An analysis of public knowledge and awareness of counterfeit medicine and approaches to minimise its supply in Ireland.

Written By

Stacey Curran

[redacted]

Dissertation submitted in partial fulfilment of the requirements for the degree of MSc in Pharmaceutical Business and Technology (QQI)

Innopharma Labs Faculty of Science
Griffith College Dublin

Dissertation supervisor: Dr. Gillian McMahon

May 2023

Candidate Declaration

Candidate Name: Stacey Curran

I certify that the dissertation entitled:

"*An analysis of public knowledge and awareness of counterfeit medicine and approaches to minimise its supply in Ireland."* submitted for the degree of **MSc in Pharmaceutical Business and Technology** is the result of my work and that where reference is made to work of others, due acknowledgment is given.

Candidate Signature: 

Date: 21 May 2023

Supervisor Name: Dr. Gillian McMahon

Supervisor signature:

Date:

Acknowledgements

This dissertation is dedicated to public health, especially to those around the world who face barriers and do not have appropriate access to genuine medicine.

I would like to take this opportunity to express gratitude to my daughter **Jasmine El Haris**, and my husband **Alaa El Haris**. You both provided me with an abundance of support, patience, motivation, and enthusiasm.

To my mother **Dolores Brogan**, thank you for demonstrating how dreams can become a reality. Your constant need for improvement and restlessness were key cornerstones during this period.

I would also express thanks to my late grandmother **Mary Curran** for her everlasting protection and guidance from above.

I would like to express my sincere gratitude to my supervisor, **Dr. Gillian McMahon** for her guidance in time of research and writing of this thesis.

I would like to thank **Regina Regan**, for the guidance in the initial stages of this dissertation.

I would like to express my sincere gratitude to each faculty of **Innopharma Labs Faculty of Science and Griffith College** for supporting my education since 2020.

I also like to thank this opportunity to express my sincere gratitude to all who participated in the study.

Thank you.

Table of Contents

Table of Tables

Table of Figures

List of Abbreviations

Table 1 List of Abbreviations

WHO	World Health Organization
US FDA	United States Food and Drug Administration
HPRA	Health Products Regulatory Authority, Ireland
EMA	European Medicines Agency
IMVO	The Irish Medicines Verification Organisation
PSI	The Pharmacy Regulator, Ireland
HIV	Human Immunodeficiency Virus
CFM	Counterfeit Medicine
API	Active Pharmaceutical Ingredient
SSFFC	Substandard, Spurious, falsely labelled, Counterfeit Medicines

Definitions

Medicinal product:

The European Medicines Agency defines a medicinal products as a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action. (EMA, 2023d)

Generic medicine:

Europeans Medicines Agency define a generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised. Its authorisation is based on efficacy and safety data from studies on the authorised medicine. A company can only market a generic medicine once the 10-year exclusivity period for the original medicine has expired. (EMA, 2023c)

Counterfeit medicine:

The European Medicines Agency define counterfeit medicine made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or rights. Counterfeit medicines infringe trademark law. (EMA, 2023a)

Falsified Medicine:

The Europeans Medicines Agency defines falsified medicine as a fake medicine that passes itself off as a real, authorised medicine. (EMA, 2023b)

Abstract

Introduction

Consumption of counterfeit medicine poses detrimental unpredictable risks to public health and impacts public health globally. Counterfeit medicinal products have been seized in Ireland by The Health Products Regulatory Authority HPRA, therefore the Irish public is at risk of being exposed to such illicit products. Assessing the public's level of knowledge and awareness of counterfeit medicine and approaches of minimising supply will enable an analysis of this problem to be performed. Research on the topic will highlight if the level of knowledge and awareness requires improvement and the implementation precautions which would contribute towards reducing supply.

Objectives

The main objective is to perform an analysis of public knowledge and awareness of counterfeit medicine in Ireland. This research aims to assess factors which impact on level of awareness. Risks associated with consumption and approaches of minimising supply will also be identified.

Methodology

The primary data was collected from an online questionnaire and interviews whereby pharmacists and health care workers were invited to participate. 116 participants from the public in Ireland partook in the online questionnaire and two participants partook in a face-to- face interview. Overall, a total of 118 individuals participated in this cross sectional research.

Results

This research highlights the requirement for raising the public level of knowledge and awareness of counterfeit medicine. Factors such as level of education, social class, region of residence, cultural practices, rates of employment and gender were all found to impact level of knowledge and awareness. Research also found that avoiding the online purchase of medicinal products through unverified sources would reduce supply of such counterfeit products.

Conclusion

Counterfeit medicine is a threat to public health globally and more specifically Ireland. With advances in technology and increased use of the internet, this is becoming a growing threat. The public level of knowledge and awareness could be improved by raising awareness through various campaigns and initiatives. Participation and backing from key stakeholders and industry professionals in Ireland would be a vital input on raising public awareness.

Keywords: *Counterfeit medicine, Supply chain, falsified medicine , serious adverse reactions (SARs), public knowledge and awareness.*

Chapter 1

Introduction

What is counterfeit medicine?

