – March 2025). Data is extracted from official recall records, HPRA and CDSCO websites, recall notices and is organised by product name, active ingredient, reason and date of recall.

	Ireland	**India**
Main OTC drugs affected	Paracetamol	Paracetamol, Ibuprofen, Diclofenac gel
Common recall reasons	Packaging errors, underdosing /overdosing	Dissolution failure, assay issues, contamination

Number of recalls in total (2023-2025)	149	1723
Number of OTC pain reliever recalls	Limited to 5 recalls (3.3%)	48 (2.78%)
Regulatory insight	Packaging and labelling focused	Systematic manufacturing, quality control

Table 3:- Representing the overall comparison OTC pain reliever recalls in Ireland and India

OTC PAIN RELIEVER RECALLS IN IRELAND

Sl no.	Brand Name	Generic Name	Reason for the recall	Licence holder	Date of recall
1.	Tipol Junior 250mg granules in sachets	Paracetamol	The reason for the recall is unknown	Clonmel Healthcare Ltd	27/01/25
2.	Tipol 500mg granules in sachets	Paracetamol	The reason for the recall is unknown	Clonmel Healthcare Ltd	27/01/25
3.	Tipol Max 1000mg granules in sachets	Paracetamol	The reason for the recall is unknown	Clonmel Healthcare Ltd	27/01/25
4.	Zentiva 500 mg tablets	Paracetamol	Underdose/overdosing	Zentiva k.s.	13/01/25
5.	Boots Paracetamol 500mg tablets 16s	Paracetamol	Incorrect packaging	Boots	04/03/2025

Table 4:- OTC pain reliever recall list in Ireland (2023-2025)

OTC PAIN RELIEVER RECALLS IN INDIA

Sl no.	Brand Name	Generic Name	Reason for the recall	Licence holder	Date of recall
1.		Paracetamol Tab IP 500 mg	It fails the tests for dissolution	Kerala Medical services Corporation Limited, Thiruvananthapuram	03/2025
2.		Paracetamol Tab IP 500 mg	It fails the tests dissolution	Kerala Medical services Corporation Limited, Thiruvananthapuram	03/2025
3.		Paracetamol IP Paediatric syrup 125mg/5ml	Labelling issues	Karuppharma Pvt.Ltd., D. Telangana	03/2025
4.	Para 500	Paracetamol	Failed dissolution test	Laborate Pharmaceuticals Haryana -132046	02/2025
5.		Paracetamol Tab IP 500 mg	It fails the test 'Dissolution'	Healer's Lab Unit II, Baddi, Distt-Solan	02/2025

6.	Parayes - 500	Paracetamol Tab IP	It fails the test 'Dissolution'	Zee Laboratories Ltd, Sahib	02/2025
7.	Fevanex Rapid - 650	Paracetamol Tab IP 650 mg	It fails the test 'Dissolution'	SPAS REMEDISE Vill, Tehsil Baddi,	02/2025
8.		Paracetamol Oral Suspension BP (100 ml) 120 mg/ 5 ml	Assay of Paracetamol	Brussels Laboratories Pvt. - Mumbai Ahmedabad	01/2025
9.	MYPAR	Paracetamol Paediatric Oral Suspension IP	Related substances	Brussels Laboratories Pvt. Gujarat	12/2024
10.	Paradolo 500	Paracetamol Tab IP 500 mg	It fails the test 'Dissolution' as per IP	Alventa Pharma Ltd, Vill, Kishanpura, Baddi-Nalagarh Road, Tehsil,	12/2024
11.	MYPAR	Paracetamol Paediatric Oral Suspension IP	Related substances	Brussels Laboratories Pvt. Gujarat	12/2024
12.		Paracetamol Tab IP 500 mg	It fails the test 'Dissolution' as per IP	M/s.Troikaa Pharmaceuticals Ltd., Ahmedabad, Gujarat	12/2024
13.		Paracetamol Tablets IP 650 mg	Test for Dissolution	M/s. Vivekpharmachem (India) Ltd., Jaipur	12/2024
14.	XYKAA	PARACETAMOL TABLETS IP 500mg	Dissolution test as per IP	M/s.Troikaa pharmaceuticals Ahmedabad	11/2024
15.		Paracetamol Tablets I.P. 500mg	Dissolution	Unicure India Ltd, goutambudh (UP)	11/2024
16.		Paracetamol Tablets IP 500mg	Not of standard quality (NSQ)	M/s. Karnataka Antibiotics and Pharmaceuticals Ltd., Bengaluru	11/2024
17.	Paracent 650 Tablets	Paracetamol Tablets IP	Dissolution	M/s. Karnataka Antibiotics and Pharmaceuticals Ltd Bengaluru	11/2024
18.	Nopain-650	Paracetamol Tablets IP 650 mg	It fails the test 'Dissolution'	Unicure India Ltd., Uttarakhand	10/2024
19.	Pararex-500	Paracetamol Tablets IP 500 mg	Dissolution	CHEMETAC PHARMACEUTICALS GHAZIABAD	10/2024
20.		Paracetamol Paediatric Oral Suspension IP	Related substances	M/s.Vivimed Labs Limited Uttarakhand	09/2024
21.		Paracetamol Tablets IP 500 mg	NSQ	M/s. Karnataka Antibiotics and Pharmaceuticals Ltd., Bengaluru	08/2024
22.	Buflam Forte Suspension	Ibuprofen & Paracetamol Oral Suspension	Uniformity of Volume	M/s. Ornate Pharma Pvt. Ltd., Gujrat, India	08/2024
23.	Vingel XL Pro Gel	Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate and Menthol Gel	Assay of Diclofenac Diethylamine & Methyl Salicylate	M/s. Universal Twin Labs, Solan, H.P	08/2024
24.	Pararex - 500	Paracetamol Tablets IP 500 mg	Dissolution" of Paracetamol.	Chemetac pharmaceuticals,ghaziabad	07/2024
25.	INFI-650 TABLETS	PARACETAMOL TABLETS I.P. 650 mg	Dissolution test.	ABARIS HEALTHCARE, Maharastra	06/2024
26.		Paracetamol 500 mg. Tablets	NSQ	ASKON HEALTH CARE,11-B, RDTL, Guwahati	06/2024
27.		Paracetamol Paediatric Oral	NSQ	Quest laboratories Pvt. Dhar	06/2024

		Suspension IP 125 mg/ml			
28.		Paracetamol Paediatric Oral Suspension IP 250 mg/ml	NSQ	Zenith Drugs Pvt. Ltd. Muradpura	04/2024
29.	Galpara	Paracetamol Tablets IP 500mg.	Dissolution	Galpha Laboratories Limited, Himachal Pradesh	04/2024
30.	DAXIPAR-650 Tablets	Paracetamol Tablets IP 650mg.	Dissolution	Daxin Pharmaceuticals Pvt. Ltd.Solan	04/2024
31.	Pyricool 500	Paracetamol Tablets IP 500 mg	Dissolution	Alkem Health Science, Kolkata	02/2024
32.		Paracetamol Tablets IP 500 mg	Dissolution	Healers Lab, Unit II, Plot Solan	11/2023
33.	Paraband-500	Paracetamol Tablets I.P.	Dissolution	Danish Health Care (P) Ltd., Ujjain	11/2023
34.	Afebril - 650	Paracetamol Tablets 650 mg	Dissolution	Astamed Healthcare (I) Palghar	10/2023
35.		Paracetamol Tablets I.P. 500 Mg.	DISSOLUTION	Scott-Edil Pharmacia Ltd., Jharmajri,	10/2023
36.	Galpara	Paracetamol Tablets I.P. 500 mg.	Dissolution	Galpha Laboratories Himachal Pradesh	10/2023
37.	Parasan 650 Tablets	Paracetamol Tablets IP 650 mg	Dissolution TEST	Redic Labs, Plot No 38, Haridwar	10/2023
38.	Ibucon Plus Kid	Ibuprofen and Paracetamol Dispersible Tablets	Diameter & Uniformity of Dispersion	Redic Labs, Plot No 38, Haridwar	10/2023
39.	Paracin Plus Suspension	Ibuprofen and Paracetamol Suspension	Assay of Ibuprofen and Paracetamol	Stadmed Private Limited, Kolkata700074	07/2023
40.		Paracetamol Tablets I.P. 500 mg	Dissolution and Assay	ORNATE LABS PVT. LTD. Muzaffarpur	07/2023
41.		Paracetamol Tablets I.P. 650 mg	DISSOLUTION	Hindustan Antibiotics Ltd., Pimpri, Pune	07/2023
42.	Galpara	Paracetamol Tablets IP 500 mg	DISSOLUTION	: M/s. Galpha Laboratories Limited, Himachal Pradesh	05/2023
43.		Paracetamol Tablets IP 500 mg	DISSOLUTION	. ORNATE LABS PVT. LTD. Bihar.	05/2023
44.	Paragus 250 Suspension	Paracetamol Oral Suspension IP	ASSAY OF PARACETAMOL	M/s. Cosmas Assay of Chandigarh	05/2023
45.		Paracetamol Tablets I.P. 500 mg	DISSOLUTION	M/s. Cosmas Assay of Chandigarh	04/2023
46.		Paracetamol Oral Suspension I.P. 60 ml.	ASSAY	M/s. ZEE LABORATORIES, Himachal Pradesh.	04/2023
47.		Ibuprofen Tablets IP 200 mg	DISSOLUTION	M/s. Cyper Pharma, K.No. Himachal Pradesh	04/2023
48.	Neorelax Gel	Diclofenac Gel I.P.	Related substances	MEYER ORGANICS PVT. LTD.Maharashtra, INDIA.	04/2023

Table 5:- OTC pain reliever recalls in India (2023-2025)

4.2.1.1 RECALL FREQUENCY OVER TIME

From 2023 to 2025, there is a clear difference in the frequency of OTC pain reliever recalls between India and Ireland. India recorded a total of 48 distinct OTC pain reliever recalls within the two -year

period. The frequency of these recalls has been consistently high, with notable spikes in early 2024 and early 2025. On average, there were 1-2 recalls per month, often clustered within specific therapeutic categories, particularly Paracetamol-based tablets and suspensions. The steady recall pattern in India suggests ongoing issues in product quality assurance and manufacturing and manufacturing standardisation across multiple brands and manufacturers. In contrast, Ireland recorded only five OTC pain reliever recalls between 2023 to 2025. All five occurred in early 2025, indicating either higher regulatory compliance, fewer products on the markets or a more selected recall reporting mechanism.

TOTAL NUMBER OF OTC PAIN RELIEVER RECALLS

YEAR	IRELAND	INDIA
APRIL 2023- MARCH 2024	0	18
APRIL 2024 – MARCH 2025	5	30

Table 6:- Representing the number of OTC pain reliever recalls due to quality issues in India and Ireland (2023 -2025)

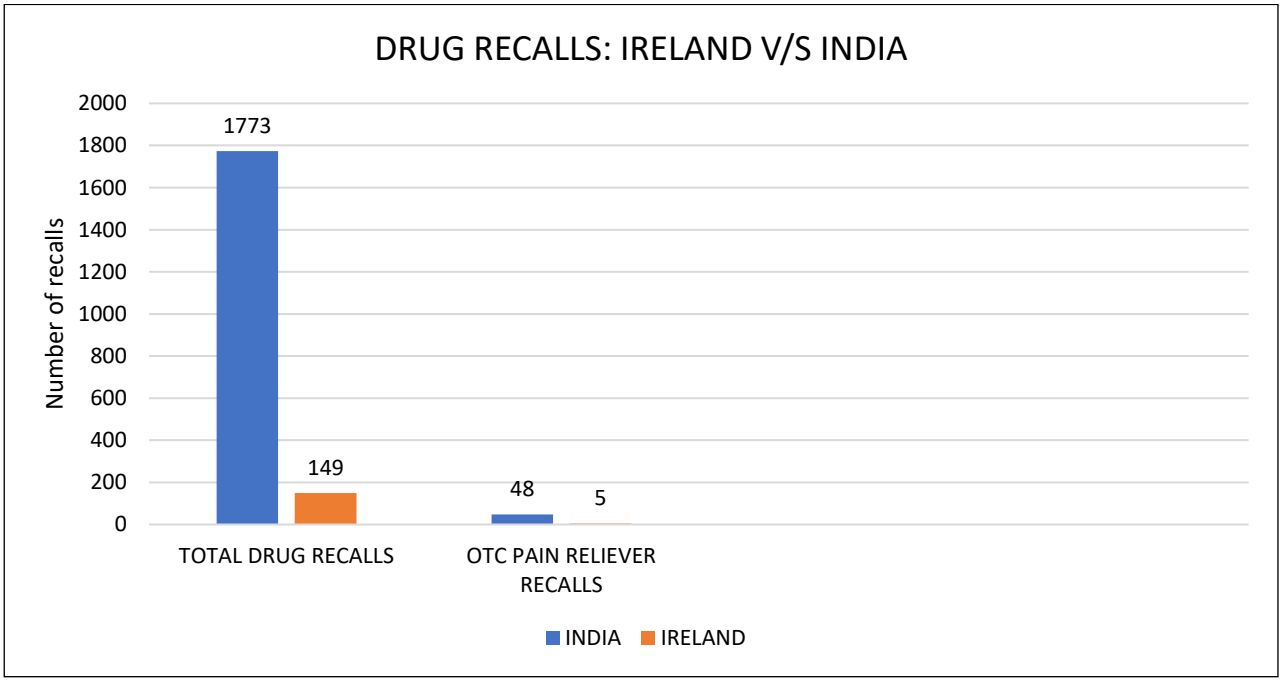

Figure 6:- Bar graph representing the drug recalls in India and Ireland

The bar chart represents the differences in recall reporting frequency and patterns, which can be attributed to factors such as regulatory environment, manufacturing practices, market volume and post marketing surveillance. The above given bar graph gives an insight that, out the 1723 recall that happened in the past 2 years 48 (2.78%) were OTC pain relievers whereas in case of Ireland out of 149 recalls that happened in the last 2 years only 5 (3.35%) of them was found to be OTC pain relievers and among that 2(1.34%) were recalled due to quality issues.

4.2.1.2 COMMONLY RECALLED GENERIC DRUGS

An analysis of the recalled OTC pain relievers from 2023 to 2025 revels a clear dominance of paracetamol as the most frequently recalled generic drug in both India and Ireland. In the Indian recall data list, Paracetamol was involved in over 90 % of the recalls. Appearing under a wide variety of brand names (e.g.; - Paradolo, Parayes, Mypar extra...). Both tablets (500mg and 650mg) and paediatric oral suspension were recalled repeatedly. Other generics that are recalled are ibuprofen: in combination with paracetamol (Buflamforte, paracin plus) and diclofenac gel (Neorelax). Similar to India, Ireland's recalls were exclusively related to paracetamol. Mainly Zentiva and Boots paracetamol were recalled due to quality issues such as packaging or labelling errors and overdosing or underdosing found in some tablets. The narrower product variety compared to India reflects Ireland's smaller market, limited number of OTC manufacturers and more centralised distribution systems.

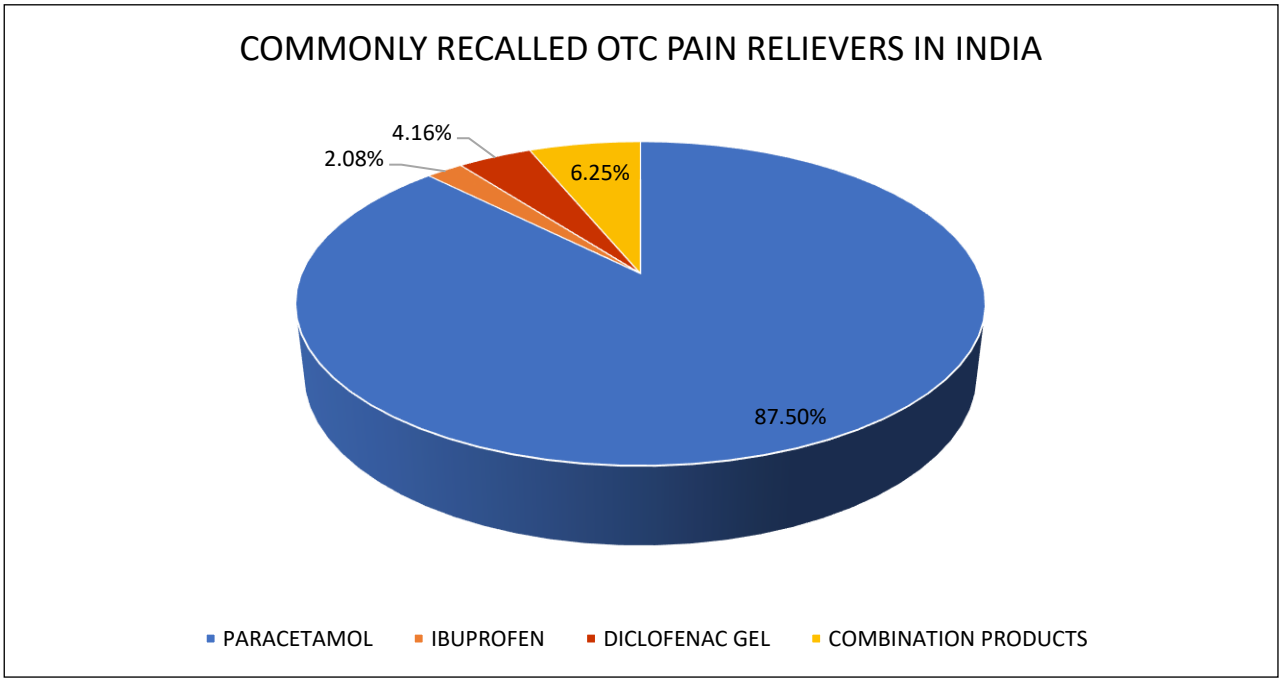

Figure 7:- Pie chart representing commonly recalled OTC pain relievers in India

4.2.1.3 REASONS FOR RECALL

The reason for OTC pain reliever recalls between 2023 and 2025 reveal distinct patterns in regulatory focus and manufacturing quality control issues between India and Ireland. The predominant cause of recalls in India was failure to meet the dissolution specifications as outlines by the Indian pharmacopeia (IP). This accounted for more than 70% of the total recalls. Along with that Assay failures, where the active pharmaceutical ingredient (API) was outside acceptable limits, presence of related substances which indicating potential degradation and contamination, labelling issues,

uniformity of volume and dispersion time particularly in paediatric oral formulations and gels. These reasons suggest challenges in manufacturing process validation, in process quality control and stability monitoring in certain Indian facilities – especially those producing high volume generics. In Ireland, the reasons for recall were more varied and mostly related to incorrect packaging with labelling issues of wrong dose and instructions, in case of Zentiva some of the tablets was found underdosing where as some was found over dosing which can led to ineffective treatment or toxicity. In Tipol granules, the specific reasons were not publicly disclosed, but recalls were still executed as a precaution. These recalls suggest a stronger emphasis on labelling accuracy, patient safety and proactive risk mitigation by the HPRA.

Reason for recall	Ireland	India
Dissolution failure	0	32
Assay failure	0	5
Related substances	0	4
Uniformity issues	0	2
Packaging and labelling	1	1
Overdosing/Underdosing	1	0
Unknown	3	4

Table 7:- Representing the reasons for OTC pain reliever recalls in Ireland and India

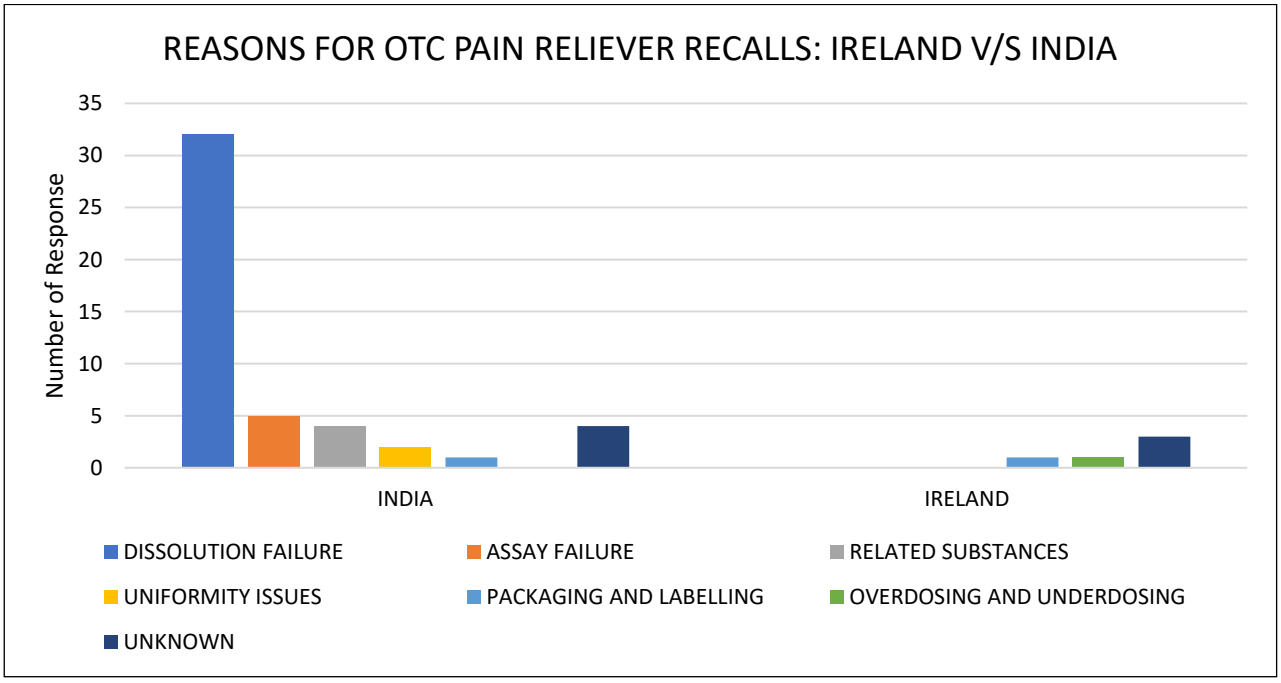

Figure 8:- Bar graph representing the OTC pain reliever recall reasons in India and Ireland

The Indian recall data reflects a manufacturing- centric quality issue, while Ireland's data points toward regulatory standards in labelling and dosage control. The contrast underlines the need for targeted improvements in GMP compliance in India and enhanced transparency and traceability in Ireland.