Counterfeit medicine is not manufactured by authorised licenced manufacturers therefore consumption poses detrimental effects to public health and safety. This medication is an imitation of an original medicine and risks associated with consuming such medicine are unpredictable. This illicit medication is deliberately made to copy original medicine and thereby infringes on trademark law and authorised copyrights. (EMA, 2023a) Counterfeit trade forms a lucrative market valued at 4.4 billion USD which preys on vulnerable consumers and a changing supply and demand market. (OECD and European Union Intellectual Property Office, 2020) Considering the covid-19 pandemic whereby distress and urgency was placed on the supply chain, such illicit counterfeit acts increased to meet bigger supply demands. By criminals tapping into the good reputation of original companies, counterfeiters' costs were saved in manufacturing, quality testing, marketing, and advertising thereby making illicit manufacturing a profitable business venture. Counterfeit medication is inferior and substandard to original medicine which lacks manufacturing quality control. This results in an end product of a lower standard which is not safe or efficacious for consumption and therefore posing many unpredictable risks to public health. (Ziavrou *et al.*, 2022)

The unknown elements and misrepresentation of information regarding distribution, composition and identity of medicine defines falsified medicine.(EMA, 2023b) All member states are impacted by this issue which is becoming increasingly worrying every year. (European Union Intellectual Property Office, 2022)

Where do you purchase counterfeit medicine?

Counterfeit medicine is a global threat to public health and is available in all countries globally, contributing to increasing threats to public health and safety. The primary means of purchasing counterfeit medicine is through online platforms from pharmacies who pretend to be registered and approved sellers of medicinal products. With increasing accessibility to the internet, this platform facilitates the illegal sales of counterfeit medicine which has become more predominant in developed countries as well as developing countries. (Pfizer, 2023b)

Why do people choose counterfeit medicine instead of legitimate medicine?

The production of counterfeit medicine is cost effective and the process of replicating branded products is easier in poorly regulated environments. Therefore, it proves to be a highly profitable business model for all stakeholders such as counterfeit sellers and manufacturers. When a consumer from certain social backgrounds is faced with the option of purchasing cheaper alternatives, counterfeits are easily falsely misidentified as genuine products due to the product's identical packaging and labelling. (European Union Intellectual Property Office, 2022) Therefore, considering the nature of human beings, consumers tend to solve the moral dilemma and purchase the product to determine if there are positive results as they expect from reading product packaging and labelling. (Louisiana, 2014) Another consideration which may prompt a person to purchase a counterfeit medicine is accessibility to the drug. Whilst most prescription drugs require a patient to consult and pay for a doctor visit first, online sources provide more convenience and may offer the option to meet with a health professional virtually. However, in Ireland there is no inspection or regulation in place of online medical services. Therefore, the Irish Medical Organisation (IMO) highlight that virtual diagnosis may lead to misdiagnosis and breaches of compliance.(Lynch, 2018) Interpol recognises this problem and actively tries to crack down on such online acts as observed under Operation Pangea XV where over 1,200 advertisements for counterfeit medicines across various social media platforms were identified. (Interpol, 2022) Such advertisements and reviews prey on the vulnerability of social media users and instil the buyer with misplaced confidence in the product. (Kowalewicz, 2022)

Organisations minimising exposure to counterfeit medicine in Ireland.

The Irish Medicines Verification Organisation (IMVO) is an organisation which works to protect Irish patients from the risk of exposure to falsified medicines distributed through legitimate supply chains. In response to the 2011 EU legislation, the Falsified Medicines Directive 2011/62/EU mandates requirements for prescription drugs to be equipped with packaging safety features such as an anti-tamper device and barcodes which contain unique identifiers. This allows verification of each product before being dispensed to patients in

Europe. A standardised EU-wide logo is also required which aids identification of genuine online suppliers. (The Irish Medicines Verification Organisation, 2023)

The Pharmaceutical Society of Ireland (PSI) maintains a public register of online retailers in Ireland and this register is accessible to the public. Prior to pharmacies being registered through PSI and operating in Ireland, PSI perform regular investigations and inspections to assess compliance with code of conduct and legislation.(The Pharmacy Regulator, 2023)

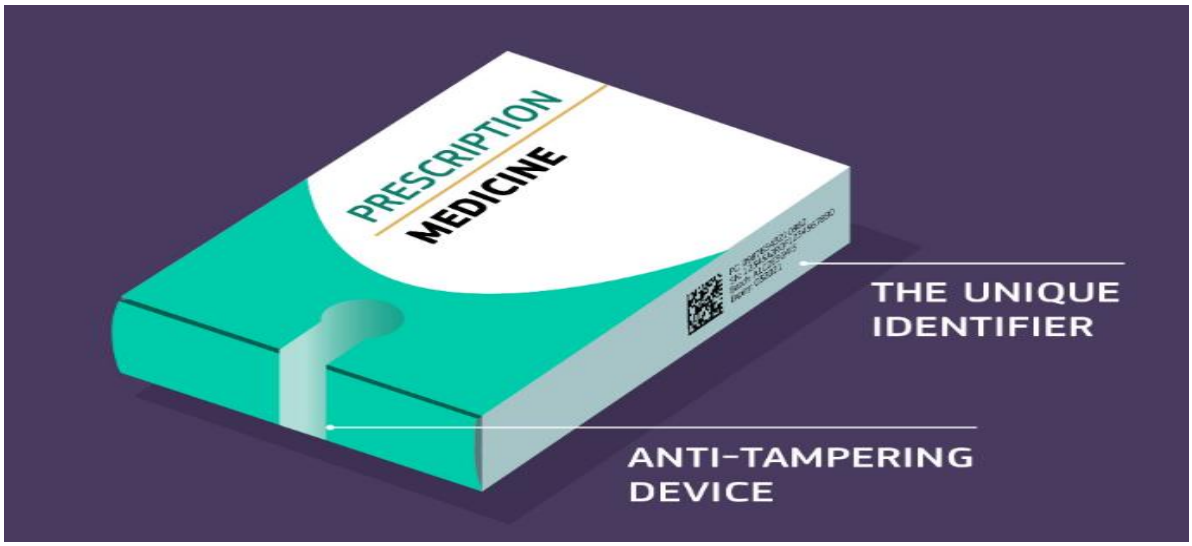

Figure 1 New safety features required on prescription drugs within Europe. (European Commission, 2019)

The Health Products Regulatory Authority HPRA provides advice to consumers warning about the risks and dangers associated with purchasing prescribed medication through online platforms. The HPRA also reiterates that the distribution of prescribed medication through the mail or courier service is classed as an illegal act in Irish law. The manufacturing of such products is also considered an illicit act.

Illegal prescription medicines that are discovered by customs officials coming into the country are destroyed. There have also been prosecutions and other actions involving website operators.(HPRA, 2023a)

Although distribution of counterfeit medicine is recognised as a criminal offence in Ireland, such medicine has been found, seized, and therefore raised awareness from the Irish government's national Health Service Executive HSE.

In 2020, the HSE in Ireland expressed concerns of contamination and overdose risks associated with fake benzodiazepines which were detained in Ireland. Concerns were expressed due to the high levels of potency at low dosages which has the potential to cause strong sedation, respiratory depression and amnesia. (Ryan, 2020)

In response to the increase of counterfeit medicine, the European Union's Falsified Medicines Directive (2011/62/EU) FMD has been implemented in Ireland since 2019. As an introduction to the FMD, Ireland practiced a use and learn phase. The fact the Covid-19 pandemic hit and that the United Kingdom experienced Brexit, such considerations were a contributing factor of holding this use and learning phase for wholesalers. In May 2022, pharmacies, hospitals, and wholesalers were not permitted to supply packages which would cause system alerts when the QR codes on the packaging have been scanned prior to dispensing. In the case that an alarm was raised, a full root cause investigation would require initiation. In the case that a root cause determined that the product integrity was not compromised, and that it was not detected to be a falsified product, a product only then can be distributed. (HPRA, 2023b)

As observed from the vaccine campaign strategies during the Covid-19 pandemic, there may be elements of communication which may enhance public awareness of counterfeit medicinal products and the unpredictable risks associated with consumption in Ireland. Initiatives such as awareness campaigns specific to target regions may enhance public knowledge and awareness of counterfeit medicine. (Ofori-Parku, 2022)

In Ireland, there is a lack of government backed advertisements and campaigns which are dedicated to increase public knowledge and awareness about counterfeit medicines and the risks they pose. Although Irish government initiatives lack in more recent years, pharmaceutical companies taking Pfizer as an example take their own initiative to raise awareness through the trend #FakePillsKill. Videos of case examples whereby patients discuss about the complications they suffer from taking counterfeit medicine are placed on YouTube which is a form of social media platform on the internet. (Pfizer, 2023a)

Risks to public health

All countries globally are affected by counterfeit medicine. However, risks associated with consumption of counterfeit medication are more apparent within low- and middle-income countries. Such products are available through illegal platforms such as unregulated markets, globally accessible websites and clinics. (WHO, 2018)

For patients who reside in regions with poorer health care systems, noncommunicable and lifestyle products are at a bigger risk of being falsified. Also, when such products provide a cheaper solution, it proves to be tempting to the consumer. (Nayyar *et al.*, 2019) Consumption of counterfeit drugs has the potential to cause serious adverse reactions and even death to the user. Such products can contain inaccurate or low dosages of Active Pharmaceutical Ingredients (API) which may be mixed with dangerous toxins, impurities and unknown excipients. Therefore, consumption may not aid in treating a patient's illness and can therefore cause problems such as counterfeit antibiotics contributing to the threat of antibiotic resistance. (Dr. Jarvas, 2020)

Counterfeit medicine and the effects of this issue was observed in the case of Gilead Science's recent discovery of counterfeit versions of their own HIV products. This has led to patients missing their required dosage of real medicine to aid treatment.(Ramey, 2022) In the United States, Gilead Sciences a biopharmaceutical company identified illicit Human Immunodeficiency Virus (HIV) drug distributors which produced falsified drugs using their brand name to target public consumers. According to an article published in the Wall Street Journal, 85,247 counterfeit bottles of Gilead branded products valued in excess of $250 million were distributed to pharmacies in the previous two years. (Ramey, 2022) This incident raises concern for HIV patients who are exposed to dangers from taking the counterfeit medicine in an effort to save money but forgoing their prescribed HIV treatment.