4.2.1.4 PRODUCT FORMS AND DOSING ISSUES

The dosing forms and product formats involved in OTC pain reliever recalls offer additional insights into underlying risks to drug stability, accuracy and user safety in both India and Ireland. In India, the majority of recalls were related to solid oral dosage forms, particularly tablets (500mg and 650mg of paracetamol) and paediatric oral suspensions. The paediatric oral suspension often flagged issues like non-uniform API distribution, assay failure and presence of related substances. This pattern suggests that quality control lapses during formulation, granulation and tableting are widespread mainly in high demand generics. Paediatric suspension, while fewer in number are particularly concerning due to the vulnerability of the patient population and the requirement for precise dosing. The common issues identified are failure in dissolution which affects drug bioavailability, assay related deviations which results in incorrect active ingredient concentration), non-compliance with volume or dispersion uniformity especially in suspensions and dispersible tablets. In Ireland, the recalled products include granules and tablets. Tipol junior and Tipol max were recalled in sachet format- a less common dosage form used for paediatric and elderly patients. Along with that boots paracetamol tablets were recalled due to incorrect packaging, which raises concerns about labelling precision and dosing clarity. Additionally, underdosing or overdosing concerns in Zentiva pointed toward manufacturing batch inconsistencies, although this was an isolated instance.

Dosage form	India- Key issues	Ireland- Key issues
Tablets	Dissolution failure, Assay errors	Labelling errors, Underdosing/Overdosing
Oral suspensions	NSQ, Related substances, Assay issues	Not reported
Granules/Sachets	Not reported	Recalls due to manufactures issues
Dispersible tablets	Uniformity of dispersion	Not reported
Gels	Assay and related substances issues	Not reported

Table 8:- Representing the dosage forms and its recall reasons in India and Ireland

India's recalls largely involve manufacturing performance failures affecting product bioavailability and potency, particularly in solid and liquid dosage forms. Ireland's recall issues occur from packaging accuracy and patient safety risks, especially in non-traditional dosage forms like granules.

This difference reflects manufacturing system challenges in India and regulatory vigilance in Ireland toward product presentation and consumer risk.

4.2.1.5. TRENDS IN MANUFACTURER INVOLVEMENT

In both India and Ireland, regulatory agencies issue recall notices to safeguard public health, however, the transparency and accessibility of manufacturer information differ notably between the two countries. in India, manufacturer names, batch number and state drug control authority responsible for the recalls are mentioned in a recall notice. The current dataset reveals that recalls span a broad range of manufacturers, including both public sector entities such as Kerala Medical Services Corporation Ltd. (Thiruvananthapuram) and Karnataka Antibiotics and Pharmaceuticals Ltd. (Bengaluru), as well as private companies like Troikaa Pharmaceuticals Ltd. (Ahmedabad), Brussels Laboratories Pvt. Ltd. (Gujarat and Mumbai), Zee Laboratories Ltd. (Sahib), Galpha Laboratories Ltd. (Himachal Pradesh), and Cosmas Assay (Chandigarh). Several manufacturers, such as Galpha Laboratories, Troikaa Pharmaceuticals, and Brussels Laboratories, appear repeatedly in the recall records, indicating persistent quality assurance challenges. While the inclusion of manufacturer names enhances traceability, the lack of standardized formatting and centralized accessibility of Indian recall data makes comprehensive manufacturer-level analysis difficult for the public and researchers alike. In contrast, Ireland's HPRA presents manufacturer and license holder information in a clear and consistent manner, all recalled products in the data set specify the responsible company, Clonmel Healthcare Ltd, Boots, and Zentiva k.s., ensuring high levels of transparency, accountability and ease of public access. The clarity of Irish recall notices supports effective pharmacovigilance, timely communication and confidence in the regulatory system. Overall Ireland's approach is significantly more organised, accessible and user-friendly serving a model for enhancing recall documentation practices in India.

4.2.1.6. SUMMARY OF KEY PATTERNS

The comparative analysis of OTC pain reliever recalls between India and Ireland from 2023 to 2025 reveals several important trends that underscore differences in regulatory enforcement, manufacturing quality and transparency between the two countries.

1. Volume of recalls
    - India had a significantly higher number of OTC pain reliever recalls (48) compared to Ireland (5) from April 2023- March 2025.
    - India showed a consistent pattern of monthly recalls, while Ireland's recalls were clustered in early 2025.

2. Dominant drug: - Paracetamol
    - In both countries, paracetamol was the most frequently recalled generic, accounting for nearly all the reported recalls.
    - In India, it appeared in multiple forms and brands, highlighting systemic quality control issues.
    - In Ireland, it appeared in different formats (granules, tablets) suggesting broader product oversight but fewer systemic failures.
3. Key recall reasons
    - India: - the most common reasons were distribution failures, assay discrepancies and related substances- all indicators of formulation or production faults.
    - Ireland- recalls were based on packaging errors and dosing inconsistencies, suggesting a focus on patient safety and labelling standards.
4. Dosage forms and risk profile
    - India's recalls are centered on tablets and suspensions, with risks to both adult and paediatric patients.
    - Ireland's recalls were concentrated in sachets and tablets, often branded consumer products where packaging plays a critical role in patient safety.
5. Manufacturer identification and transparency
    - The repetition of recalls from some manufactures (e.g., Galpha Laboratories, Brussels Laboratories, Troikaa Pharmaceuticals) raises concerns about ongoing quality assurance lapses. India can be benefited from centralising and digitizing recall information, using standardised templates can benefit for better public and healthcare professionals' accessibility.
    - Both India and Ireland provide information about manufactures, licence holder information and so on which can enable the traceability of the recall information although, Ireland's system presents the data in a more structured, accessible and publicly transparent manner.

India's recall pattern reflects systemic manufacturing quality challenges, particularly in high-volume generics like paracetamol. Ireland's fewer but more diversified recall reasons highlight a mature regulatory environment, with a strong focus on patient safety, dosage integrity and transparent reporting. These findings underscore the importance of robust GMP enforcement in India and suggest that Ireland's regulatory model offers valuable best practices in transparency and consumer protection that could be adapted internationally.

4.2.2. SURVEY FINDINGS

The survey begins with an opening paragraph and two initial questions to ensure that participants understood the research's objectives, ethical compliance and significance of the study. The study aimed to explore perspectives on the recall of over- the-counter (OTC) pain relievers, with a particular focus on regulatory practices, consumer safety and industry impact- specifically comparing responses between India and Ireland. It was essential that participants had some familiarity with the pharmaceutical sector and the concept of product recalls, as this directly affected the relevance and accuracy of their responses. The first question gathers information whether they consented to take part in the study and only who selected yes were allowed to proceed. The second question confirmed whether that the participant fully understood the need and significance of the study. These questions were essential for confirming informed consent and ensuring that responses were gathered from individuals who are aware of the study's purpose and scope. the sample size for the survey was found to be 97 participants, a total of 112 participants completed the survey. These 112 participants have met the eligibility, understood the significance of the study and have given the consent for the participation in the study.

The responses obtained from the first two questions were:

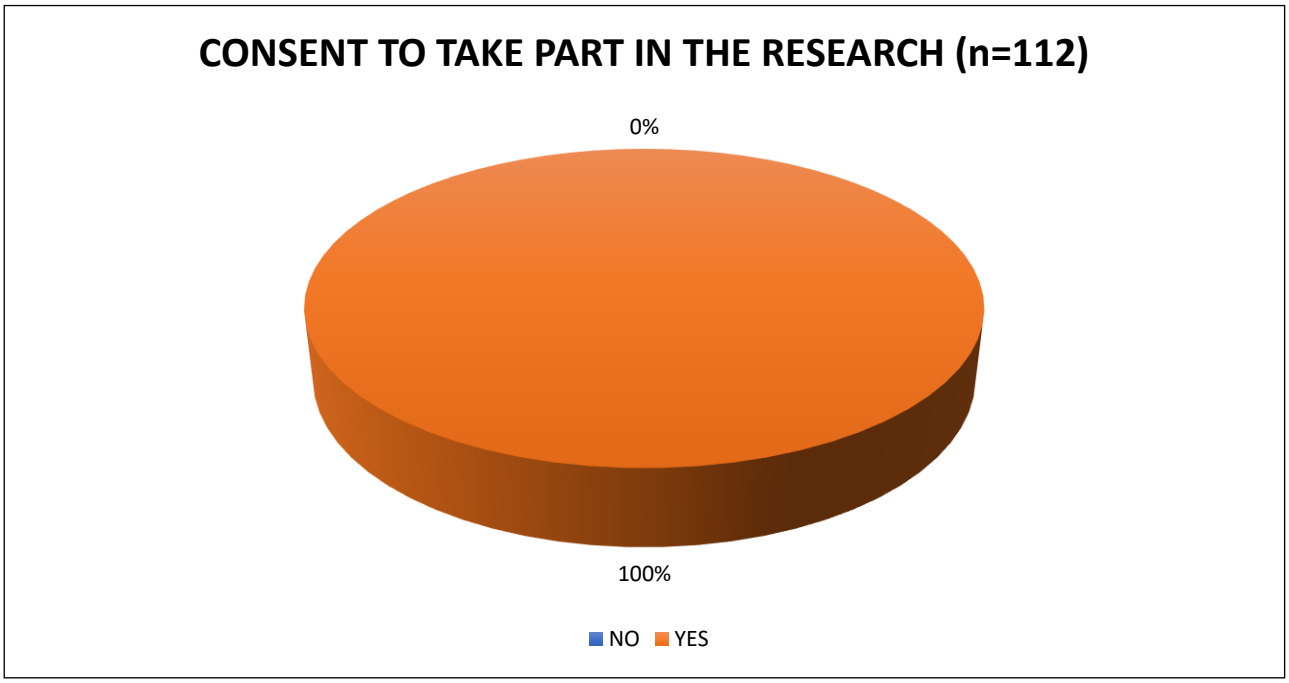

Figure 9:- Pie chart representing the consent of participants to take part in the research

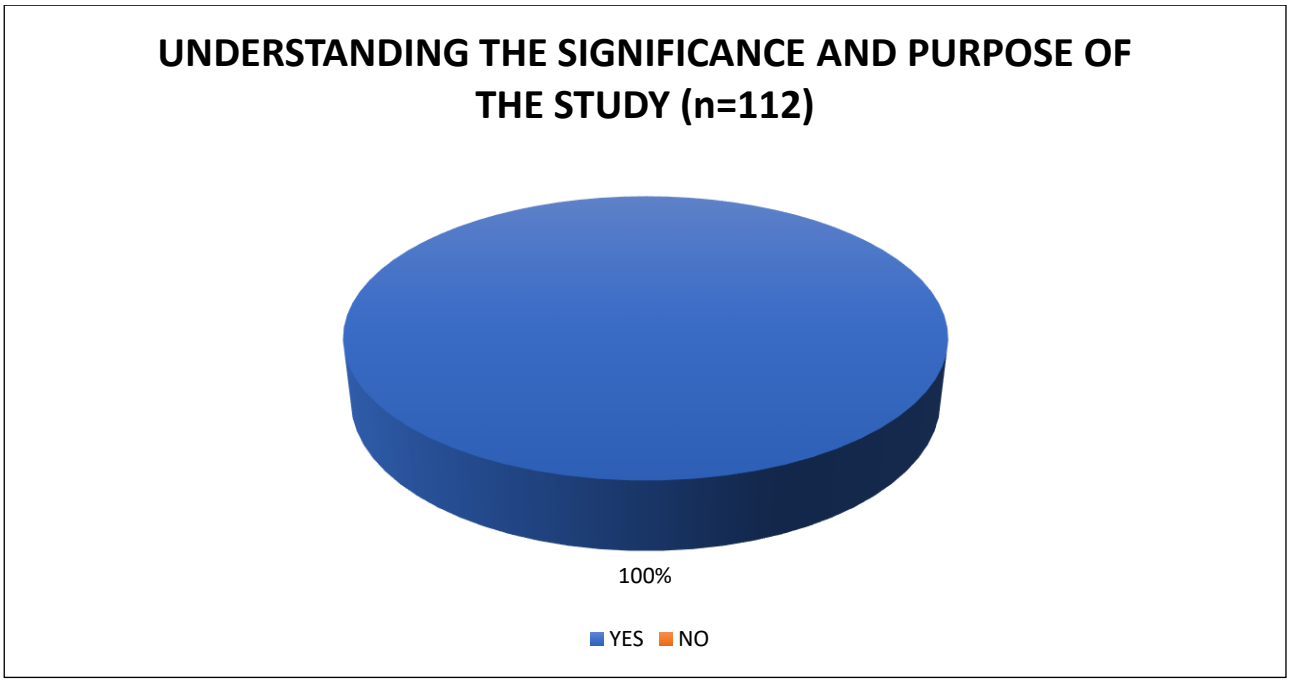

Figure 10:- Pie chart representing the understanding of the purpose of the research by the participants

From the given diagram, it is evident that all participants understood the research purpose and are willing to participant in the survey research. The total number of participants in the study was 112.

4.2.2.1. SECTION 1: - GENERAL INFORMATION

Following initial consent and understanding check, the survey included a series of demographic and background questions to capture the professional profile and relevant experience of each participant. These questions were essential to do the comparative analysis of the findings and to understand the diversity of perspectives on OTC pain reliever recalls. Respondents were asked to identify their role in relation to OTC pain relievers, with options ranging from regulatory officials and pharmaceutical industry professionals, consumers and healthcare providers.

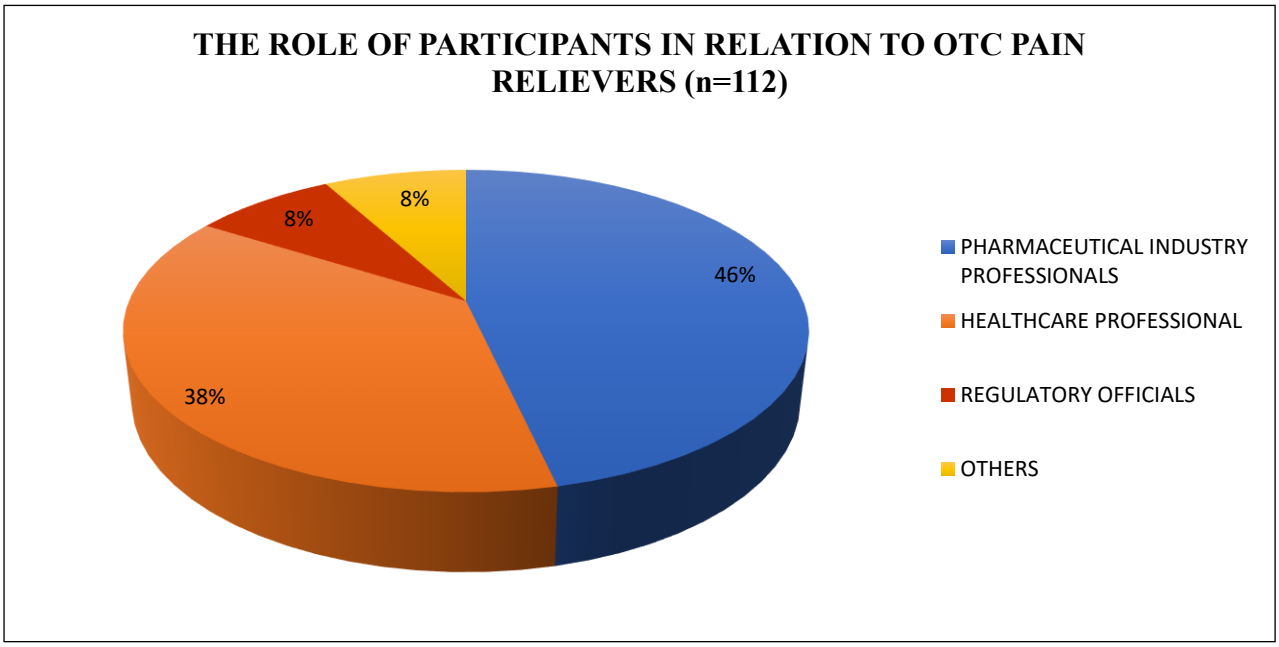

Figure 11: Pie chart representing the role of participants in relation to OTC pain relievers

A total of 112 participants responded to the survey question regarding their role in relation to OTC pain relievers. The roles included regulatory officials, pharmaceutical industry professionals, healthcare providers (such as doctors, nurses, and pharmacists), and others (consumers, physiotherapist). The largest proportion of respondents identified as pharmaceutical entry professional (46%), followed by healthcare professionals (38%) mainly pharmacist. This distribution highlights that the majority of insights were provided by individuals directly involved in the development, distribution, or oversight of pharmaceutical products, making the data highly relevant to the study's focus on recall management and regulatory processes.

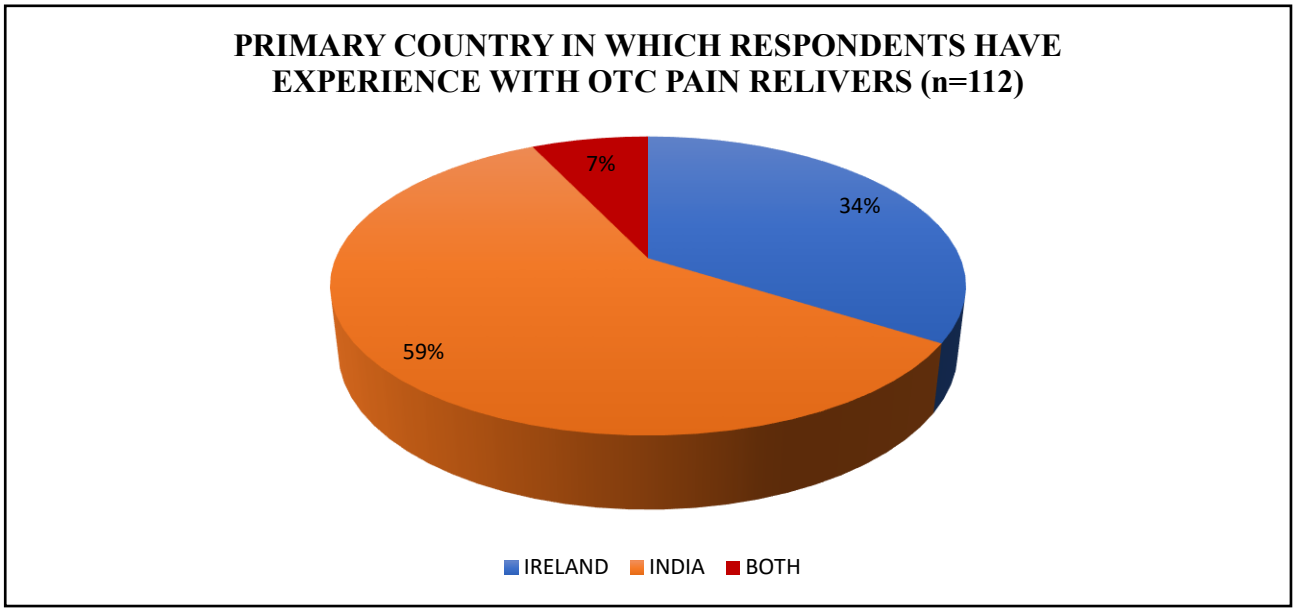

Figure 12:- Pie chart showing the primary country in which respondents have experience with OTC pain relievers

One of the key survey questions, that was asked to the participants is to indicate the country in which they primarily work or have experience with OTC pain relievers recall- India, Ireland or both. This question was essential for distinguishing regional perspectives and identifying any cross-country differences in knowledge, practices or experiences related to OTC pain reliever recalls. The results showed that 59%(n=66) of respondents reported experience primarily in India whereas 34% (n=38) is from Ireland and indicated that out of the 112 participants 7%(n=8) has experience in both Ireland and India. This distribution enabled meaningful comparative analysis between two regulatory environments, which is main the basic requirement to study the objectives of the research.

WORK EXPERIENCE (IN YEARS)	NUMBER OF PARTICIPANTS	PERCENTAGE OF RESPONSE (%)
< 1 year	13	11.6%
1 – 5 years	64	57.1%
6 – 10 years	25	22.3%
> 10 years	10	8.9%

Table 9:- Representing the experience of participants in relation to OTC pain relievers

Participants were asked to indicate the duration of their involvement in the pharmaceutical or healthcare industry. This question helped to assess the level of professional experience among the respondents, which is important for interpreting their perspectives on OTC pain reliever recalls. Among the participants, the majority (57.1%) reported that they are having 1 to 5 years of experience, followed by 22.3% of people with 6- 10 years of experience. A smaller proportion of respondents (11.6%) had less than a year of experience, suggesting that most participants were reasonably well-informed and professionally established within the sector.