Drugs such as Viagra which used are for erectile dysfunction are most common amongst the illicit market. (Viatris, 2022) Within the United Kingdom, erectile dysfunction medication is available to patients who meet criteria after having a consultation with a pharmacist or after partaking in a questionnaire from an online pharmacy. The outcomes determine if the patient is a suitable candidate for this drug and avoids misuse. However, there are many

considerations why a person may purchase an illegal product beyond the obvious economic one. For example, patients can be ineligible for this treatment or they may even be embarrassed to speak to a professional. (Lloyds Pharmacy UK, 2022)

Pfizer performed research into counterfeit Viagra tablets by investigating online search results. Out of 22 orders of tablets placed, their chemical composition revealed that the percentage of the active ingredient - sildenafil citrate -varied between 30% and 50% of the original product specification. Also, patient information leaflets, safety information and the formulations used were not provided or used as they should have been. (Campbell *et al.*, 2012)

Although falsified medicine is different to counterfeit medicine (EMA, 2023b).Rahman et al. (2018) performed an analysis of health consequences caused by falsified medicines. This highlighted 48 reported incidents whereby health was damaged by falsified medicines in developing regions (56%) and developed countries (43%).(Rahman *et al.*, 2018)

In Figure 2 below, an image of an original and counterfeit medication is captured by the Australian Government Therapeutic Goods Administration. On the Left-hand side, the original product's packaging has lines in equal lengths. On the right-hand side, the counterfeit product has packaging with lines in varied lengths and each line is not spaced equally. (Administration (TGA), 2022)

Figure 2 Image of original and counterfeit product packaging (Administration (TGA), 2022)

What are generic drugs and biosimilar drugs and is it available in Ireland?

Generic and biosimilars are rigorously tested to prove equivalence with the approved reference drug prior to becoming commercially available to patients. Generic drugs comprise of chemicals therefore the manufacturing process results in an active ingredient achieving the same critical quality attributes. (Health Products Regulatory Authority, 2023)

The Irish government currently permits registered Irish pharmacy's provide patients with safe and more cost-effective alternative variations of prescribed medicines, whereas previously branded medicines were dispensed as prescribed. The implementation of this substitution is only dispensed if it contains the same amount of Active Pharmaceutical Ingredient API, is in the same form and offers the same method of administration. This compliance to the Pricing and Supply of Medical Good Act 2013 is aimed towards saving costs to consumers. (HSE, 2023)

In response to the Pricing and Supply of Medical Good Act 2013, alternative medicines are stated on the Interchangeable List. This list is updated and maintained by the Irish Medicines Board and regulated by the Health Products Regulatory Authority HPRA. (HPRA, 2023c)

Biosimilar drugs are manufactured from microorganisms, therefore biosimilars provide affordable access to lifesaving medications. It is cheaper to produce and manufacture biosimilars as such products are not the identical copy of the original product. This entails that the cost associated with research and development R&D, testing and drug trials is reduced. However, biosimilar medication provides the same result in treatment as the biologic medication. (Pfizer, 2022)
The U.S. FDA defines biosimilar as a biological product which has no clinical variation to FDA-approved reference product by means of safety, efficacy, purity, and potency. (Research Center for Drug and Evaluation, 2023)

According to the United States pharmacist resource for clinical excellence, the risk associated with the distribution of counterfeit drugs also applies to non-branded generic medicines which is promoted by criminals to offer an even cheaper alternative to consumers. Although

counterfeit has no similarity to generic medicines, consumers can easily confuse both generic medicine and counterfeit drugs. This is partly due to the lack of awareness and knowledge consumption of both generic and counterfeit medicine which has become more common around the globe. This results in reputable generic medicine manufacturers to be faced with barriers in countries where manufacturing is more predominant for example European Union state members, India, Japan etc. (Louisiana, 2014)

Research Question

What is the level of public awareness of counterfeit medicine and, would improving public awareness help reduce global supply of counterfeit medicine? Would an individual's social class, culture and level of education have an impact on level of awareness?

Research aims and objectives.

Previously research on this topic of counterfeit medicine has been performed but mainly involved participants who were pharmacists. No study has been found by this author which analyses the public's level of awareness and knowledge in Ireland. As gaps in previous research exist, this dissertation will analyse the public awareness and knowledge of counterfeit medicine and determine approaches which will effectively reduce risks of supply in Ireland.

Assessing public knowledge of counterfeit medicine and approaches of minimising supply in Ireland is beneficial for public health and therefore may contribute to reducing exposure to such illicit types of medicine.

This study aims to assess the following factors:

- Public awareness of counterfeit pharmaceutical products
- Impact of social class, culture, and level of education on level of awareness of counterfeit medicine.
- Identification of potential impacts, threats to public health and business due to counterfeit medicinal products.
- Approaches to minimising supply of counterfeit pharmaceutical products

Chapter 2

Literature Review

Although similar research has been performed before, gaps in research exist due to the lack of assessment of public knowledge in studies. There has also been little consideration of the following factors in relation to this issue: level of education, social class, cultural practices and participant gender.

Other gaps in previous similar research into this topic display evidence of being limited to a particular region. As a result a cohort of participants in a region of focus provides a platform for further research to build on. Gaps also persist in the identification of the key drivers for the continuation of illicit counterfeit production and trade by region, and if unemployment rates of the various regions are reflected in counterfeit activity. Therefore, further research to identify potential impacts, threats and factors contributing to this activity will be performed.

This literature review comprises of published articles, journals and a book which examines education, societal class, and cultural collisions around medicine practices.

To understand and identify factors which contribute to improving public awareness and knowledge of counterfeit medicine in Ireland, successful research studies which were published on a global scale will be assessed and referenced. The recommendations of previous studies will also be assessed in this literature review.

Where do counterfeit Medicines come from?

Although China and India are the main manufacturers of illicit medication, the United Arab Emirates, Singapore, and Hong Kong are market economies. The main distribution links involved in the transportation of counterfeit pharmaceuticals are through couriers by air, post mail, road, and sea transport with a potential for products to be distributed anywhere in the world. Through a series of smaller shipments, the potential of being detected and products becoming seized by authorities is lower. This is due to the risk of detection being lower, considering smaller batches being distributed as opposed to larger and fewer batches being distributed.(OECD and European Union Intellectual Property Office, 2020)

OECD/EUIPO (2020) performed a joint analytical study on illicit trade in counterfeit pharmaceutical products published in a series of annual reports. This was performed with the intention of providing a deeper understanding backed up by empirical evidence to policy makers.(OECD and European Union Intellectual Property Office, 2020)

In Figure 1 below, data from the 2020 status report on IPR Infringement reflect top the 20 shares of global exportation of pharmaceutical products which shows Germany as the top exporter. (European Union Intellectual Property Office, 2020)

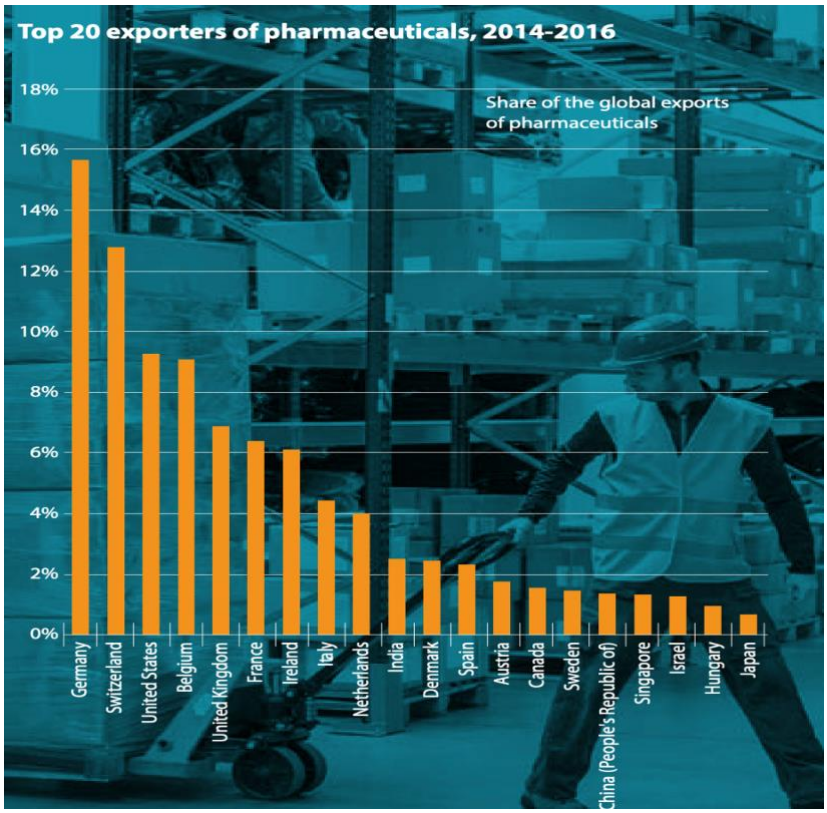

Figure 3 Trade of pharmaceutical products (European Union Intellectual Property Office, 2020)

As new opportunities arose for counterfeiters during the Covid-19 pandemic, criminals fed into demands for certain goods and provided illicit products. The European Union Intellectual Property Office reported that most reports of counterfeit products originated from countries such as China (45%), Hong Kong (24%), Turkey (19%), Singapore (6%) and remaining other countries comprising of (4%). (European Union Intellectual Property Office, 2022)