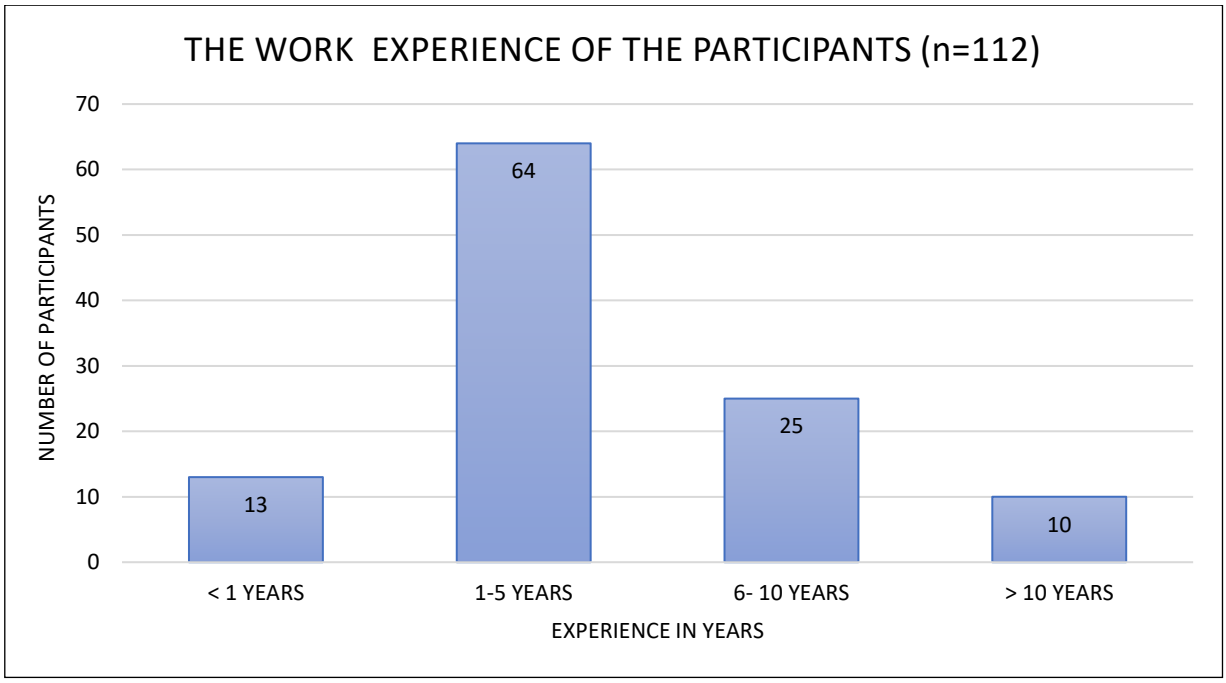

Figure 13:- Bar graph representing the experience of participants in years

From the given diagram (Figure 8), we can identify that most of the participants has an experience of over 1 years with OTC pain reliever recalls highlighting the credibility and understanding of the study.

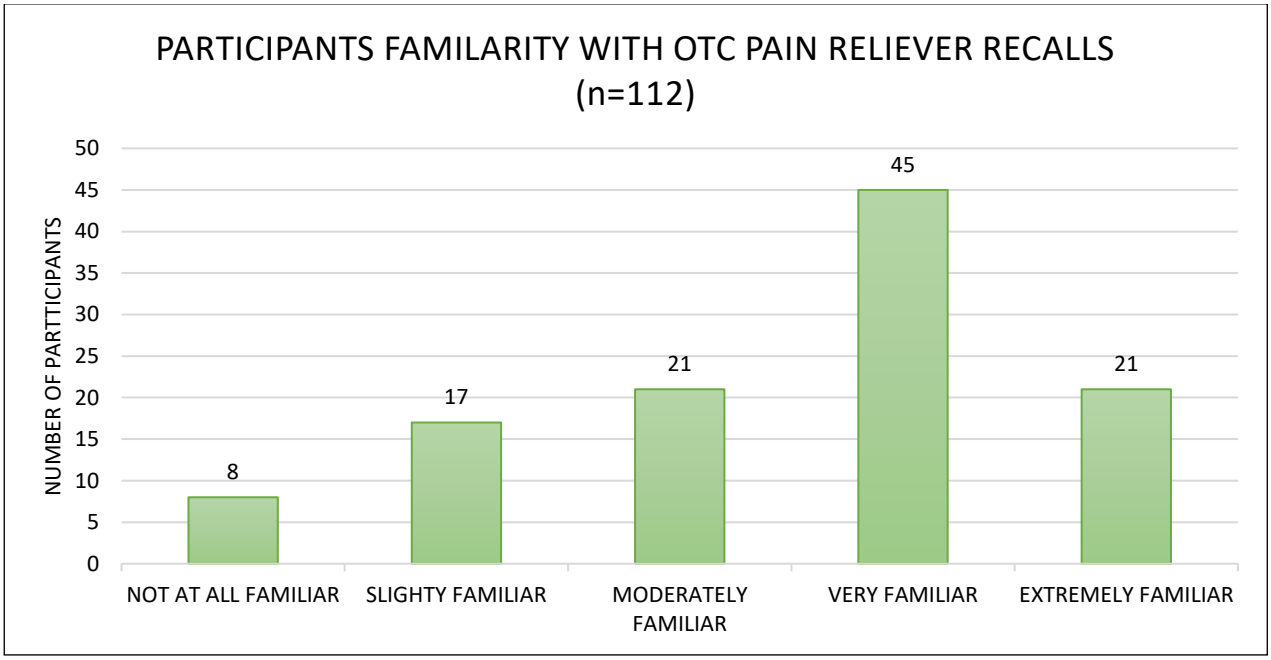

Figure 14: - Bar graph representing the familiarity of the participants with OTC pain reliever recalls

To assess the level of awareness among respondents, they were asked to rate their familiarity with OTC pain reliever recalls. The responses are ranged across five levels: Not at all familiar, slightly familiar, moderately familiar, very familiar, and extremely familiar. Out of 112, a 40% (n=45) of participants reported that they are a very familiar with the OTC pain reliever recalls. Although among that, 8 participants responded that they do

not have any familiarity with the OTC pain relievers. suggesting some variation in recall knowledge across the sample. These results help establish the overall awareness baseline of the group, which is critical when interpreting their responses to more detailed questions about recall processes and challenges.

4.2.2.2. SECTION 2: - RECALL TRENDS AND CAUSES

This section explores participants' insights into the trends, frequency, and root causes of OTC pain reliever recalls. Respondents were asked to share their experiences with recall incidents, their views on how often such recalls occur, and what they believe are the primary causes—such as contamination, mislabelling, potency issues, or regulatory non-compliance. Understanding these trends is essential for identifying systemic weaknesses within the pharmaceutical supply chain and regulatory oversight. The responses offer valuable perspectives on how frequently recalls are observed, whether they are increasing or decreasing, and what quality control failures typically trigger them. These findings help highlight areas where pharmaceutical companies and regulatory bodies may need to improve preventative measures and recall readiness.

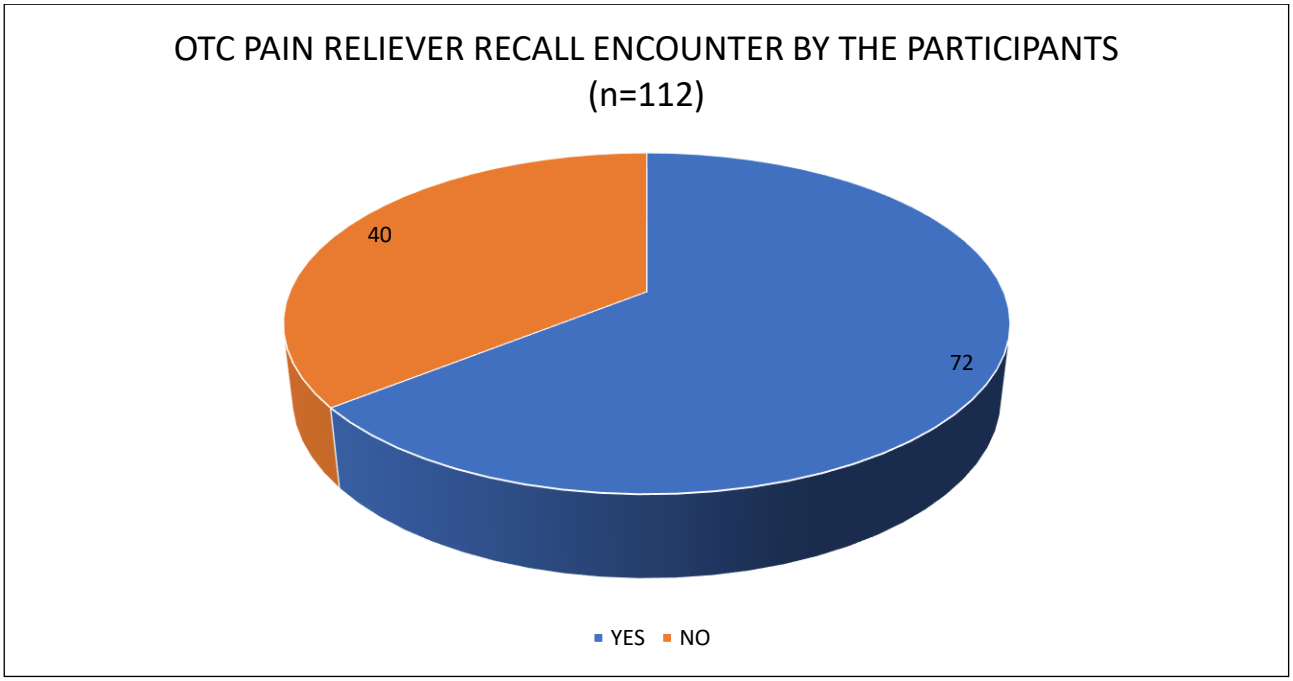

Figure 15:- Pie chart representing the OTC pain reliever recall encounter by the participants

Participants were asked whether they had ever encountered an OTC pain reliever recall in their professional or personal experience. As shown in Figure 10, the majority of respondents indicated "Yes" (64.2%), suggesting direct exposure to recall events. A smaller portion, 35.71 %, reported that they had not encountered any recalls. These responses reflect the prevalence of recall experience among professionals in the pharmaceutical and healthcare sectors, which adds depth to their insights in subsequent sections of the survey. The high level of recall exposure may also suggest that such incidents are relatively common in the field, underscoring the importance of robust recall management systems.

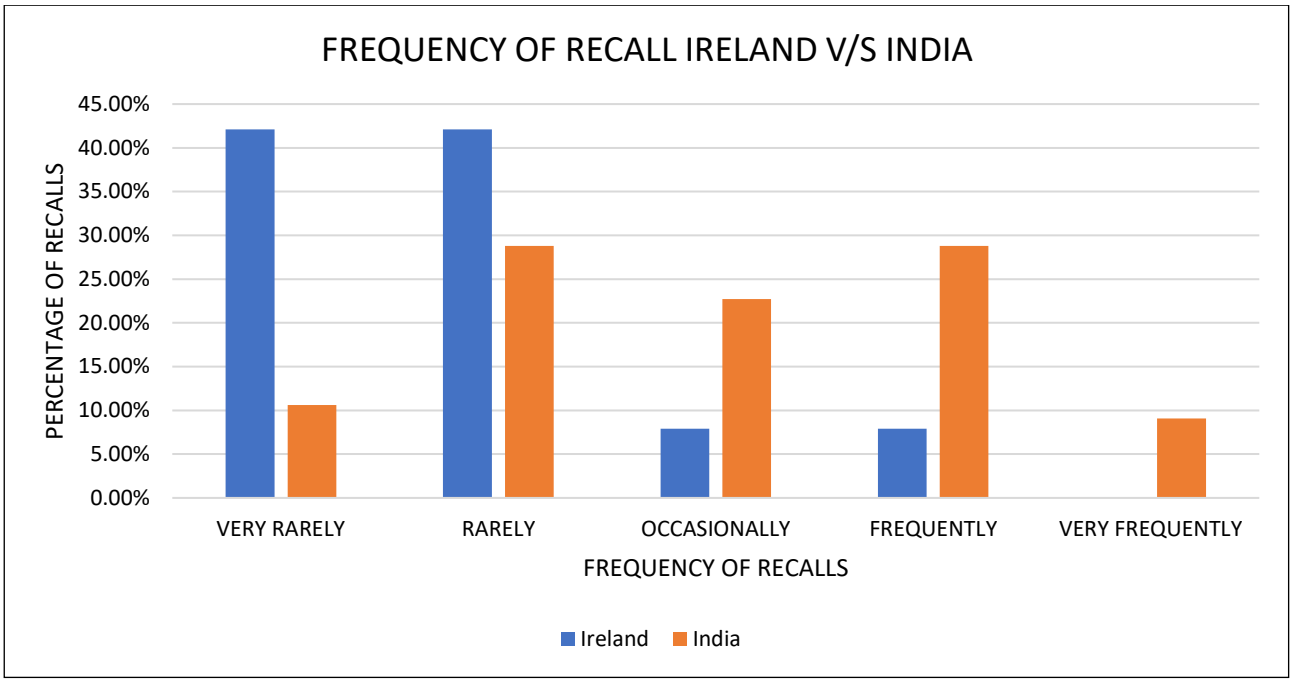

Figure 16:- Bar graph representing the comparison of frequency of recalls across Ireland and India

Based on their personal or professional experience, participants were asked to rate how frequently they believe OTC pain reliever recalls occur in their country. A notable difference was observed between the two countries. Participants from India reported a higher frequency of recalls, with more responses falling under the Occasionally (28.78%) and Frequently (28.78%) categories. In contrast, respondents from Ireland have selected Rarely (42.10%) and Very Rarely (42.10%). This disparity may reflect differences in market size, regulatory enforcement, reporting mechanisms, or awareness levels between the two regulatory environments. The comparison underscores the importance of context when evaluating the effectiveness and transparency of recall systems in different countries.

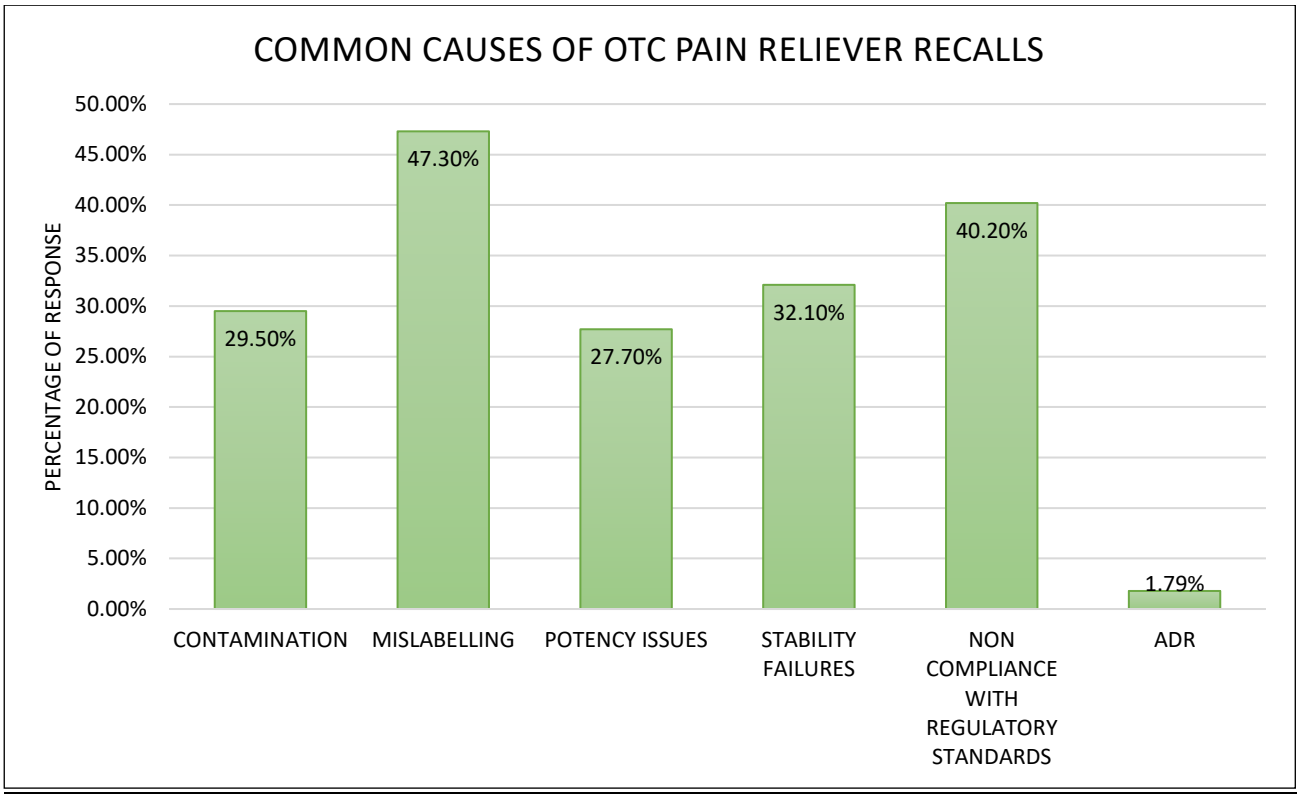

Figure 17:- Bar chart representing the common causes of OTC pain reliever recalls

Figure 12 presents a bar chart illustrating the most commonly reported causes of OTC pain reliever recalls as identified by the survey participants. Respondents were allowed to select multiple causes, including *Contamination, Mislabelling, Potency issues, Stability failures,* and *Non-compliance with regulatory standards.* The most frequently cited cause was Mislabelling (47.3%) followed by Non-compliance with regulatory standards (40.20%) and stability failures (32.10%). ADR with 1.79% reported as the least cause for recalls of OTC pain relievers. These findings indicate that manufacturing and quality control issues continue to be a leading factor in OTC product recalls. The prominence of these causes highlights the need for stricter enforcement of Good Manufacturing Practices (GMP), regular quality checks, and clearer labelling standards to minimize risks to patient safety.

4.2.2.3. SECTION 3: REGULATORY FRAMEWORK AND RECALL STRATEGIES

This section focuses on participant's perceptions on the regulatory environment and the effectiveness of recall strategies related to OTC pain relievers. It evaluates how national regulatory bodies—such as HPRA in Ireland and CDSCO in India—manage recall procedures, communicate risks, and enforce compliance. Participants were asked to assess the speed and appropriateness of regulatory actions, the transparency of recall processes, and the accessibility of recall information to consumers and healthcare professionals. Additionally, the survey gathered opinions on the challenges regulators face and the extent to which international standards (such as from the WHO, EMA, or FDA) influence local recall practices. These insights help identify gaps in current

systems and inform potential improvements in recall protocols, communication, and global coordination in recall managements.

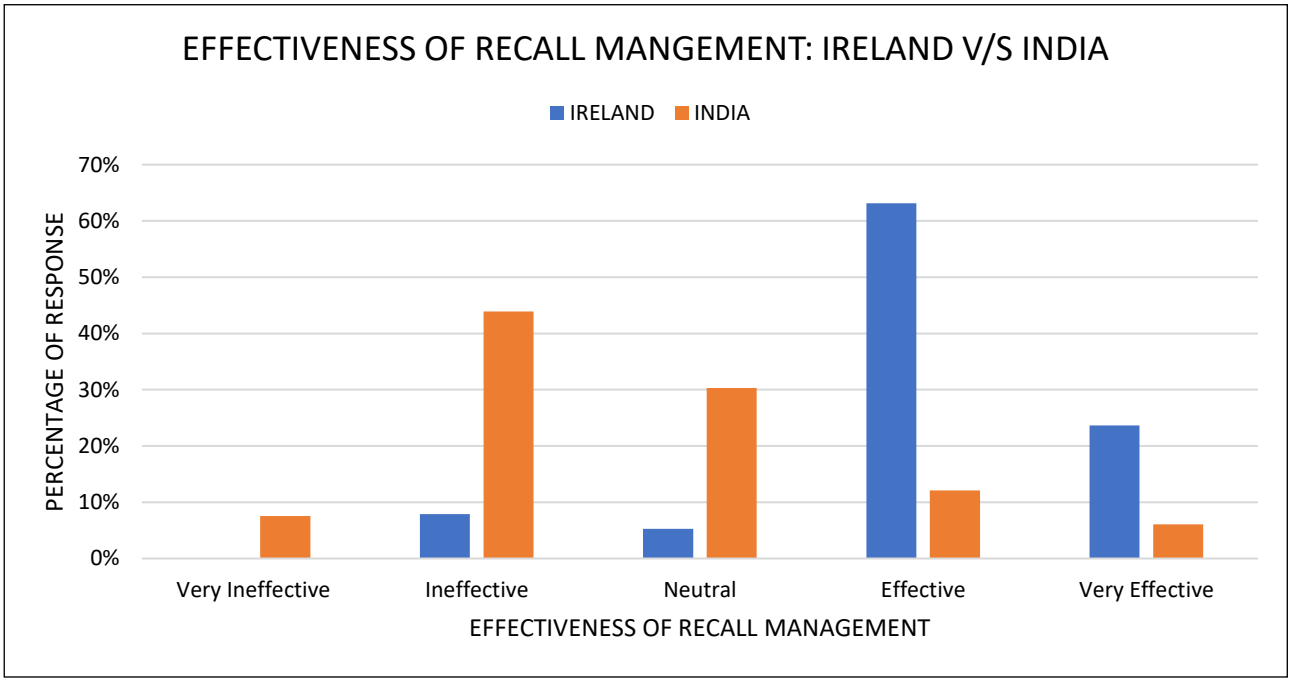

Figure 18:- Bar graph representing the effectiveness of recall management in Ireland and India

The respondents rated recall management on a five-point scale: Very Ineffective, Ineffective, Neutral, Effective, and Very Effective. The bar graph shows that a higher percentage of participants from Ireland rated their country's system as Effective (63%) or Very Effective (24%), indicating confidence in structured protocols and communication by the HPRA. In contradiction to that 8% of the participants reported that the HPRA recall management systems are ineffective, which makes it impossible to conclude about the HPRA recall management effectiveness. Conversely, participants from India more frequently selected Neutral (30.3%) or Ineffective (43.93%), suggesting concerns about delays, enforcement, or gaps in public awareness. This comparison highlights differing perceptions of regulatory robustness and offers insight into areas where improvements may be needed, particularly in communication, monitoring, and centralized tracking systems.