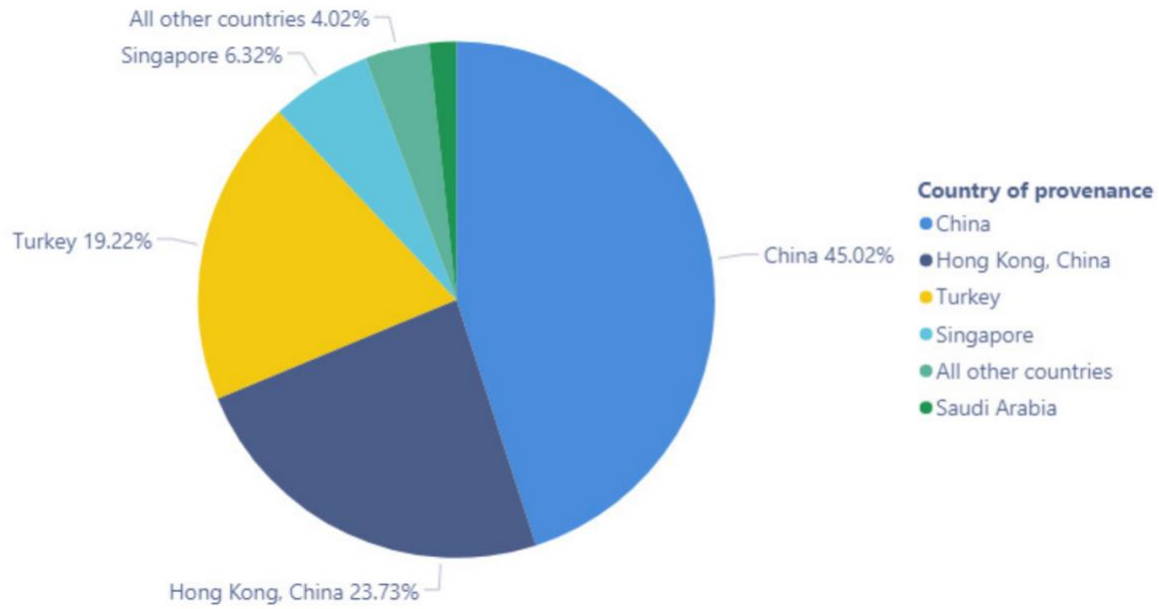

Figure 4 Counter of provenance by value of IPR Infringed goods in 2020.(European Union Intellectual Property Office, 2022)

How are counterfeit drugs detected in Ireland?

According to the Irish Medications Verification Organisation (IMVO), there has not been any counterfeit medicine detected in registered pharmacies in Ireland. However, IMVO highlights that counterfeit medicinal products were detected in Ireland and were purchased through various online platforms. (IMVO, 2023)

The Health Products Regulatory Authority (HPRA) seized 1,604,589 million units of illegal medicines in Ireland in 2021 all of which were then transferred to an Garda Siochana. Grainne Power, HPRA Director of Compliance raised concern over the 3.2 million units of counterfeit medicinal products detected during 2021 and 2020 combined in Ireland. (HPRA, 2022a)

An Garda Siochana, the national police service in Ireland actively engage in activities to suppress criminal activity in the state. Criminal activities range from a wide range of classifications and include acts such as theft, organised Burglary, illicit sales all of which impacts on Irish society.

In October 2022, Operation Thor was carried out by the Garda National Drugs and Organised Crime Bureau (GNDOCB) with the support from specialised units, such as the Special Crime Task Force (SCTF), the Strategic Tactics and Operations Command (STOC), the Garda Dog Unit and other specialised personnel which fall within the vicinity of Dublin and other eastern areas. Operation Thor entailed a search being performed in nine predetermined places within West and North Dublin. The search in the nine selection areas revealed stolen property with a value of €30,000. The detected stolen goods also included pharmaceutical products amongst other various stolen items. Under Operation Thor, seven people were arrested for breaking the Criminal Justice Act, 1984. All seven criminals included male and females, the individuals varied in ages between age 17 to age 35 and had previous offences. Further investigations are still being performed to date to examine seized evidence. (An Garda Siochana, 2022)

What are the most common types of counterfeit drugs seized in Ireland?

In Figure 1 below, the most significant categories of illegal drugs which infiltrated the Irish supply chain and were detained by HPRA during 2021 are represented in units. Sedative medicines were the highest category of illegal drug detained in Ireland. (HPRA, 2022a) Benzodiazepines are a type of sedative drug which are illegally available online or through illegal drug dealers.

Self-medication of this drug without prescription raises safety concerns over potency, excipients, adverse reactions and overdosing. (Drug and Alcohol Information and Support in Ireland, 2023)

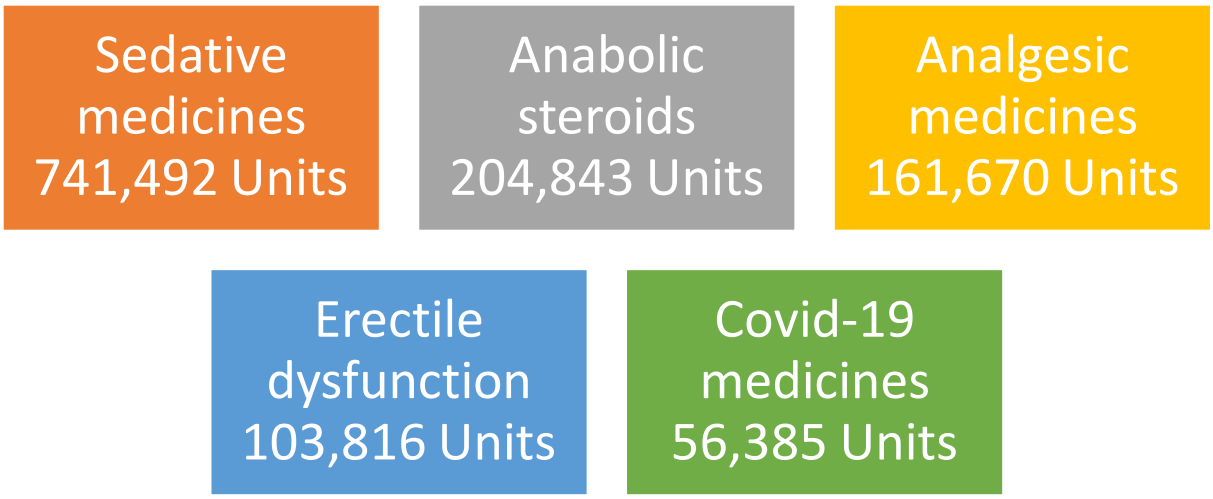

Figure 5 Most significant categories of illegal drugs detained in Ireland 2021 (HPRA, 2022a)