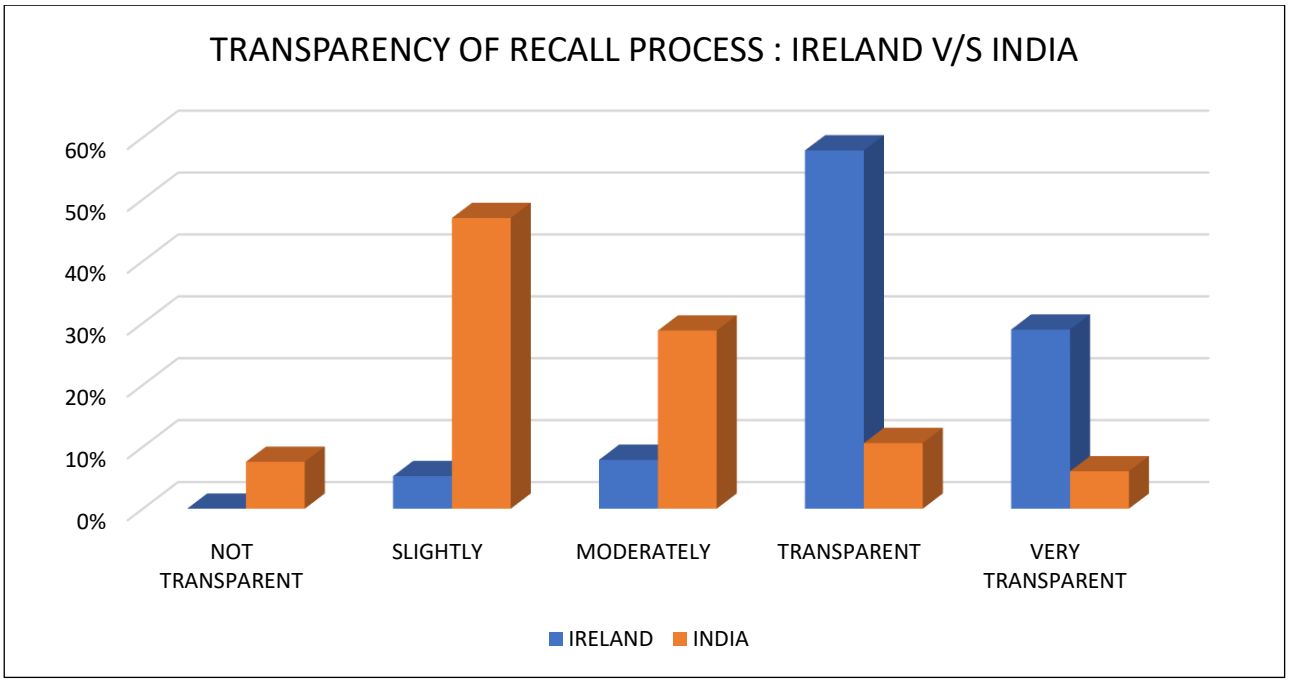

Figure 19:- Bar graph representing the transparency of recall process in Ireland and India

Figure 14 compares participant's views on the transparency of OTC pain reliever recalls in Ireland and India. Ratings ranged from not transparent at all to very transparent. Most respondents from Ireland rated the process as transparent (58%) and very transparent (29%), while participants from India more commonly selected slightly transparent (46.97%) and moderately transparent (28.79%) lower. This indicates that recall information may not be consistently disseminated or easily accessible to the public and healthcare providers in India whereas it is easily accessible in Ireland.

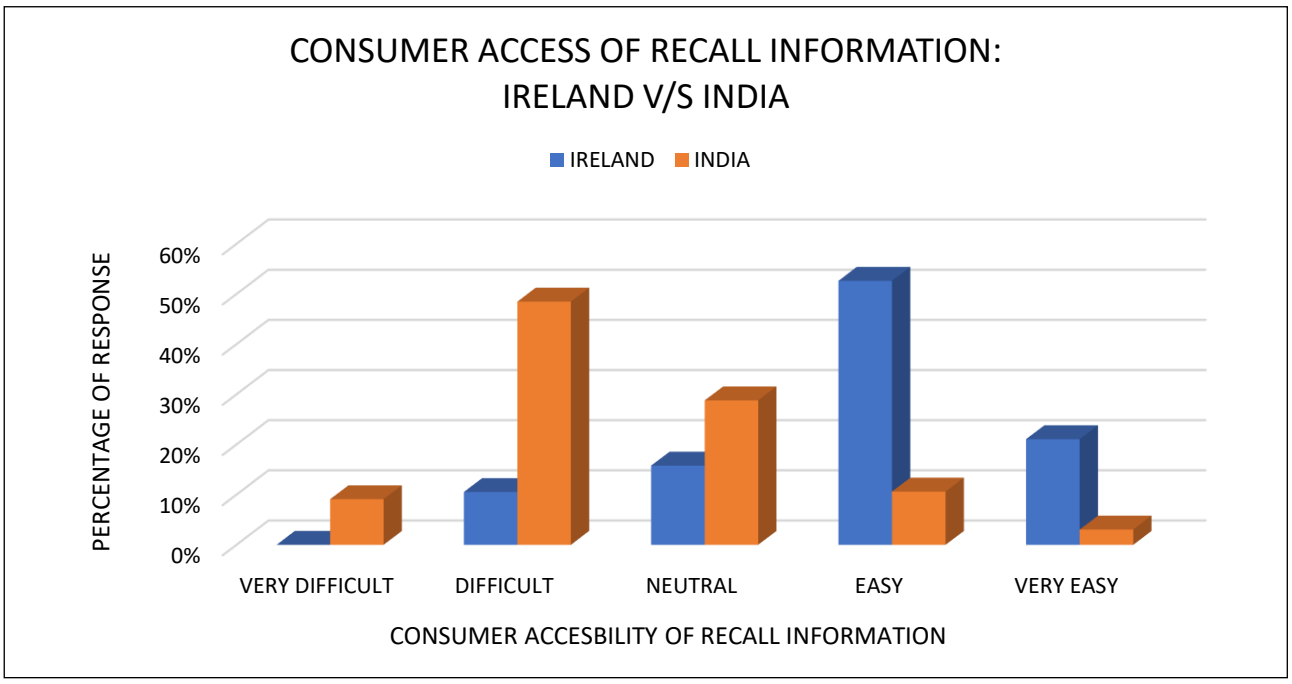

Figure 20:- Bar graph representing the consumer accessibility of recall information in Ireland and India

Participants were asked how easy it is for consumers to access information about OTC pain reliever recalls. Participants from Ireland generally found access to be easy (53%) and very easy (21%), which suggests a better consumer communication mechanism in Ireland. While the Indian participants response as difficult (48.48%) and neutral (28.79%), indicating that current recall systems may not effectively reach consumers. This survey findings highlights the need for improved public-facing communication and centralized recall databases.

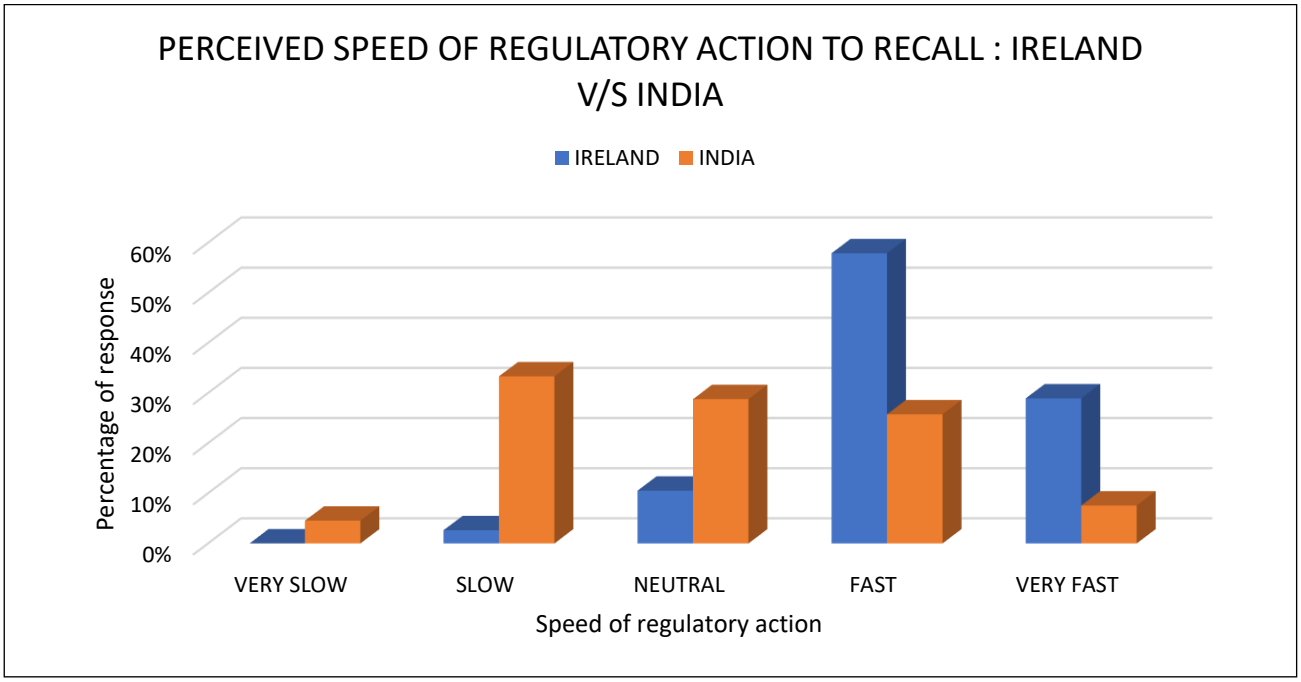

Figure 21:- Bar graph representing the speed of regulatory actions to OTC pain reliever recalls in Ireland and India

Participants rated the responsiveness of regulatory authorities—HPRA in Ireland and CDSCO in India—when an unsafe OTC pain reliever is identified. Most Irish respondents selected fast (33.3%) and very fast (29%), reflecting confidence in timely regulatory action. In contrast, a significant portion of Indian respondents chose neutral (28.79%) or slow (33.33%), suggesting perceived delays in the recall process. These results highlight a more efficient recall response system in Ireland compared to India.

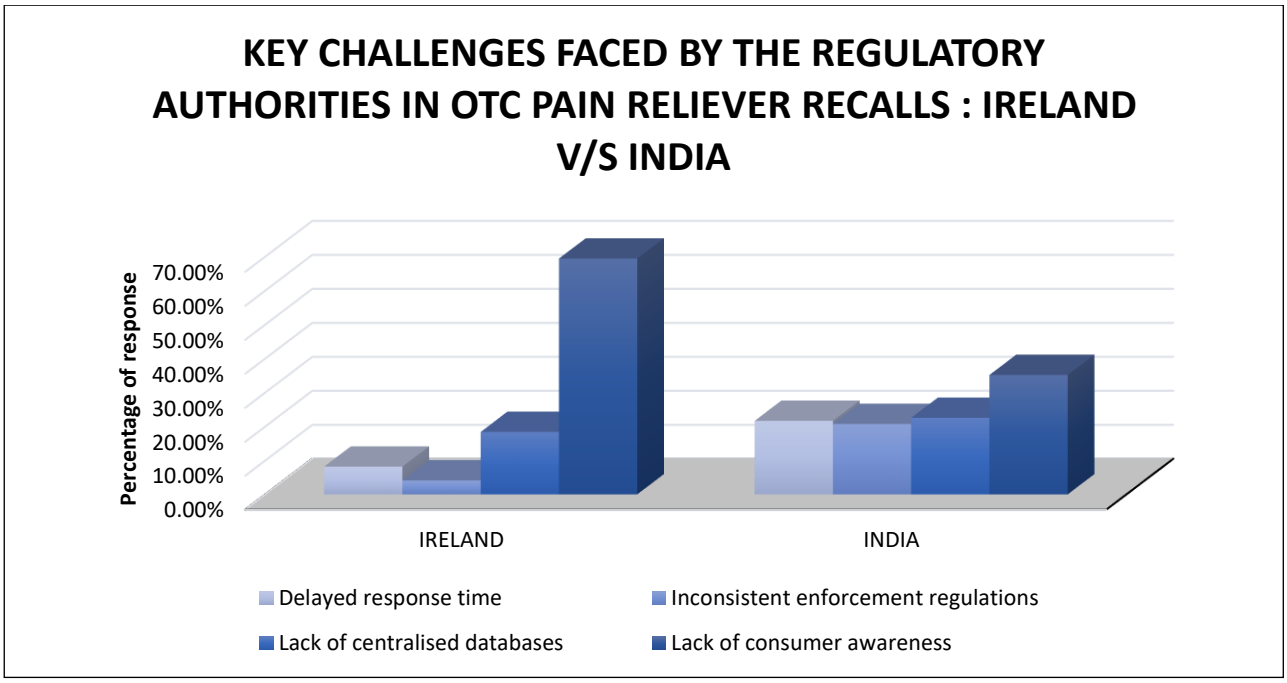

Figure 22:- Bar graph representing the key challenges faced by regulatory authorities in OTC pain reliever recalls in Ireland and India

Figure 17 highlights the main challenges faced by regulatory authorities regarding regulatory recall management in Ireland and India. Common challenges included Delayed response time, Inconsistent enforcement, Lack of centralized databases, and Limited consumer awareness. In India, limited consumer awareness (35.14%) is reported as the most common challenge. along with that, lack of centralised data (22.52%), delayed response time (21.62%) and inconsistent enforcement regulations (20.72%) were reported to almost similar response indicating that all the options given has a role in acting up as a challenge in Indian sector. Similarly, Irish participants more often cited limited consumer awareness (69.39%) as a serious challenge. These results suggesting that with India and Ireland should address the public communication gaps while focusing on others too.

4.2.2.4. SECTION 4: IMPACT ON PATIENT SAFETY

Recalled products can lead to adverse drug reactions, ineffective treatment, long-term health complications, and in some cases, toxicity. These risks can significantly compromise patient well-being, particularly when patients continue using these medications unknowingly. Ensuring the safety of OTC medications through stringent quality control and prompt recall procedures is essential to protect patients from preventable harm and maintain public trust in pharmaceutical products.

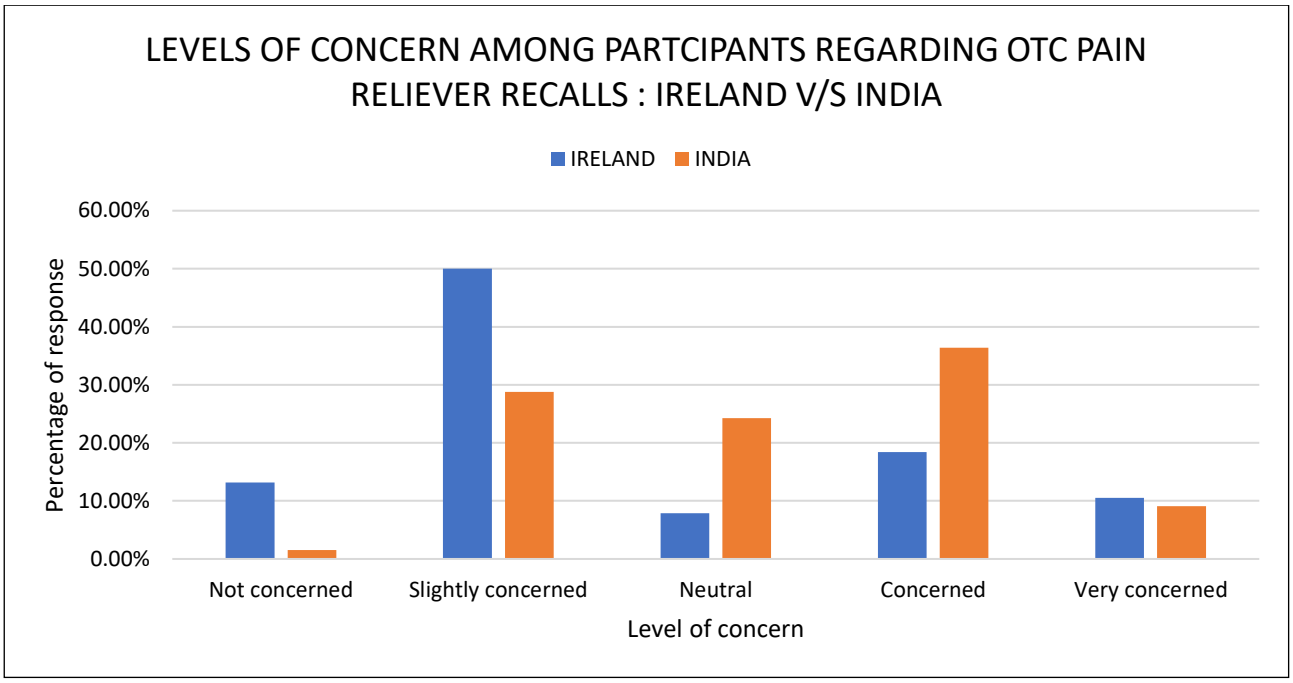

Figure 23:- Level of concern among respondents regarding OTC pain reliever safety in India and Ireland

Figure 18 compares the level of concern among respondents in India and Ireland regarding the safety of OTC pain relievers due to past recalls. The responses ranged from Not concerned to Very concerned. A higher percentage of participants in India reported being Concerned (36.37%), indicating stronger apprehension about product safety. In contrast, respondents from Ireland showed a more balanced distribution across Not concerned (13.16%) and slightly concerned (50%), suggesting a relatively higher level of confidence in their regulatory oversight and recall processes.

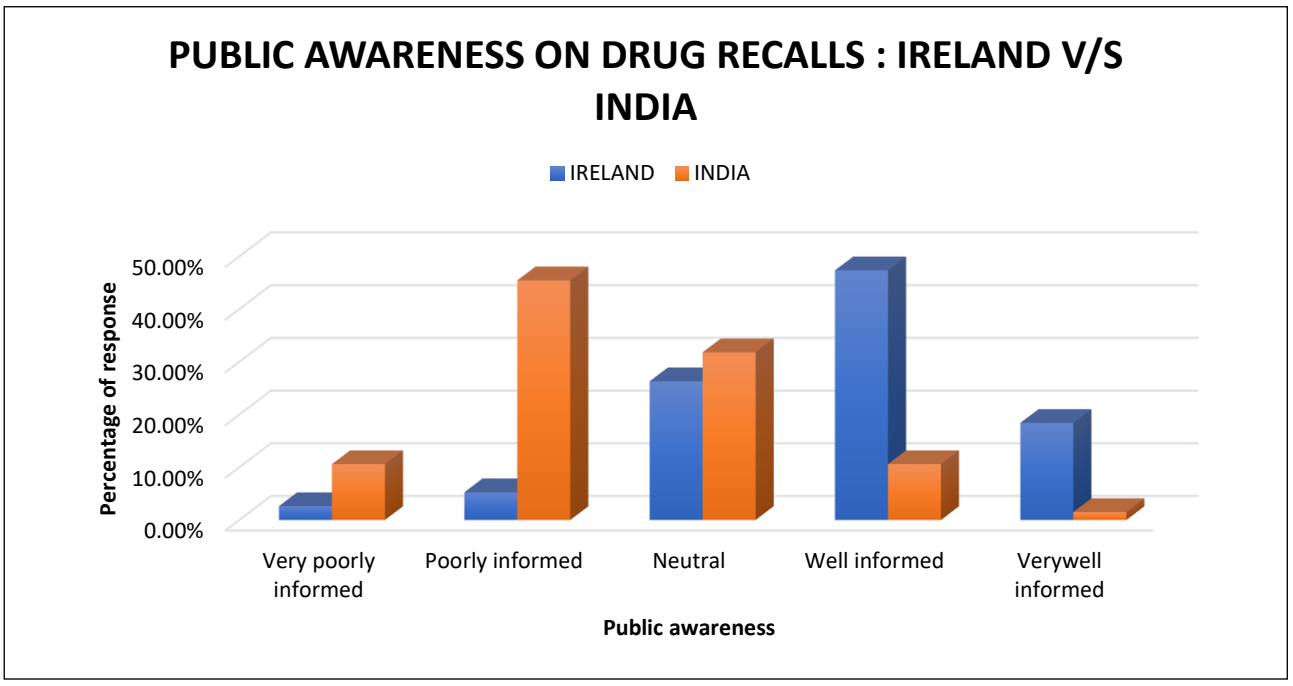

Figure 24:- Bar graph representing the public awareness on recalls in Ireland and India

The given figure, indicates that the public in Ireland shows a relatively high level of awareness when it comes to recalls (47.37%), possibly due to more robust regulatory systems and frequent public notifications. Whereas, the awareness level in India appears to be lower in comparison. This could be due to a variety of factors such as limited public access to information about recalls (45.45%), lower media coverage, or perhaps less stringent enforcement of recall systems.

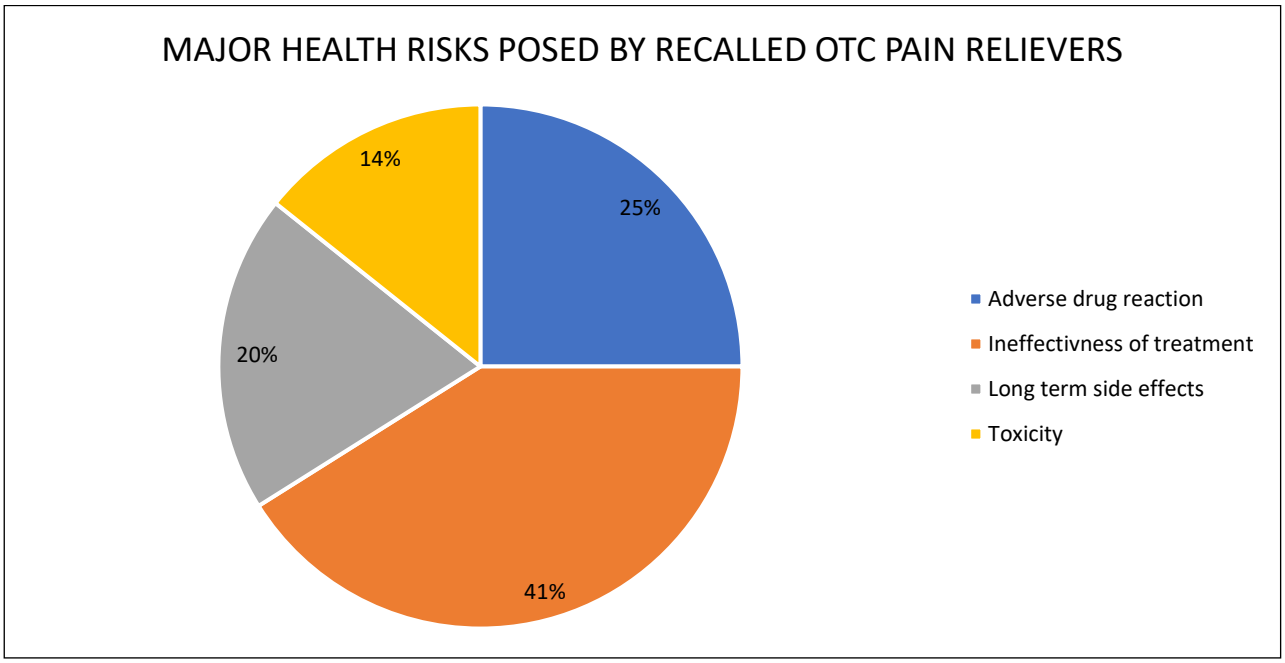

Figure 25:- Bar graph representing the major health risks to patients by recalled OTC pain relievers

The major risks posed by recalled over-the-counter (OTC) pain relievers were assessed. The results revealed that the greatest concern was the ineffectiveness of treatment, which was identified by 41% of respondents. Adverse drug reactions were the second most significant risk, with 25% of professionals highlighting this issue. Long-term side effects were a concern for 20% of participants, while toxicity, though less frequently reported, accounted for 14% of the responses. These findings underscore the diverse health risks associated with recalled OTC pain relievers, emphasizing the need for greater vigilance and safety protocols in both countries.

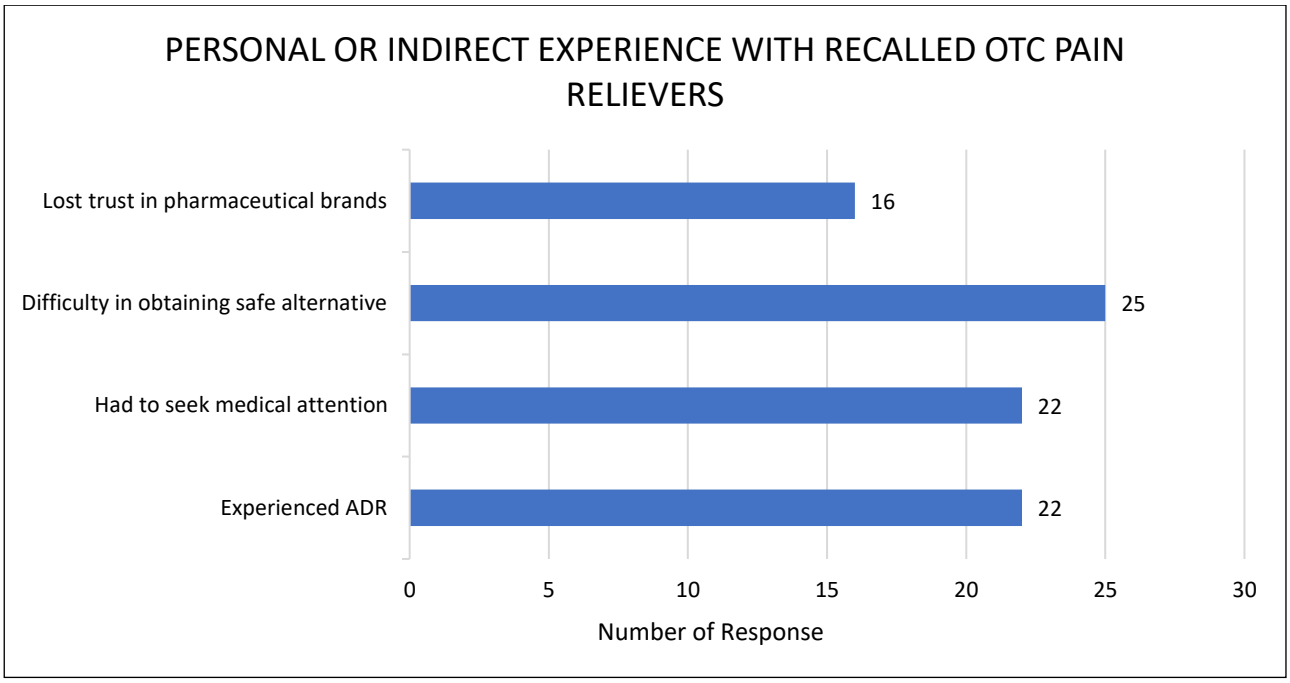

Figure 26:- Bar graph representing the experience of participants with recalled OTC pain relievers

The survey highlights several negative impacts of OTC pain reliever recalls, both directly and indirectly. 16 respondents reported a loss of trust in the affected brands, while 25 participants faced challenges in finding safe alternatives. Additionally, 22 respondents had to seek medical attention and 22 others experienced adverse drug reactions (ADR), underscoring the health and safety concerns triggered by the recalls. These results reflect the broad consequences recalls have on both consumer trust and public health.

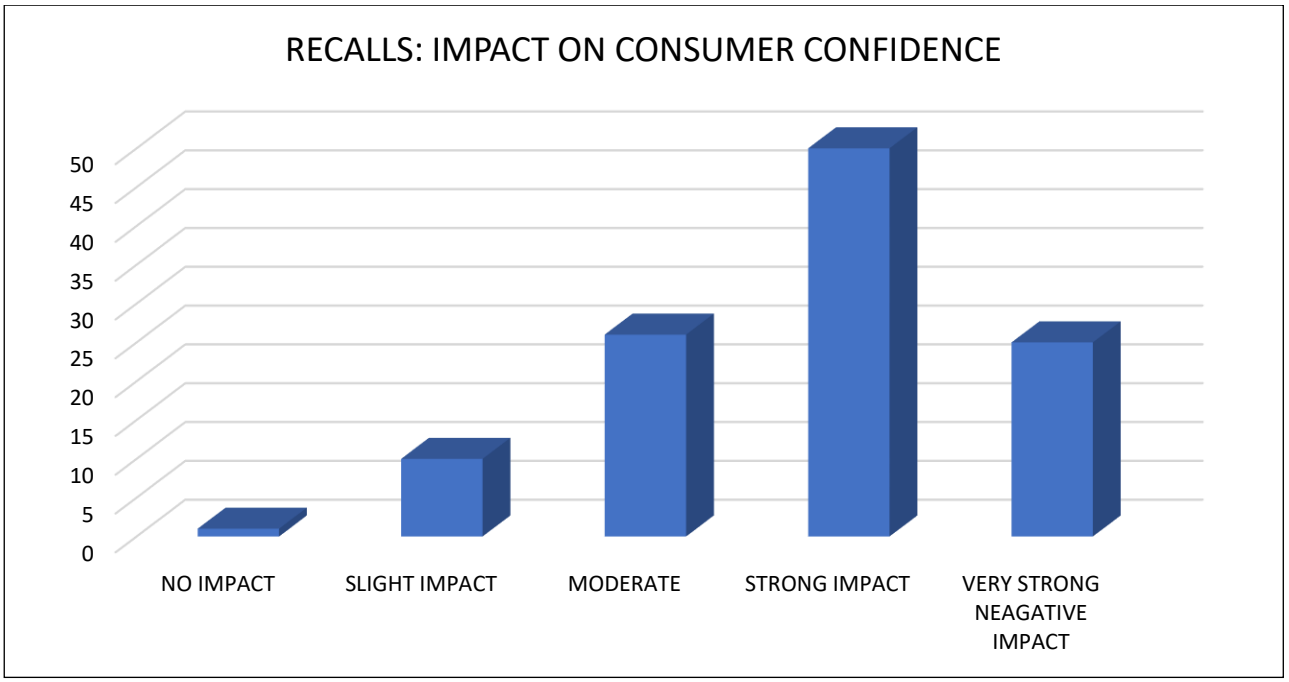

Figure 27:- Bar graph representing the impact of recall on consumer confidence

The findings from the survey clearly demonstrate that pharmaceutical recalls can have a profound effect on consumer confidence, with more than half of participants believe that consumers experience a strong (50%) or very strong negative impact (25%) in confidence due to OTC pain reliever recalls. This highlights the critical importance of effective communication, transparency, and swift corrective actions by pharmaceutical companies in maintaining consumer trust. Companies need to ensure that recalls are handled properly and consumers are reassured that their health and safety are the top priorities.

4.2.2.5. SECTION 5: IMPACT ON PHARMACEUTICAL BUSINESS

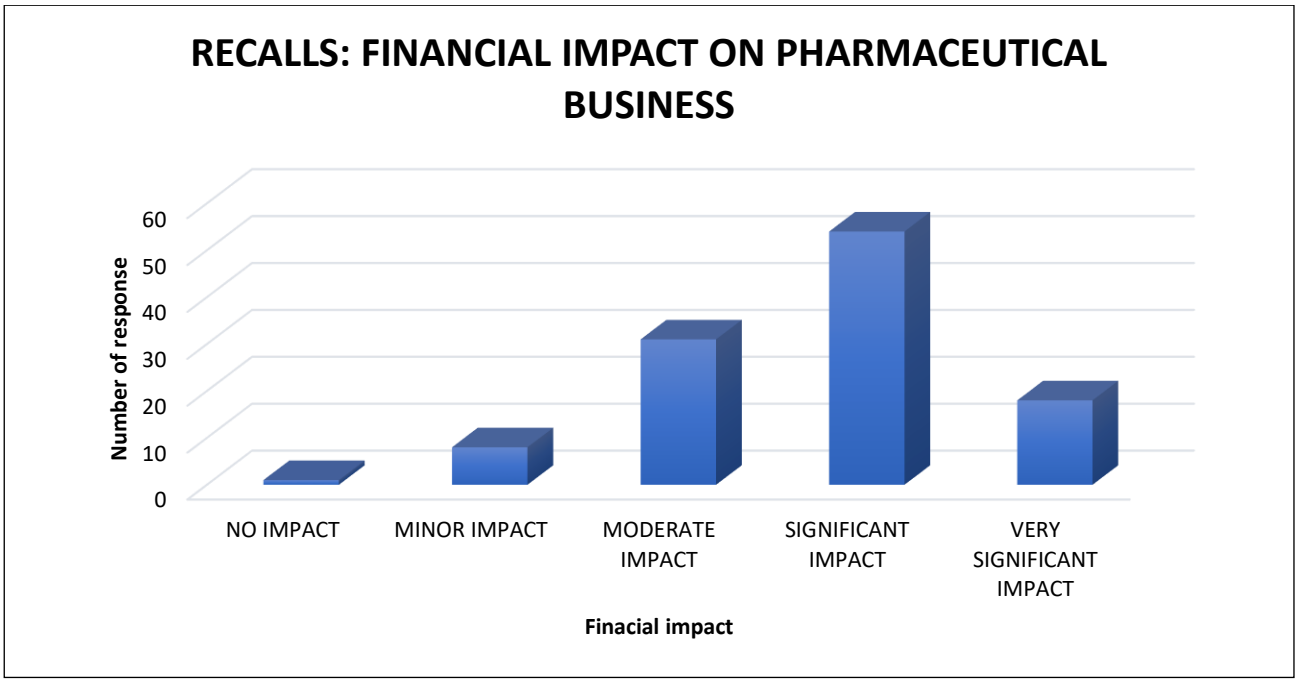

Figure 28:- Bar graph representing the financial impact of recalls on pharmaceutical business

The survey results on the financial impact of OTC (over-the-counter) pain reliever recalls on pharmaceutical companies show that the majority of respondents believe recalls have a significant to very significant impact. 54% report that the financial impact is significant, while 18% believe it is very significant. A notable portion, 31%, say recalls have a moderate impact, and 8% consider the impact to be minor. Only 1% think the recalls have no impact on the financial performance of pharmaceutical companies. This suggests that recalls of OTC pain relievers are generally viewed as having a substantial financial burden on companies.

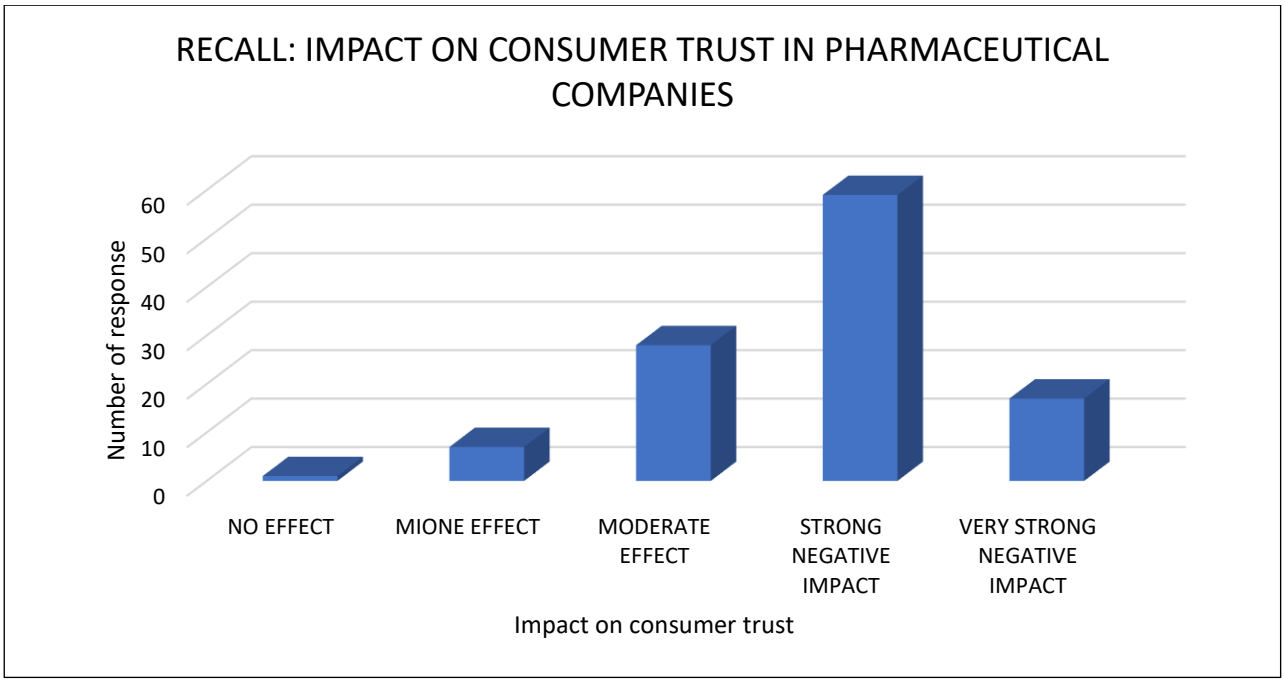

Figure 29: Bar graph representing the impact of recalls on consumer trust on pharmaceutical companies

The survey results indicate that recalls have a strong to very strong negative impact on consumer trust in pharmaceutical brands. 52.67% of respondents believe recalls have a strong negative impact, and 15.17% feel they have a very strong negative impact. A smaller portion, 25%%, report a moderate impact, while 6.2 % say recalls have a minor impact. Only 0.8% of respondents think recalls have no effect on consumer trust. These findings highlight the significant damage recalls can do to a pharmaceutical brand's reputation and consumer confidence.

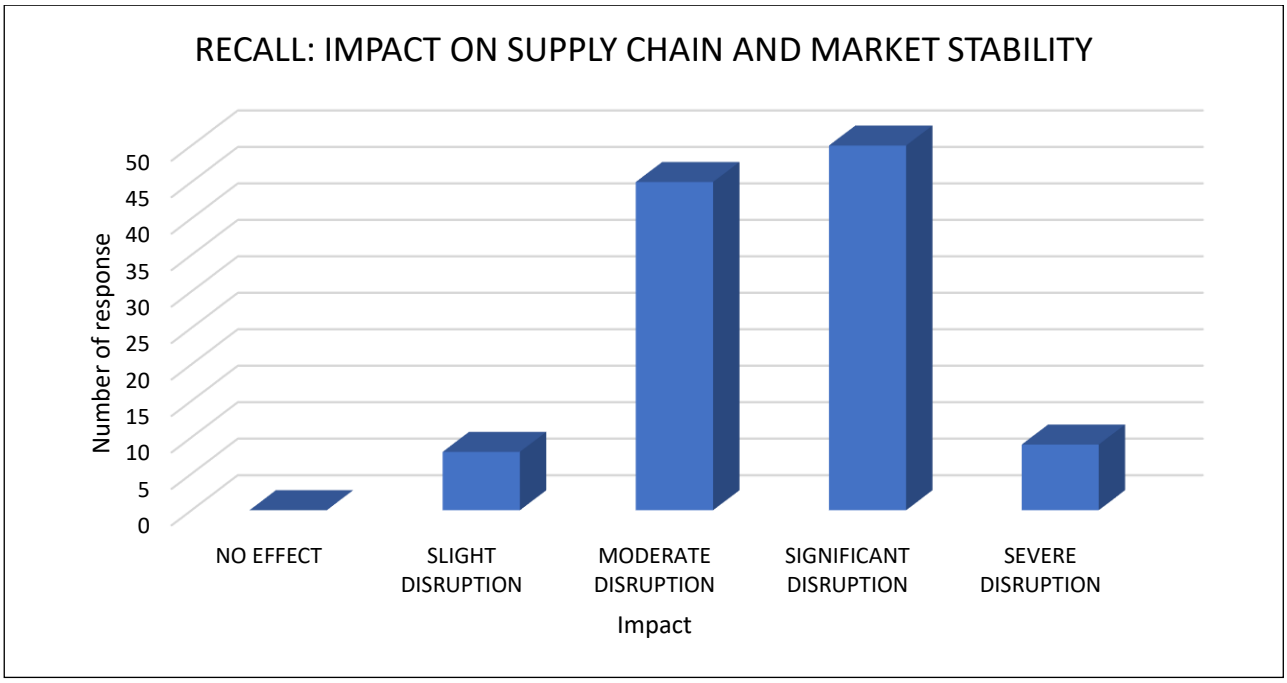

Figure 30:- Bar graph representing the impact of recalls on supply chain and market stability

The survey results regarding the impact of recalls on supply chain and market stability show that 50% of respondents believe recalls cause significant disruption. Additionally, 40.17% report moderate disruption, indicating that a large majority of respondents feel that recalls disrupt operations to varying degrees. A smaller portion, 7%, mention slight disruption, while 8% believe recalls result in severe disruption. Interestingly, no respondents felt that recalls have no effect on supply chain and market stability. This suggests that recalls are generally perceived as having a notable impact on both supply chains and market dynamics.

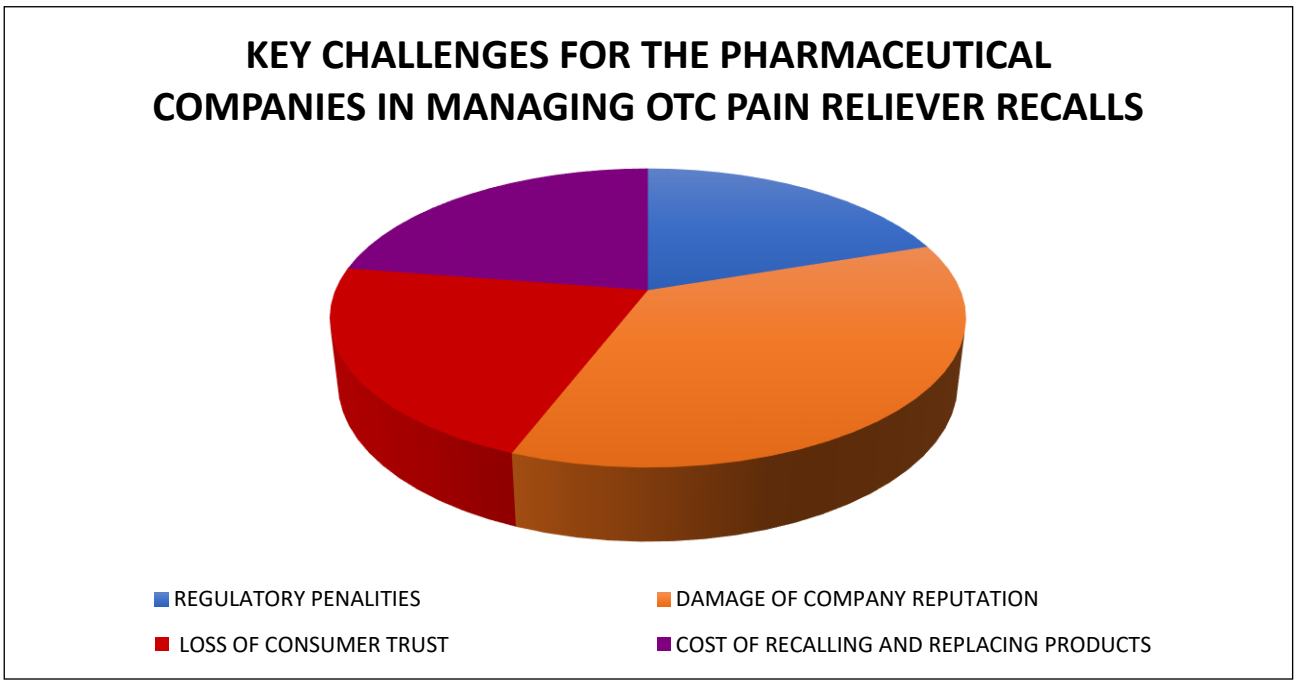

Figure 31:- Bar graph representing the Key Challenges for Companies in Managing OTC Pain Reliever Recalls

The study reveals that pharmaceutical companies face several challenges in managing recalls. The most significant concern is the damage to company reputation (32.14%), as recalls can severely undermine public trust in a brand. The cost of recalling and replacing products (20.53%) also poses a major challenge, with companies incurring substantial expenses for logistics and product replacement. Loss of consumer trust (19.64 %) follows closely, as a recall can led to long-term damage to brand loyalty and market share. Regulatory penalties (17.85%) are another key concern, as non-compliance can result in heavy fines and legal consequences.