The data collected from the amount of units seized and the five categories of drug are observed in *Figure.6 below,* showing a bar chart to enhance the visualisation of data.

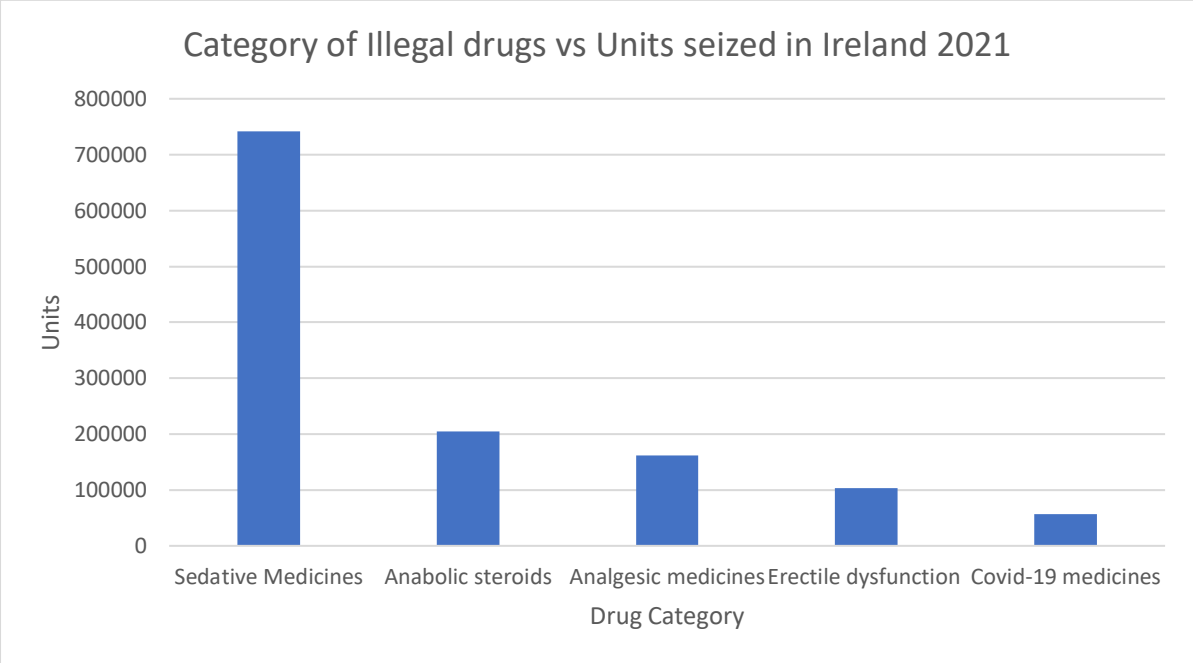

Figure 6 Category of illegal drugs by units all of which were seized by an Garda Siochana in Ireland, 2021 (HPRA, 2022b)

A similar issue regarding the detection of counterfeit medicinal products has also been identified by the Hungarian and Norwegian National Police with aid from Europol and Eurojust whereby 9 million sedative drugs were removed from public circulation. (Europol, 2022)

Awareness of counterfeit medicine among pharmacists

Bashir (2020) performed a study performed cross-sectional survey in Alexandria, Egypt involving 175 community pharmacists during 2014 and 2015. The research involved a chi-squared test which enabled the assessment of the pharmacists perceptions, awareness and practices in relation to counterfeit medicine. 47.4% of pharmacists confessed stocking counterfeit medicines unintentionally. Research findings identified that 6.7% of the pharmacists had insufficient professional knowledge and awareness about counterfeit medicine. 46.1% of pharmacists displayed poor knowledge of legislation, danger to patients, inspection, and handling details relevant to counterfeit medicine. The pharmacist's viewpoint of counterfeit medicine was not aligned with an accurate definition of counterfeit medicine and therefore were unable to differentiate counterfeit medicines and inferior products. Many pharmacists 78.3%, assumed medicine counterfeiting was common in Egypt and they had the ability to contribute to reducing the extent of this issue. However, the remaining 21.7% of pharmacists did not believe this task fell within their line of work.