4.2.2.6. SESSION 6: BEST PRACTICES AND RECOMMENDATIONS

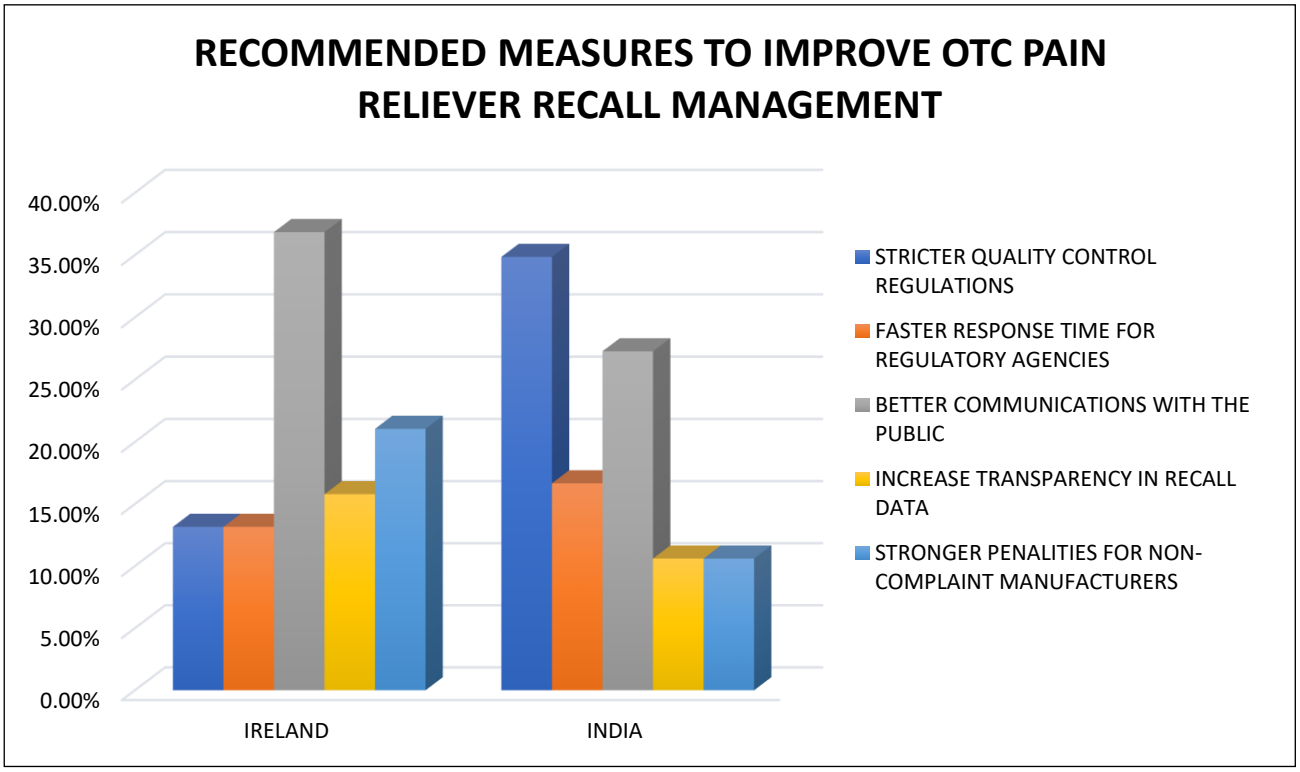

Figure 32:- Bar graph representing the recommended measures to improve OTC pain reliever recall management in India and Ireland

The survey reveals some key differences and similarities in recommendations for improving recall management between India and Ireland. Both countries prioritize stricter quality control and faster regulatory response, though a higher percentage of Irish participants (34.85%) emphasize quality control compared to India (13.16%). Better communication with the public is more strongly favoured in India (36.84%) than in Ireland (27.27%). While both countries agree on the importance of transparency in recall data, Indian respondents (15.79%) show more concern for this than Irish respondents (10.61%). Finally, stronger penalties for non-compliant manufacturers are more strongly supported in India (21.05%) compared to Ireland (10.61%). Overall, while both countries agree on key actions, India places greater emphasis on penalties, transparency, and communication.

4.3. QUALITATIVE ANALYSIS

This study investigates the perceptions, experiences, and expert insights surrounding OTC pain reliever recalls in India and Ireland. To capture the nuanced understanding of regulatory practices, patient safety implications, and operational challenges, a qualitative approach was adopted using semi-structured interviews and open-ended survey questions.

4.3.1 INTERVIEW

As part of the qualitative component of this research, online interviews were conducted with 1 professional working within the pharmaceutical industry in Ireland and 2 professionals working as a pharmacist in India. The objective of these interviews was to gain in-depth perspectives on the recall of over-the-counter (OTC) pain relievers, including industry experiences, regulatory responses, and the challenges involved in recall management. The interviews were conducted via Zoom to ensure flexibility and accessibility for the participants. Prior to beginning each interview, participants were asked to confirm their current role and level of experience to ensure they possessed relevant expertise. These interviews provided valuable insights into real-world practices, professional challenges, and potential strategies for improving recall effectiveness in the pharmaceutical sector.

4.3.1.1. SECTION 1: - GENERAL INFORMATION

The initial section of each interview served to confirm the participant's current role in the pharmaceutical or healthcare sector and to establish their level of experience. This ensured that the insights gathered were informed by individuals with relevant expertise and practical involvement in the handling or oversight of OTC medications and recall procedures.

	Job title	Responsibilities	Experience
Respondent 1 (INDIA)	Clinical pharmacist	Direct patient counselling, ensuring the rational use of medications, monitoring drug interactions, and providing drug information services to both patients and healthcare professionals.	5 years
Respondent 2 (IRELAND)	Pharmaceutical professional	Overseeing compliance with HPRA and EMA regulations, particularly in the area of product quality, batch release, and post-market surveillance.	10 years
Respondent 3 (INDIA)	Retail pharmacist	Dispensing medications, counselling patients, and ensuring compliance with drug safety and regulatory requirements.	7 years

Table 10:-Representing the job title and responsibilities of interviewees

4.3.1.2. SECTION 2: - RECALL TRENDS AND CAUSES

Respondents from India and Ireland provided distinct but overlapping insights into the causes and trends of OTC pain reliever recalls in their respective countries. In India, the most common reasons for recalls include microbial contamination—especially in liquid formulations—incorrect labelling, substandard API content,

dissolution failures, and non-compliance with GMP. Similarly, the Irish respondent also cited microbial contamination and labelling errors, along with substandard API content and failure to meet EMA standards, particularly among third-party manufacturers. However, Indian respondents emphasized more systemic issues such as inadequate GMP compliance, poor manufacturing hygiene, and lack of robust quality assurance during distribution—especially among small- and medium-scale enterprises. In contrast, the Irish perspective pointed more toward post-market detection of problems with third-party manufacturers, suggesting stronger pre-market regulatory expectations. All three respondents observed a slight to marginal increase in product recalls over the past two years. Indian professionals attributed this trend to intensified surveillance by the CDSCO, increased state-level inspections, and better reporting by healthcare providers. Meanwhile, the Irish respondent linked the increase to enhanced pharmacovigilance systems, more frequent audits by the HPRA, and improved whistleblower mechanisms. Regarding the types of products most often recalled, Indian respondents consistently pointed to generic paracetamol (both tablets and syrups), ibuprofen tablets, and combination pain relievers, while the Irish respondent did not identify any specific product category as more frequently recalled. This contrast highlights both shared concerns and region-specific challenges in maintaining the quality of OTC medications.

This section was divided into 3 questions. The response obtained to each question were as follows;

QUESTIONS	RESPONDENT 1 (INDIA)	RESPONDENT 2 (IRELAND)	RESPONDENT 3 (INDIA)
1. In your experience, what are the most common reasons for OTC pain reliever recalls in your country?	Dissolution failures	It occurs rarely but still, microbial contamination (particularly in liquid formulations), incorrect labelling.	Microbial contamination, incorrect labelling, substandard active pharmaceutical ingredient (API) content, and non-compliance with manufacturing standards.
2. What do you think are the main reasons these quality issues occur in manufacturing and distribution?	Lack of stringent quality checks, inadequate GMP compliance, and occasional lapses in manufacturing hygiene standards.	Third-party manufacturers fail to meet EMA standards, which becomes apparent only post-market.	Non-adherence to GMP guidelines, poor oversight of small and medium-scale manufacturers, and lack of robust quality assurance
3. Have you observed any changes in recall frequency over the past 2 years? If so, what do you think has contributed to these changes?	Yes, there has been a slight increase, likely due to improved monitoring by the CDSCO and better reporting mechanisms.	Yes, there's been a marginal increase, largely due to enhanced pharmacovigilance systems, more frequent HPRA audits, and stronger whistleblower reporting mechanisms within the industry.	Yes, there has been a slight increase. This is likely due to stronger surveillance by CDSCO, more frequent state-level inspections, and greater awareness among healthcare professionals to report adverse drug events
4. Are there any specific brands or types of OTC pain relievers that have been more frequently recalled?	Generic paracetamol tablets and combination pain relievers	Nothing specifically	Generic paracetamol syrups and ibuprofen tablets.

Table 11:- Representing the recall trends and causes

4.3.1.3. SECTION 3: REGULATORY FRAMEWORK AND RECALL STRATEGIES

Ireland and India differ significantly in how they manage OTC pain reliever recalls. Ireland follows a centralized, transparent, and structured approach under the HPRA, with clear risk classifications, public recall databases, and strong integration of EMA and WHO guidelines. In contrast, India's CDSCO-led process is more fragmented and less uniform, particularly across rural areas, with reliance on manual communication and limited public access to recall information. While Ireland's system is considered highly effective, it still faces challenges in consumer outreach. India's recall management is moderately effective in urban areas but weakened by poor communication, limited enforcement in semi-urban and rural regions, and low consumer awareness. International regulations influence both systems, but more directly shape Irish policies, whereas in India they primarily impact export-oriented and multinational-related recalls. Overall, Ireland demonstrates higher transparency and consistency in recall strategy compared to India.

QUESTIONS	RESPONDENT 1 (INDIA)	RESPONDENT 2 (IRELAND)	RESPONDENT 3 (INDIA)
5. How does your country's regulatory authority (HPRA/CDSCO) handle OTC pain reliever recall? What are the key steps involved?	CDSCO typically issues a recall notice, which is then communicated to manufacturers, distributors, and pharmacies. They categorize recalls based on risk and require immediate cessation of sale and retrieval of the affected batch.	HPRA classifies recalls into Class I (serious risk), Class II (medium risk), and Class III (low risk). Once a recall is issued, the MAH (Marketing Authorisation Holder) is responsible for prompt communication to the supply chain and the public. HPRA supervises the process, ensures batch traceability, and publishes recall notices publicly.	CDSCO typically issues a recall alert through zonal or state drug controllers. This is then communicated to distributors, hospitals, and pharmacies.However, the process lacks nationwide uniformity and often relies on manual communication chains.
6. How effective do you think your country's recall management system is ensuring drug safety? What are the challenges that exist?	Moderately effective. It works better in urban areas, but rural implementation and awareness are lacking	Ireland's recall system is very effective. Challenges still exist in ensuring timely communication to all retail pharmacies and in public awareness, especially when it comes to minor recalls.	Moderately effective in urban tertiary centres where pharmacists are vigilant and systems are somewhat structured. But in rural or semi-urban areas, lack of awareness, poor recall communication, and minimal regulatory follow-up make the system inconsistent.
7. What are the main differences in how Ireland and India handle OTC pain reliever recalls?	Ireland has more structured recall protocols, with higher transparency and public communication. In India, enforcement and awareness are still catching up.	Ireland benefits from a centralized, transparent system under HPRA and the EMA, with strict enforcement and public recall databases. India's recall process, as I understand, is more fragmented due to its decentralized regulatory	Ireland follows a more centralized, transparent system with real-time updates and public access to recall databases. India, on the other hand, suffers from fragmented recall pathways, limited consumer-level communication, and slow dissemination of recall

		approach and limited rural enforcement.	alerts to frontline healthcare providers.
8. How does international regulations (WHO, EMA, FDA) influence recall procedures in your country?	WHO GMP guidelines and periodic alerts from the FDA or EMA influence CDSCO actions, especially for exported products or multinational companies.	EMA guidelines are directly integrated into Irish law, and HPRA works closely with both the EMA and WHO to harmonize standards. Recalls prompted by alerts from FDA or WHO also influence market actions in Ireland, especially for imported products.	They influence indirectly. CDSCO often references WHO GMP and FDA safety alerts, especially when dealing with multinational companies or exported drugs. However, domestic recalls for local manufacturers are still primarily handled under national regulations.
9. How transparent is recall information in your country? Is it easily accessible to healthcare professionals, pharmaceutical companies and consumers?	Only moderately transparent. Professionals may be informed, but consumers often remain unaware unless there is media coverage.	Very transparent. HPRA maintains a publicly accessible database, and alerts are disseminated to pharmacies and healthcare providers. However, consumer engagement could still be improved through wider use of digital platforms.	It is partially transparent. Information is shared through official notifications and sometimes hospital networks. But there's no centralized recall portal for consumers or even consistent updates for pharmacists in all settings.

Table 12:- Representing the regulatory frameworks and recall strategies

4.3.1.4. SECTION 4: IMPACT ON PATIENT SAFETY

The recall of OTC pain relievers poses significant risks to patient safety in both India and Ireland, with common concerns including therapeutic failure, toxicity, and adverse reactions—especially among vulnerable populations like children and the elderly. In India, respondents emphasized that continued consumption of substandard or contaminated products often stems from delayed recall communication and low patient awareness. The Irish respondent similarly noted that the greatest risk lies in patients unknowingly using defective products due to inadequate awareness, particularly in the case of mislabelling or contamination. When it comes to public trust, all respondents agreed that recalls can damage confidence in pharmaceuticals and regulatory agencies if poorly managed. However, the Irish perspective added that transparent and prompt recall processes may actually strengthen trust over time. To better protect consumers, Indian experts recommended centralized recall databases, pharmacist alerts, public awareness campaigns, and stronger oversight of smaller manufacturers. The Irish respondent advocated for enhanced digital traceability, real-time public alerts via pharmacies and healthcare apps, and improved post-marketing surveillance. All three observed changes in patient behaviour post-recall, such as reduced adherence, fear of generics, and increased preference for branded or imported medications—highlighting the broader psychological and behavioural impact of recall events on public health.

QUESTIONS	RESPONDENT 1 (INDIA)	RESPONDENT 2 (IRELAND)	RESPONDENT 3 (INDIA)

10. What are the biggest risks to patient safety when an OTC pain reliever is recalled?	The biggest risk is therapeutic failure — the medicine might not work as expected, or in some cases, it could cause harm, especially if impurities are involved.	Delayed awareness and continued usage of defective batches pose the biggest risk, especially if the product is contaminated or incorrectly labelled. For vulnerable groups like children or elderly patients, these risks are magnified.	The primary risks are continued consumption of contaminated or substandard products due to delayed awareness and lack of patient education. This can result in therapeutic failure, toxicity, or adverse reactions—particularly among children and elderly patients.
11. How do recalls impact public trust in pharmaceutical products and regulatory agencies?	They can cause panic and reduce confidence in drug safety, especially if not communicated effectively.	If handled promptly and transparently, recalls can actually strengthen public trust. However, frequent or poorly communicated recalls may raise concerns about industry oversight and manufacturing standards.	Affect public confidence, lack of clear communication can lead patients to distrust generic brands, avoid self-medication, or switch to imported or more expensive products.
12. What measures do you think should be implemented to better protect consumers from unsafe OTC pain relievers?	Regular inspections, mandatory barcode tracking, public recall announcements, and digital awareness campaigns.	Enhanced digital traceability, stronger post-marketing surveillance, and mandatory public notifications via pharmacies and healthcare apps.	There should be a centralized recall database, real-time pharmacist alerts, consumer SMS notifications, and better regulation of smaller manufacturers.
13. Have you observed any changes in medication adherence in consumers due to past recalls? If so, what are the changes?	Yes, some patients become hesitant to use generic brands and switch to more expensive alternatives or stop self-medicating altogether.	Yes. Some patients develop mistrust, especially with generics, and may seek branded options or avoid self-medication altogether, even for minor conditions.	Yes. Patients have become cautious, often asking whether their medicines are safe or recently recalled. Some even stop medications mid-course or insist on branded versions only, fearing poor-quality generics.

Table 13:-Representing the impact on patient safety

4.3.1.5. SECTION 5: IMPACT ON PHARMACEUTICAL BUSINESS

OTC pain reliever recalls have significant repercussions for pharmaceutical businesses in both India and Ireland, affecting financial performance, legal exposure, and brand reputation. Indian respondents highlighted severe losses due to unsold inventory, product retrieval costs, logistics, and legal penalties—especially for smaller companies and those engaged in government contracts. Similarly, the Irish respondent noted that repeated recalls can erode brand credibility and even lead to the loss of market authorizations. Across both countries, challenges in maintaining quality standards stem from cost-cutting, complex supply chains, and inadequate internal audits. The Irish perspective emphasized the difficulty of enforcing GMP standards across

globally outsourced manufacturing networks, while Indian professionals pointed to underinvestment in quality control infrastructure. Recalls also disrupt supply chains and market stability in both settings, particularly for widely used pain relievers like paracetamol. These disruptions often result in temporary shortages, stockouts at pharmacies, and even price surges or panic buying, all of which undermine consistent patient access and trust in the healthcare system.

QUESTIONS	RESPONDENT 1 (INDIA)	RESPONDENT 2 (IRELAND)	RESPONDENT 3 (INDIA)
14. From the industry perspective, how do recalls affect pharmaceutical companies in terms of financial losses, legal risks and brand reputation?	They can be severe—losses due to product retrieval, lawsuits, reputational damage, and regulatory scrutiny.	Significantly. Repeated incidents can damage brand credibility and lead to the loss of market authorisations.	Recalls lead to substantial financial losses due to unsold inventory, logistics costs, and penalties. Damage brand reputation, especially for smaller firms that lack crisis management frameworks. Legal risks also increase, particularly for companies supplying government contracts.
15. What are the biggest challenges pharmaceutical companies face in maintaining quality standards and preventing recalls?	Cost-cutting in manufacturing, supply chain complexity, and insufficient internal audits.	Maintaining GMP standards across complex global supply chains, especially with outsourced manufacturing.	Lack of investment in quality control infrastructure, and insufficient internal audits.
16. How do recalls impact supply chains, product availability and market stability?	Recalls can lead to temporary shortages and disrupt the supply chain, especially for high-demand pain relievers.	Recalls can lead to temporary shortages, especially if there are few alternative suppliers. This can cause price surges and panic buying in the short term.	In the short term, they disrupt availability—especially for high-demand medications like paracetamol. This leads to stockouts in pharmacies and delays in treatment.

Table 14:-Representing the impact on pharmaceutical business

4.3.1.6. SESSION 6: BEST PRACTICES AND RECOMMENDATIONS

India and Ireland share a commitment to improving OTC pain reliever recall management, but each faces unique challenges and opportunities. In India, major gaps include delayed communication, a lack of centralized digital recall systems, weak rural outreach, and inconsistent coordination between state and central authorities. Respondents emphasized the need for a national digital alert platform, stricter penalties, and better GMP enforcement. In contrast, Ireland's system is more effective but could benefit from real-time pharmacy software integration and broader digital communication with consumers. Both countries recognize the value of leveraging international best practices: Indian experts praised Ireland's structured, transparent HPRA recall model, while the Irish respondent suggested adopting Australia's consumer notification apps. Collaboration among pharmaceutical companies, regulators, and healthcare providers was identified as essential—through shared audits, joint training, and digital tracking systems. The most urgent needs identified include public

awareness campaigns and stronger oversight of small manufacturers in India, and enhanced traceability tools like consumer-verifiable QR codes in Ireland. All respondents recommended increasing public engagement, mobile app integration for alerts, and incorporating recall education into broader health communication efforts—underscoring the importance of combining regulatory rigor with proactive public outreach.

QUESTIONS	RESPONDENT 1 (INDIA)	RESPONDENT 2 (IRELAND)	RESPONDENT 3 (INDIA)
17. What are the main gaps and inefficiencies in the current recall management system in your country?	Delayed communication, lack of centralized databases, poor rural awareness, and inconsistent enforcement.	Effective but could benefit from better integration with pharmacy software for real-time alerts, and more direct consumer communication.	Delayed dissemination of recall information, lack of digital tracking systems, inconsistent coordination between state and central drug authorities, and minimal public communication.
18. What strategies or regulatory improvements would you suggest to enhance recall management?	Implementing real-time digital recall alerts, enhancing GMP audits.	Integrating recall alerts with e-prescription systems, mandating manufacturer self-reporting timelines, and expanding HPRA's digital outreach.	Implementing a national digital recall alert platform, stricter penalties for non-compliance, mandatory inspections and training to professionals
19. Are there best practices from other countries that could be adopted to improve recall handling in Ireland and India?	Ireland's public recall database and automated pharmacy alerts are excellent models India could adopt.	Ireland could benefit from Australia's consumer notification apps India's challenges highlight the importance of Ireland maintaining strong centralized oversight and digital infrastructure.	India could benefit from Ireland's centralized HPRA model, which includes public-facing recall databases and structured classifications.
20. How can pharmaceutical companies, regulatory agencies and healthcare providers work together to reduce recall risk?	Regular training, joint audits, consumer education programs, and technology-based tracking systems.	By sharing quality audit data, and aligning on standard protocols for recall communication and corrective actions.	Open communication, sharing data on quality issues, and creating joint training programs on GMP and recall handling.
21. Based on your experience, what is the most important change needed to improve OTC pian reliever recalls?	Nationwide awareness campaigns and stricter oversight of small and mid-sized manufacturers.	Greater public engagement and traceability—leveraging technology like QR codes for consumers to verify product status instantly.	Creating a centralized, accessible digital recall notification system for healthcare providers and patients alike.
22. Do you have any additional insights, or recommendations on recall management, patient safety or	Yes, integrating recalls into mobile health apps could help spread awareness quickly. Also, stricter penalties for repeat offenders would enhance deterrence.	A national recall notification mobile app linked to HPRA would be a game-changer. Also, requiring periodic recall simulations for pharmaceutical	Yes—public education is often overlooked. Including recall awareness in national health campaigns, school health education, and pharmacy posters could

regulatory improvements?		companies could boost readiness and compliance.	go a long way in improving recall management

Table 15:- Representing the recommendation and improvements for recall management

4.3.2. SURVEY- OPEN ENDED QUESTIONS

Open-ended survey questions were used to gather in-depth insights from healthcare and pharmaceutical professionals in India and Ireland regarding OTC pain reliever recalls. Questions focused on the causes of recalls, regulatory challenges, and their impact on patient safety, trust, and business operations. The open format allowed participants to share detailed, experience-based responses, highlighting country-specific practices, systemic gaps, and recommendations for improvement in recall management.

A. Can you describe a specific OTC pain reliever recall incident that has a significant impact?

Participants from India cited multiple significant OTC pain reliever recalls, including Ibuprofen, Paracetamol, Aceclofenac-paracetamol-serratidopeptidase combinations, Meftal Spas, Combiflam, and Dolo, primarily due to mislabelling, substandard quality, and contamination. The September 2024 CDSCO alert on substandard paracetamol batches was frequently mentioned, as was the globally significant Johnson & Johnson Children's Tylenol recall. In contrast, only one recall—Boots-branded paracetamol—was noted in Ireland, suggesting fewer incidents or lower visibility. These findings suggest a higher recall frequency and greater awareness in India, likely driven by a larger generic drug market, variable manufacturing practices, and more active regulatory oversight.

B. What improvements do you think should be made to recall policies in your country?

Indian participants strongly advocated for a transparent, standardized recall policy supported by real-time communication and robust digital infrastructure. Key recommendations included establishing a centralized recall database, public alerts, uniform national protocols, and enhanced consumer education. Suggestions emphasized AI-driven tracking, pharmacy-level batch integration, and automated alert systems to improve traceability and responsiveness. Calls for stricter regulatory enforcement and greater manufacturer accountability were also prominent. In contrast, Irish responses—though fewer—highlighted the need for public-facing recall databases and improved consumer engagement. Overall, the findings underscore India's urgent need for systemic reforms and technological upgrades, while Ireland's focus lies in refining transparency and public outreach within its existing framework.

C. In your opinion, how does your country's recall process compare to international best practices?

The responses highlight a stark contrast in perceptions of OTC pain reliever recall systems between Ireland and India. Irish participants generally viewed their recall framework as efficient, timely, and aligned with international standards, citing rapid responses, transparent communication, and accessible databases as key strengths. Many considered Ireland's system among the best in Europe. In contrast, Indian respondents expressed concerns over delayed alerts, poor communication, and the absence of centralized, enforceable protocols. While some acknowledged ongoing improvements, most emphasized the need for stronger enforcement, better post-market surveillance, and adoption of global models like those of the FDA or EMA. Overall, Ireland is seen as a benchmark of regulatory efficiency, while India is viewed as progressing but still falling short of international standards.

D. What additional measures should be taken to improve consumer safety regarding OTC pain relievers?

Participants from both Ireland and India emphasized the critical role of education, regulation, and communication in enhancing consumer safety around OTC pain relievers, though their priorities reflected differing systemic needs. Irish respondents advocated for stronger public education through media channels, clearer labelling, and stricter enforcement to ensure safe usage, while also calling for ongoing training for medical professionals and improved manufacturing oversight. Indian participants echoed similar concerns but expressed a more urgent need for public awareness campaigns, digital tools, and pharmacist-led interventions to address widespread misuse and limited recall visibility. They stressed the importance of regulatory reforms, routine inspections, and standardized labelling to prevent health risks such as liver and kidney damage. Overall, the responses highlight that while Ireland focuses on refining an already functional system, India requires a more comprehensive, multi-layered approach involving education, technology, regulatory overhaul, and pharmacist engagement to bridge current safety gaps.

E. How can consumers be better informed about OTC pain reliever recalls?

To improve consumer awareness of OTC pain reliever recalls, both India and Ireland support a comprehensive, multi-channel communication strategy. Key methods include leveraging traditional media (newspapers, TV), digital platforms (social media, apps), and direct notifications (SMS, email). Pharmacists and healthcare providers play a frontline role by informing patients during dispensing. Educational initiatives, public campaigns, and centralized online recall portals further enhance outreach. By integrating real-time alerts, accessible resources, and professional engagement, both countries aim to build an informed public and strengthen consumer safety around OTC medication use.

F. Are you aware of any best practices from other countries that could be adopted to improve recall process?

Several best practices from other countries could significantly improve India's OTC pain reliever recall process. One key example is the U.S. FDA's MedWatch Program, which provides a centralized platform for monitoring and reporting adverse drug events, including recalls. This program ensures timely and transparent notifications for consumers, healthcare professionals, and manufacturers. Ireland's media campaigns, which effectively use news broadcasts and social media to disseminate recall information, are also an effective model for raising public awareness quickly. To enhance India's recall process, adopting online databases for consumers to access recall information could improve transparency and convenience. Streamlining retailer communications, ensuring that pharmacies and retailers are promptly notified, would help relay recall information directly to customers. Additionally, integrating technologies like track-and-trace systems and centralized communication platforms—similar to those in the U.S. and EU—could improve the speed and efficiency of recalls. A centralized recall database would allow consumers and healthcare professionals to easily access recall details, ensuring better safety and faster response times. By adopting these best practices, India could strengthen its recall system, enhancing consumer safety and ensuring more rapid and coordinated responses to issues

G. Do you have any additional insights or suggestions for improving OTC pain reliever recall management in your country?

To improve OTC pain reliever, recall management in India, several key strategies can be implemented. First, enforcing strict regulatory measures would hold manufacturers accountable for the timely reporting and handling of recalls. A mandatory digital reporting system could ensure that manufacturers notify authorities immediately, allowing for swift action. Collaborating with e-pharmacies and retail chains would facilitate faster dissemination of recall alerts to consumers, both in urban and remote areas. Training pharmacists to educate consumers during purchases and returns would help ensure that recall information reaches people at the point of sale. Additionally, developing global-based recall databases would enable both consumers and healthcare professionals worldwide to access real-time data, improving transparency and trust.

Leveraging AI technology could streamline the recall process through automated tracking and management systems, increasing efficiency. An app providing live recall updates and SMS alerts would add another layer of communication, ensuring that consumers stay informed in real time. Finally, strengthening media campaigns across traditional and social media platforms would broaden the reach and impact of recall information, improving public awareness. By implementing these strategies, both India and Ireland can manage OTC pain reliever recalls more

effectively, ensuring quicker responses, better consumer safety, and a more efficient process overall.

4.4. CONCLUSION

This chapter presented the key findings from both the quantitative survey and qualitative interviews, highlighting current practices, challenges, and perceptions surrounding OTC pain reliever recalls in India and Ireland.

4.4.1. RESEARCH CONCLUSIONS

The comparative analysis of over-the-counter (OTC) pain reliever recalls in Ireland and India has revealed significant differences in regulatory structures, recall execution efficiency, and public safety outcomes. In Ireland, the centralised and EU-aligned recall system—supported by the HPRA —demonstrates greater efficiency in communication, product traceability, and stakeholder engagement. In contrast, India's decentralised regulatory framework under the CDSCO results in fragmented enforcement, delayed recall execution, and limited consumer awareness, particularly in rural areas. Quality issues such as contamination, mislabelling, and stability failures were found to be the leading causes of recalls in both countries. However, India exhibited a higher volume and recurrence of recalls, often linked to inconsistent Good Manufacturing Practices (GMP) compliance, substandard raw materials, and weaker post-marketing surveillance. The data also revealed that both countries experience financial and reputational consequences from recalls, along with a negative impact on patient safety.

4.4.2. STRATEGIC CONCLUSIONS

From a strategic perspective, it is evident that both regulatory authorities and pharmaceutical companies must adopt more integrated, transparent, and technology-driven recall management systems. For Ireland, strengthening digital traceability and more enhanced EU-wide coordination can enhance recall responsiveness. In India, strategic improvements must focus on establishing a centralised national recall database, mandating stricter compliance with recall protocols, and increasing investments in regulatory enhancement. Further, there is a critical need for both countries to improve public recall communication and consumer awareness. This is particularly urgent in India, where the lack of accessible recall information has led to continued use of unsafe medications. Pharmaceutical companies must also strengthen internal quality systems to prevent recurring issues, especially among small and medium-sized manufacturers.

CHAPTER 5: - CONCLUSIONS AND RECOMMENDATIONS

5.1. SUMMARY OF MAIN FINDINGS AND IMPLICATIONS OF RESEARCH QUESTIONS

- Ireland's recall system, regulated by the HPRA, is more structured, centralised and transparent, resulting in faster execution and more consistent public communication.
- India's recall system, governed by the CDSCO, is decentralised and inconsistently enforced leading to delays and incomplete product withdrawal, particularly across states.
- Contamination and assay failures were dominant causes in India: packaging and labelling errors were more frequent in Ireland.
- Patient safety is compromised in both countries, but significantly in India due to low consumer awareness and ineffective recall communication.
- Pharmaceutical companies in both countries suffer financial losses, reputational damage and regulatory penalties due to recalls, with Indian companies facing more systemic issues.
- There is a clear gap in post-marketing surveillance, in both countries requiring improved mechanism for monitoring drug quality after release.
- Stakeholders in India reported greater concerns regarding transparency, regulatory delays and enforcement inconsistency compared to their Irish counterparts.

5.2 SUMMARY OF DIFFERENCES BETWEEN FINDINGS AND THE LITERATURE

- While the literature suggests increasing convergence in global recall standards, this research highlights persistent disparities between high- and middle-income countries in implementation and enforcement.
- Contrary to some studies claiming improved recall transparency in emerging markets, the study found India's system still lacks a centralised recall database and adequate consumer outreach.
- Theoretical models in the literature emphasise Good Manufacturing Practices (GMP) as a key preventative measure, yet recurring recalls from the same Indian manufacturers suggest continued non-compliance despite regulatory mandates.
- Literature notes increasing public engagement through digital platforms, but India lags significantly in this area; most consumers remain unaware of recalls unless directly contacted.

5.3 PRACTICAL AND ACADEMIC RECOMMENDATIONS

5.3.1. PRACTICAL RECOMMENDATIONS:

- India should implement a centralised digital recall database, accessible to both consumers and healthcare professionals.

- Pharmaceutical companies must adopt real-time traceability technologies, such as barcoding and blockchain, to enhance product tracking.
- Consumer communication protocols need to be improved, using SMS alerts, pharmacy notifications, and media campaigns for urgent recalls.
- Training programs for pharmacists and healthcare providers should include guidelines on recall management and patient counselling.
- Ireland should enhance its cross-border coordination within the EU to reduce inter-agency lag times in pan-European recalls.

5.3.2. ACADEMIC RECOMMENDATIONS:

- Future research should explore the effectiveness of AI-driven quality control in preventing recalls.
- Comparative studies should be conducted across more countries, including those with similar regulatory models to India and Ireland, to identify scalable best practices.
- Universities should integrate regulatory science into pharmaceutical and healthcare curricula to improve stakeholder awareness from early stages.

5.4 LIMITATIONS AND CONTRIBUTIONS OF THE RESEARCH

5.4.1. LIMITATIONS:

- Limited access to comprehensive CDSCO recall data affected cross-country comparability.
- The small number of interview participants have constrained the diversity of qualitative insights.
- The cross-sectional design captured current perceptions but not longitudinal changes in recall trends.
- Manual thematic analysis, though own interpretation, may carry some degree of researcher bias.

5.4.2. CONTRIBUTIONS:

- Provides the first in-depth comparative analysis of OTC recall management in Ireland and India.
- Offers a novel integration of regulatory theory with stakeholder perspectives, producing practical and policy-relevant insights.
- Establishes a baseline for recall pattern tracking over time, laying the groundwork for future longitudinal studies.
- Generates actionable strategies for improving drug safety and public trust, particularly in emerging markets.

5.5 SUGGESTIONS FOR FURTHER RESEARCH

- Future studies should explore consumer behavioural responses to recalls, including trust levels, adherence, and risk perception.
- There is a need for research into economic consequences of recalls, especially their long-term effects on brand equity and investor confidence.
- Studies should also investigate supply chain vulnerabilities, especially in India, where raw material sourcing and quality assurance practices vary significantly.
- The potential of mobile applications and digital alert systems for real-time recall notifications should be evaluated.

5.6 FINAL REFLECTIONS

Completing this dissertation has deepened my understanding of regulatory complexities and public health challenges within the pharmaceutical sector. It has shown me the value of mixed-methods research in bridging technical data with human experiences. More personally, it has strengthened my capacity to critically evaluate global disparities in drug safety and shaped my passion for working in a field where evidence-based policy can protect millions of lives.

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APPENDICES

APPENDIX A: SURVEY QUESTIONNAIRE

Available at:- https://forms.gle/EdZR4cdHhoJLF9tM9

COMPARATIVE ANALYSIS OF OVER-THE-COUNTER (OTC) PAIN RELIEVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA

I am Aleena Manoj, pursuing my Masters in Pharmaceutical Business and technology at Griffith College, Dublin. I intend to do the research to conduct a comprehensive comparative analysis of Over-the-Counter (OTC) pain reliever recalls in Ireland and India. It would be highly appreciated if you show interest in taking part in my research study. This research seeks to evaluate the trends and regulatory responses to these recalls while examining their impact on patient safety and pharmaceutical business. This research identifies the gaps in existing recall management systems, assess the effectiveness of regulatory oversight and analyse recall trends over a five-year period to provide an evidence- based evaluation of the key challenges faced by both countries. Furthermore, the study explores best practices in recall process by proposing strategic recommendations for enhancing recall management. Please take time to read the information attached to this form carefully. The survey comprises of multiple; choice questions and short answers ones.by filling the survey, you are voluntarily agreeing to take part in the research study and I assure you that confidentiality of the responses will be highly maintained. The data generated will be handled as per General Data protection Regulation (GDPR). The survey will take around 5-7 minutes to complete. If you have any queries concerning this survey, do not hesitate to contact me at the following email Id:

aleena.manoj@student.griffith.ie

Sign in to Google to save your progress. Learn more

* Indicates required question

Do you consent to take part in the research? *

- ○ Yes
- ○ No

Is the need and significance of the study fully understood? *

- ○ Yes
- ○ No

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Section 1: General information

What is your role in relation to the OTC pain relivers? *

- ◯ Regulatory official
- ◯ Pharmaceutical industry professional
- ◯ Healthcare provider (Doctor, Nurse, Pharmacist)
- ◯ Consumer
- ◯ Other: _____

In which country do you primarily work or have experience with OTC pain relievers? *

- ◯ Ireland
- ◯ India

How long have you been involved in the pharmaceutical or healthcare industry? *

- ◯ Less than a year
- ◯ 1 to 5 years
- ◯ 6 to 10 years
- ◯ More than 10 years

How familiar are you with OTC pian reliever recalls? *

	1	2	3	4	5	
Not at all familiar	◯	◯	◯	◯	◯	Extremely familiar

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Section 2: - Recall Trends and causes

Have you ever encountered an OTC pain reliever recall? *

- ◯ Yes
- ◯ No

In your experience, how frequently do OTC pain reliever recalls occur in your country? *

	1	2	3	4	5	
Very rarely	◯	◯	◯	◯	◯	Very frequently

What do you think are the most common causes for OTC pain reliever recalls? *

(select all that may apply)

- ☐ Contamination
- ☐ Mislabelling
- ☐ Potency issues
- ☐ Stability failures
- ☐ Non-compliance with regulatory standards
- ☐ Other: _____

Can you describe a specific OTC pain reliever recall incident that has a significant impact?

Your answer

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Section 3: Regulatory framework and Recall strategies

How would you rate the effectiveness of recall management in your country? *

	1	2	3	4	5	
Very Ineffective	○	○	○	○	○	Very Effective

How transparent is the recall process in your country? *

	1	2	3	4	5	
Not transparent at all	○	○	○	○	○	Very Transparent

How easy is it for consumers to access recall information for OTC pain relievers? *

	1	2	3	4	5	
Very Difficult	○	○	○	○	○	Very Easy

Do you think the regulatory authorities in your country take quick and appropriate action in recalling unsafe OTC pain relievers? *

- ○ Yes
- ○ No
- ○ Not sure

How quickly do regulatory authorities (HPRA/CDSCO) act when an unsafe OTC pain reliever is identified? *

	1	2	3	4	5	
Very slow	○	○	○	○	○	Very Fast

What are the biggest challenges regulatory authorities face in managing OTC pain reliever recalls? *

- [ ] Delayed response time
- [ ] Inconsistent enforcement regulations
- [ ] Lack of centralised recall databases
- [ ] Limited consumer awareness about recalls
- [ ] Other: _____

What improvements do you think should be made to recall policies in your country?

Your answer

In your opinion, how does your country's recall process compare to international best practices?

Your answer

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Section 4: Impact on Patient Safety

How concerned are you about the safety of OTC pain relievers due to past recalls? *

	1	2	3	4	5	
Not Concerned	○	○	○	○	○	Very Concerned

Have you or someone you know ever been affected by a recalled OTC pain reliever? *

- ○ Yes
- ○ No

If yes, how did the recalled OTC pain reliever affect you or the person you know?

- ☐ Experienced adverse health effects
- ☐ Had to seek attention or treatment replacement
- ☐ Difficultly in obtaining safe alternative medication
- ☐ Lost trust in the brand or pharmaceutical industry
- ☐ Other: _____

How well do you think the public is informed about drug recalls in your country? *

	1	2	3	4	5	
Very poorly	○	○	○	○	○	Very well informed

What additional measures should be taken to improve consumer safety regarding OTC pain relievers?

Your answer

What are the biggest risks that recalled OTC pain relievers pose to patient health? *

- ○ Adverse drug reaction
- ○ Ineffectiveness of treatment
- ○ Toxicity
- ○ Long term health effects
- ○ Other: _____

How do recalls impact consumer confidence in pharmaceutical products? *

	1	2	3	4	5	
No impact	○	○	○	○	○	Very strong negative impact

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Section 5: Impact on Pharmaceutical Business

How significant do you think is the financial impact of OTC pain reliever recalls on pharmaceutical companies? *

	1	2	3	4	5	
No impact	○	○	○	○	○	Very strong negative impact

How do you think recalls affect consumer trust in pharmaceutical brands? *

	1	2	3	4	5	
No effect	○	○	○	○	○	Very strong negative impact

How much do recalls impact supply chain and market stability? *

- ○ No effect
- ○ Slight Disruption
- ○ Moderate Disruption
- ○ Significant Disruption
- ○ Severe Disruption

In your opinion, what are the biggest challenges for companies in manging recalls? *

- ○ Cost of recalling and replacing products
- ○ Damage of company reputation
- ○ Regulatory penalties
- ○ Loss of consumer trust
- ○ Other: _____

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Session 6: Best practices and Recommendations

What steps should be taken to improve OTC pain reliever recall management in your country? *

- ○ Stricter quality control regulations
- ○ Faster response time for regulatory agencies
- ○ Better communications with the public
- ○ Increase transparency in recall data
- ○ Stronger penalties for non-complaint manufacturers
- ○ Other: _____

How can consumers be better informed about OTC pain reliever recalls?

Your answer

Are you aware of any best practices from other countries that could be adopted to improve recall process? *

- ○ Yes
- ○ No

If yes, please describe

Your answer

Do you have any additional insights or suggestions for improving OTC pain reliever recall management in your country?

Your answer

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APPENDIX B: ETHICS FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: COMPARATIVE ANALYSIS OF OVER THE COUNTER (OTC) PAIN RELIVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA

RESEARCHER'S NAME: ALEENA MANOJ

PROGRAMME OF STUDY: MSc PHARMACEUTICAL BUSINESS AND TECHNOLOGY

SUPERVISOR'S NAME: GANIRU PRISCILLA UGWU

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: 

DATE: 25/03/2025

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE: 

DATE: 26 Mar 2025

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 *[300 words maximum/ use literature review findings to guide]*

Purpose of the research

This study contributes to the pharmaceutical industry by providing an evidence-based analysis of recall management practices in Ireland and India. The purpose of the study is to conduct the comparative analysis of Over-the-counter (OTC) pain reliver recalls in Ireland and India, focusing on regulatory frameworks and impact on patient safety and pharmaceutical business. Given the increasing globalization of pharmaceutical supply chains, understanding how different regulatory environments handle drug recalls is crucial for improving medication safety and public trust. This research identifies the gaps in existing recall management systems, assess the effectiveness of regulatory oversight and analyse recall trends over a five-year period to provide an evidence- based evaluation of the key challenges faced by both countries. Additionally, this study seeks to quantify and categorize the primary quality-related issues leading to recalls, offering insights into the most prevalent manufacturing and compliance failures. By evaluating the economic consequences of recalls on pharmaceutical companies, this research highlights the financial risk, and operational disruptions caused by substandard products. Furthermore, the study explores best practices in recall process by proposing strategic recommendations for enhancing recall management. As a result, this research contributes in improving pharmaceutical regulatory policies, strengthening quality control measures and ensure better protection for consumers in both Ireland and India.

Research objectives

1. To analyse recall trends of OTC pain relivers in Ireland and India.
2. To compare the regulatory frameworks and recall strategies employed in Ireland and India.
3. To evaluate the impact of OTC pain reliver recalls on patient safety in Ireland and India
4. To assess the economic and business impact of OTC pain reliver recalls on pharmaceutical companies in Ireland and India
5. To quantify and categorise the types of quality issues leading to recalls in India and Ireland over a period of 5 years.
6. To explore the best practices and propose strategic recommendations based on findings for improving OTC recall management.

1.2 Research methodology: *[300 words maximum/ detail how you will acquire your primary data (focus groups/interviews/online surveys etc). Proposed questions for questionnaires and/or interviews **must be included** in the appendix].*

To ensure a robust analysis of OTC pain relivers in Ireland and India, the research will incorporate a mixed approach, leveraging both qualitative and quantitative data collection techniques. This involves collection of quantitative data from analysis of recall reports from regulatory bodies that is Health Products Regulatory Authority (HPRA) and Central Drugs Standard Control Organisation (CDSCO). Structured questionaries targeting pharmaceutical companies and regulatory bodies can also provide some insights into the research. Qualitative data will be collected from face to face or zoom based semi-structed interviews with regulatory bodies, quality assurance professionals and pharmaceutical industry leaders. By examining the significant recall incidents from Ireland and India, the causes of recall and regulatory process can be identified. The data collected will be categorised in themes and will be analysed. Will be conducting a comprehensive review of academic paper, industry reports and regulatory guidelines to collect information regarding the recall trends recalls across the country. The statistical analysis of collected data will provide insights into the trends and patterns in the recalls. Case studies of specific recall incidents in both countries will be examined to gain greater insights into recalls due to quality issues. Will be conducting interviews with regulatory officials, quality assurance professionals and industry experts to get a more resourceful and widened information regarding

possible recommendations for improvements. The surveys are also conducted to gather data from pharmaceutical companies on quality control practices and challenges analysis. There could be some possible challenges that may be faced during the study which may include data availability and consistency between two countries, their differences in reporting standards and transparency.

Informed consent will be obtained from all participants prior to data collection. Participant confidentiality and anonymity will be ensured throughout the study. Ethical approval will be sought from supervisor. The research process is estimated to be completed within 2 months, including data collection, analysis and report writing. Research findings will be disseminated through academic publications, to facilitate knowledge sharing in the pharmaceutical sector.

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

RESEARCH PROCEDURES

Does the research proposal involve:

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

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	~~Yes~~ No
Does your research group include any of the following vulnerable groups	~~Yes~~ 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 *[Do not provide names except where it is deemed impossible to conceal identity].*

Pharmaceutical manufacturers: *This group includes individuals involved in the manufacturing and distribution of OTC pain relievers products in Ireland and India. They possess insights into the quality control measures, internal recall strategies and the impact of recalls on their operations. Their perspectives will shed light on the industry role and response to recall events.*

Regulatory authorities: *participants from agencies such as Ireland's Health Products Regulatory authority (HPRA) and India's Central Drugs Standard Control Organisation (CDSCO) will provide insights into the regulatory frameworks, recall procedures and enforcement mechanisms in their respective countries. Their involvement is crucial for understanding the official protocols and challenges faced during recall processes.*

Healthcare professionals: *Doctors, pharmacists and other healthcare providers who recommend or dispense OTC pain relivers will be engaged to understand how recalls affect patient safety. Their experiences will highlight the direct implications of recalls on healthcare delivery.*

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

Pharmaceutical manufacturers: *Utilising industry databases and directories to identify pharmaceutical companies and distributors of OTC pain relivers across India and Ireland. Reaching out to these manufacturers through email, zoom meetings or phone calls, introducing research study and requesting participation.*

Regulatory authorities: *Initiating contact through official channels, such as LinkedIn, email and zoom meetings outlining the research objectives and seeking participation.*

Healthcare Professionals: *Approaching hospitals, clinics and pharmacies across different regions of India and Ireland to engage with healthcare professional and the data should be collected through surveys.*

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 summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, 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 ~~No~~
Details of what participation will involve	Yes ~~No~~
Rights to anonymity	Yes ~~No~~
Confidentiality	Yes ~~No~~
Rights to withdraw from the research	Yes ~~No~~
The contact details of the researcher and supervisor (if necessary)	Yes ~~No~~

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, phonecalls, 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.
No: ~~my research study involves an online survey only and/or does not require signed consent~~

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 storage: The research data will be securely stored in digital format using password-protected files and encrypted storage to prevent unauthorised access. A centralised repository or cloud-based storage platform with robust security measures will be utilised for data storage.

Retention period: The research data will be retained for a specified period in accordance with ethical guidelines and institutional policies. Data will be retained for 2 years after completion of research project.

Data management plan: Data will be organised and labelled systematically to ensure ease of retrieval and analysis. Access to research data will be restricted to authorised personnel involved in the research project. Data sharing protocols will be established to facilitate collaboration and dissemination of research findings while ensuring data confidentiality and integrity.

Data protection measures: Personnel identifiable information of participants will be anonymised to protect their privacy. Informed consent forms will be obtained from participants clearly outlining the purpose of data collection, how their data will be used and their rights regarding data protection. Data encryption techniques will be employed during data transmission and storage to safeguard against unauthorised interception or access. Compliance with relevant data protection regulations such as general data protection regulation (GDPR) and applicable national laws will be ensured throughout the research process.

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?

~~Yes~~ 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 ~~No~~

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. 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 ~~N/A~~
9.2 Informed Consent Form (ICF) for participant	Yes ~~N/A~~
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes ~~N/A~~
9.4 Any other documents e.g. Non-Disclosure Agreement	~~Yes~~ N/A

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

For Student:

STUDENT SIGNATURE: 

DATE: 25/03/2025

SECTION 10: APPENDIX

INTERVIEW QUESTIONS

Section 1: General information

1. Can you briefly introduce yourself and your role in the pharmaceutical or healthcare industry?
2. How familiar are you with OTC pain reliver recalls in your country?

Section 2: - Recall Trends and causes

3. In your experience, what are the most common reasons for OTC pain reliver recalls in your country? (Contamination, mislabelling, potency issues etc...)
4. What do you think are the main reasons these quality issues occur in manufacturing and distribution?
5. Have you observed any changes in recall frequency over the past five years? If so, what do you think has contributed to these changes?
6. Are there any specific brands or types of OTC pain relivers that have been more frequently recalled? Why?

Section 3: Regulatory framework and Recall strategies

7. How does your country's regulatory authority (HPRA/CDSCO) handle OTC pain reliver recall? What are the key steps involved?
8. How effective do you think your country's recall management system is in ensuring drug safety? What are the challenges that exist?
9. What are the main differences in how Ireland and India handle OTC pain reliver recalls?
10. How does international regulations (WHO, EMA, FDA) influence recall procedures in your country?
11. How transparent is recall information in your country? Is it easily accessible to healthcare professionals, pharmaceutical companies and consumers?

Section 4: Impact on Patient Safety

12. What are the biggest risks to patient safety when an OTC pain reliever is recalled?
13. How do recalls impact public trust in pharmaceutical products and regulatory agencies?
14. What measures do you think should be implemented to better protect consumers from unsafe OTC pain relivers?
15. Have you observed any changes in medication adherence in consumers due to past recalls? If so, what are the changes?

Section 5: Impact on Pharmaceutical Business

16. From the industry perspective, how do recalls affect pharmaceutical companies in terms of financial losses, legal risks and brand reputation?
17. What are the biggest challenges pharmaceutical companies face in maintaining quality standards and preventing recalls?
18. How do recalls impact supply chains, product availability and market stability?

Session 6: Best practices and Recommendations

19. What are the main gaps and inefficiencies in the current recall management system in your country?
20. What strategies or regulatory improvements would you suggest to enhance recall management?
21. Are there best practices from other countries that could be adopted to improve recall handling in Ireland and India?
22. How can pharmaceutical companies, regulatory agencies and healthcare providers work together to reduce recall risk?
23. Based on your experience, what is the most important change needed to improve OTC pian reliver recalls?
24. Do you have any additional insights, or recommendations on recall management, patient safety or regulatory improvements?

SURVEY QUESTIONS

I am Aleena Manoj, pursuing my Masters in Pharmaceutical Business and technology at Griffith College, Dublin. I intend to do a research to conduct a comprehensive comparative analysis of Over-the-Counter(OTC) pain reliver recalls in Ireland and India. It would be highly appreciated if you show interest in taking part in my research study. This research seeks to evaluate the trends and regulatory responses to these recalls while examining their impact on patient safety and pharmaceutical business. This research identifies the gaps in existing recall management systems, assess the effectiveness of regulatory oversight and analyse recall trends over a five-year period to provide an evidence- based evaluation of the key challenges faced by both countries. Furthermore, the study explores best practices in recall process by proposing strategic recommendations for enhancing recall management. Please take time to read the information attached to this form carefully. The survey comprises of multiple; choice questions and short answers ones.by filling the survey, you are voluntarily agreeing to take part in the research study and I assure you that confidentiality of the responses will be highly maintained. The data generated will be handled as per General Data protection Regulation (GDPR). the survey will take approx. 5-7 minutes to complete. If you have any queries concerning this survey, do not hesitate to contact me at the following email Id: aleena.manoj@student.griffith.ie

1. *Do you consent to take part in the research?*
    - *Yes*
    - *No*
2. *Is the need and significance of the study fully understood?*
    - *Yes*
    - *No*

Section 1: General information

3. What is your role in relation to the OTC pain relivers?
    - Regulatory official
    - Pharmaceutical industry professional
    - Healthcare provider (Doctor, Nurse, Pharmacist)
    - Consumer
    - Other (please specify)
4. In which country do you primarily work or have experience with OTC pain relivers?
    - Ireland
    - India
    - Both
5. How long have you been involved in the pharmaceutical or healthcare industry?
    - Less than a year
    - 1 to 5 years
    - 6 to 10 years
    - More than 10 years
6. How familiar are you with OTC pian reliver recalls?
    - Not at all familiar
    - Slightly familiar
    - Moderately familiar
    - Very familiar
    - Extremely familiar

Section 2: - Recall Trends and causes

7. Have you ever encountered an OTC pain reliver recall?
    - Yes
    - No
8. In your experience, how frequently do OTC pain reliver recalls occur in your country?
    - Very rarely
    - Rarely
    - Occasionally
    - Frequently
    - Very frequently
9. What do you think are the most common causes for OTC pain reliver recalls? (*select all that may apply)*
    - Contamination
    - Mislabelling

- Potency issues
- Stability failures
- Non-compliance with regulatory standards
- Other (please specify)

10. Can you describe a specific OTC pain reliver recall incident that has a significant impact? *(short answer)*

Section 3: Regulatory framework and Recall strategies

11. How would you rate the effectiveness of recall management in your country?
    - Very Ineffective
    - Ineffective
    - Neutral
    - Effective
    - Very Effective
12. How transparent is the recall process in your country?
    - Not transparent at all
    - Slightly Transparent
    - Moderately Transparent
    - Transparent
    - Very Transparent
13. How easy is it for consumers to access recall information for OTC pain relivers?
    - Very Difficult
    - Difficult
    - Neutral
    - Easy
    - Very Easy
14. Do you think the regulatory authorities in your country take quick and appropriate action in recalling unsafe OTC pain relivers?
    - Yes
    - No
    - Not sure
15. How quickly do regulatory authorities (HPRA/CDSCO) act when an unsafe OTC pain reliver is identified?
    - Very slow
    - Slow
    - Neutral
    - Fast
    - very fast
16. What are the biggest challenges regulatory authorities face in managing OTC pain reliver recalls?
    - Delayed response time
    - Inconsistent enforcement regulations
    - Lack of centralised recall databases

- Limited consumer awareness about recalls
- Other (please specify)

17. What improvements do you think should be made to recall policies in your country?
    (short answer)
18. In your opinion, how does your country's recall process compare to international best practices?
    (short answer)

Section 4: Impact on Patient Safety

19. How concerned are you about the safety of OTC pain relivers due to past recalls?
    - Not Concerned
    - Slightly Concerned
    - Moderately Concerned
    - Concerned
    - Very Concerned
20. Have you or someone you know ever been affected by a recalled OTC pain reliver?
    - Yes
    - No
21. If yes, how did the recalled OTC pain reliver affect you or the person you know?
    - Experienced adverse health effects
    - Had to seek attention or treatment replacement
    - Difficultly in obtaining safe alternative medication
    - Lost trust in the brand or pharmaceutical industry
    - Other (please specify)
22. How well do you think the public is informed about drug recalls in your country?
    - Very poorly
    - Poorly informed
    - Neutral
    - Well informed
    - Very well informed
23. What additional measures should be taken to improve consumer safety regarding OTC pain relivers?
    (short answer)
24. What are the biggest risks that recalled OTC pain relivers pose to patient health?
    - Delayed response time
    - Inconsistent enforcement of regulations
    - Lack of centralised recall databases
    - Limited consumer awareness about recalls
    - Other (please specify)
25. How do recalls impact consumer confidence in pharmaceutical products?
    - No impact
    - Slight impact
    - Moderate impact
    - Strong impact
    - Very strong negative impact

Section 5: Impact on Pharmaceutical Business

26. How significant do you think is the financial impact of OTC pain reliver recalls on pharmaceutical companies?
    - No impact
    - Minor impact
    - Moderate impact
    - Significant impact
    - Very significant impact
27. How do you think recalls affect consumer trust in pharmaceutical brands?
    - No effect
    - Minor impact
    - Moderate impact
    - Strong negative impact
    - Very strong negative impact
28. How much do recalls impact supply chain and market stability?
    - No effect
    - Slight Disruption
    - Moderate Disruption
    - Significant Disruption
    - Severe Disruption
29. In your opinion, what are the biggest challenges for companies in manging recalls?
    - Cost of recalling and replacing products
    - Damage of company reputation
    - Regulatory penalties
    - Loss of consumer trust
    - Other (please specify)

Session 6: Best practices and Recommendations

30. What steps should be taken to improve OTC pain reliver recall management in your country?
    - Stricter quality control regulations
    - Faster response time for regulatory agencies
    - Better communications with the public
    - Increase transparency in recall data
    - Stronger penalties for non-complaint manufacturers
    - Other (please specify)
31. How can consumers be better informed about OTC pain reliver recalls?
    (short answer)
32. Are you aware of any best practices from other countries that could be adopted to improve recall process?
    - Yes
    - No

    If yes, please describe
33. Do you have any additional insights or suggestions for improving OTC pain reliver recall management in your country?

GRIFFITH COLLEGE

Participant Information Letter

COMPARATIVE ANALYSIS OF OVER THE COUNTER (OTC) PAIN RELIVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

I am Aleena Manoj, pursuing my Masters in Pharmaceutical Business and technology at Griffith College, Dublin. I intend to do the research to conduct a comprehensive comparative analysis of OTC pain reliver recalls in Ireland and India. This research seeks to evaluate the trends and regulatory responses to these recalls while examining their impact on patient safety and pharmaceutical business. Furthermore, this research will quantify and categorise the types of quality issues leading to recalls over a five-year period and explore best practices to enhance recall management in Ireland and India. This study contributes to the pharmaceutical industry by providing an evidence-based analysis of recall management practices in Ireland and India. This research identifies the gaps in existing recall management systems, assess the effectiveness of regulatory oversight and analyse recall trends over a five-year period to provide an evidence- based evaluation of the key challenges faced by both countries. Additionally, this study seeks to quantify and categorize the primary quality-related issues leading to recalls, offering insights into the most prevalent manufacturing and compliance failures. By evaluating the economic consequences of recalls on pharmaceutical companies, this research highlights the financial risk, and operational disruptions caused by substandard products. Furthermore, the study explores best practices in recall process by proposing strategic recommendations for enhancing recall management. As a result, this research contributes in improving pharmaceutical regulatory policies, strengthening quality control measures and ensure better protection for consumers in both Ireland and India. This topic is highly relevant to the course I am doing and after successful completion of this dissertation I can achieve my Master's degree which is my biggest dream.

WHAT WOULD TAKING PART INVOLVE?

The participation involves actively sharing knowledge, experiences and perspectives related to OTC pain reliever recalls due to quality issues and its impact on the pharmaceutical industry and on patients. The data will be collected through surveys and interviews. The interview taken

online would be audio recorded and survey responses will be protected in password protected files.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in the research because of your expertise, knowledge and involvement in the pharmaceutical sector in either India or Ireland. Your insights and perspectives are valuable for understanding the current state OTC pain reliver recalls in both countries, as well as the regulatory polices involved in the recall process and its potential impact on pharma business and on patients. Your participation will contribute in identifying exiting challenges and vulnerabilities in Ireland and India during OTC pain reliver recall due to quality issues. Your expertise and experiences make you a crucial participant in generating valuable insights and recommendations for improving recall management systems in India and Ireland.

DO YOU HAVE TO TAKE PART?

Participation in the research is completely voluntary. You are not obligated to take part in the study. However, your insights and perspectives as a stakeholder in the pharmaceutical sector would be valuable for addressing the research objectives and contributing to the development of strategic recommendations aimed at enhancing OTC pain reliver recall management systems in India and Ireland. If you choose to participate, your input will be helpful in generating valuable data and information that can be a potential solution to address the challenges faced in OTC recalls systems. You have the right to refuse participation, refuse any question and withdraw at any time without any consequences whatsoever. If you wish to withdraw, please contact the undersigned personnel.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Possible risks

Confidentiality concerns: There may be concerns about the confidentiality of your responses, especially if sensitive information about your organisation or practices is disclosed during the research process. As to reduce this risk, all the responses will be anonymised and no personally identifiable information will be disclosed in the study. Data will be securely stored and only accessed by authorised researchers

Time commitment: Participating in surveys or interviews may require a significant time commitment, potentially impacting your daily schedule or workload. As to reduce this burden I will ensure that the surveys and interviews are concise, with estimated time commitments. Flexible scheduling options will be offered for interviews also.

Organisational or professional information: Regulatory officials and pharmaceutical professionals may feel hesitant to provide critical insights on recall inefficiencies due to potential consequence. To reduce this risk the participants, have the option to skip any questions they are uncomfortable answering. The study will emphasize the at responses will remain anonymous and used strictly for research purposes.

Data security: There may be concerns about the data security, particularly if it is stored pr transmitted electronically, leading to potential risks of data breaches or unauthorised access.

To ensure the safety of the data collected the collected information will be stored in a password protected folder with access to only authorised personnel.

Benefits

Contribution to knowledge: Participating in the research allows you to contribute valuable insights and perspectives to a study aimed at addressing critical issues in the pharmaceutical sector, potentially leading to advancements in OTC pain reliver recall systems across India and Ireland.

Professional development: Involvement in the research activities can enhance your professional development by increasing your understanding of current recall trends, challenges, impacts and potential solutions to the problems.

Impact on policy and practice: Your input may inform the development of strategic recommendations aimed at enhancing the OTC pain reliver recall systems in Ireland and India and thereby potentially influencing policy decisions and industry practices.

WILL TAKING PART BE CONFIDENTIAL?

Yes, taking part in the research will be confidential. Your responses and any information you provide during surveys or interviews will be treated with utmost confidentiality. Only authorised researchers will have access to the data collected and your identity will be kept anonymous to the extent possible. Any data shared will be aggregated and reported in a way that ensures individual participants cannot be identified. Additionally, strict data protection measures will be implemented to safeguard your privacy and confidentiality throughout the research process.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All the data collected during the research, including survey responses, interview transcripts and other relevant documents will be stored in secure digital formats until after my degree has been conferred. This will involve using password-protected files or encrypted storage solutions to prevent unauthorised access. Your identity and any personally identifiable information will be kept confidential. Responses will be anonymised to ensure your privacy is protected. Only authorised researchers involved in the study will have access to the data and strict confidentiality protocols will be followed. The retention period for collected data will be 2 years.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be analysed and synthesised to generate insights and conclusions regarding the current state of OTC pain reliver recalls due to quality issues in India and Ireland. It also provides insights into regulatory policies for OTC recalls across India and Ireland and its impact on pharmaceutical business and on patients. The results will be accessible in the college library and could potentially be made available in online e-journals or repositories, subject to the policies and guidelines of the institution.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Aleena Manoj

MSc Pharmaceutical Business and Technology

Mob:0899529797

Email: aleena.manoj@student.griffith.ie

THANK YOU

Consent to take part in research

COMPARATIVE ANALYSIS OF OVER THE COUNTER (OTC) PAIN RELIVER RECALLS DUE TO QUALITY ISSUES: A CASE STUDY OF IRELAND V/S INDIA

- I [*insert participant name*] voluntarily agree to participate in this research study
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
- I understand that participation involves sharing my knowledge, experiences and perspectives related to OTC pain reliever recalls due to quality issues and its impact on the pharmaceutical industry and on patients.
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in the dissertation conducted by Aleena Manoj followed by her publication in relevant journal.
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be retained in an encrypted password protected files for 1 year.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for 2 years.

- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name: Aleena Manoj

Degree Programme: MSc Pharmaceutical Business and Technology

College Details: Griffith college, Dublin

Contact number: 0899529797

Contact mail: aleena.manoj@student.griffith.ie

Signature of participant

[Full Name – Printed]

Signature of research participant

---------- ---------- Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

---------- ---------- Date

Signature of researcher