The research findings highlight that the pharmacy curriculum requires an update and continuing professional developmental activities assigned to contribute to aiding the pharmacists' responsibility in combating counterfeit medicines. The report also addresses that further research should be performed to address gaps and the need for an implementation of a strategy consisting of a strong legislation on drug distribution and counterfeiting would contribute to reducing this issue. The research also highlights the promotion of partnerships between stakeholders and the collaboration with international organisations are also essential. (Bashir *et al.*, 2020)

El-Dahiyat (2021) performed a cross-sectional investigation to determine the identification rate of substandard and falsified medications and its association with knowledge amongst the public. This study was performed in various geographic regions on 320 people over the age of 18. The data was collected from an online questionnaire involving a five-point Likert scale containing 12 questions split into three parts of which identified Socio demographic data, knowledge of counterfeit medicines and ability to distinguish counterfeit medicines. The researcher implemented univariate and multivariate logistic regression to assess the links between sociodemographic factors and the identification of counterfeit medication. Research concluded that 30.6% participants identified the counterfeit medications. This investigation identified that people with higher education had a higher counterfeit medication identification rate as follows: high school 29.2%, bachelor's degree 30%, Postgraduate 75%. Participants who are older, single, Asian, American and those who verify certification and report counterfeit medications to authorities had higher identification rates. Also, findings reflected participants from the Middle East region had lower counterfeit medication identification rates in comparison to participants from other regions. Research concluded the importance behind the need for increasing public awareness of the risks associated with counterfeit medicines. *El-Dahiyat* recommended participation of vigilant healthcare professionals in raising public awareness and by holding educational campaigns.(El-Dahiyat *et al.*, 2021a)

Sholy et al (2018) assessed pharmacist awareness and views towards counterfeit medicine in Lebanon. Although pharmacists value well-being and safety, safety and efficacy of treatments may be compromised due to counterfeit medicine as it causes serious problems to public health. This research was performed in various regions within Lebanon. The research strategy utilised convenience sampling whereby pharmacists were chosen to participate based on willingness. 223 pharmacists participated in a cross-sectional survey questionnaire which identified experiences and views towards counterfeit medicine. Research highlighted all participants' ability to define counterfeit medicine as a bad quality medicine or of unknown source however, definitions reflected varied answers. (67.7%) identified the effect of consumption and (66.8%) identified by the cost. (43%) of Pharmacists knew others who dispensed such medicine to patients. Also, participants asserted that pharmacists who dispensed such products were unprofessional (89.2%) and unethical (86.5%), and that it was

a simple business (87.9%) yet highly large profitable (86.5%). The study concluded by highlighting the requirement for awareness through campaigns, especially the key responsibility of pharmacists and the importance their duty is in protecting patients. *Sholy et al* also identify the need for an official definition of counterfeit medicine which mitigate variances. The Lebanese Ministry of Public Health and regulatory authorities should also monitor the distribution links of medicine in Lebanon and work to enforce the law.(Sholy *et al.*, 2018)

Knowledge and perspective of counterfeit medicine among doctors

Yadav et al (2018) performed study on knowledge and perspective towards counterfeit medicine amongst doctors in tertiary care hospitals. The study was performed due to the global issue counterfeit medicine causes and the threat to life and drain on health the system in India. A cross sectional questionnaire which assessed knowledge, practices, and sentiment towards counterfeit medicine. Therefore, the impact on the heath system was identified.
Although the questionnaire was sent to 100 registered doctors, 80 medical doctors participated from the Northern region of India in the study. Due to insufficient information submitted in the questionnaire, 20 participants were excluded from the study. Findings observed that 57.77% of participants had knowledge of questionnaire and the meaning of counterfeit medicine. 90% of participants confirmed awareness of dangerous risks associated with consumption of counterfeit medicine. Over 50% of the participants suggested the use of technology and its ability to contain counterfeiting. Research concluded that counterfeit medicine poses health hazards and waste to consumer income. *Yadav et al* recommended that sufficient knowledge, awareness, and the implementation of modern technological approaches has potential to contribute to minimising counterfeit medication.(Yadav et al., 2018)

Wagiella et al. (2020) assessed the extent, awareness, and attitude of the public in Sudan towards counterfeit medicine. A cross-sectional study was performed on 386 participants. The study consisted of a questionnaire to statistically assess awareness, attitude and the association between various demographic factors using Fisher exact test and Spearman

correlation. Results showed that 58% of the participants were aware of counterfeit medicine through social media. 73% of the participants thought counterfeit medicine contained the worst quality product and therefore recommended sourcing medicine from a trustworthy pharmacist to avoid buying such medicine. 56% confirmed their ability to detect counterfeit medicines from the side effects as opposed to packaging and cost of product. 82% of the respondents highlighted that education has an important role in reducing spread and that running workshops and campaigns would enhance awareness. Although 68% of participants had a fair awareness, 80% displayed a good sentiment towards counterfeit medicine. The research concluded that the literature includes gaps in knowledge and attitude towards counterfeit medicine. Research recommended attention and efforts are required on the part from the government, drug manufacturers and health care providers' especially pharmaceutical analysts to ensure that only drugs of acceptable quality reach the consumer.*(Wagiella et al., 2020)*

Substandard and falsified medicine forms a growing criminal business venture. ***Ofori-Parku and Park (2022)*** highlighted factors as follows: supply chain process, technology, legal mechanisms, consumer judgement and decision-making. By using Amazons Mechanical Turk (MTurk), social, psychological, and factors which impact consumer behaviour, attitude, perception of risk, and purchase intentions. 427 US consumers participated in the survey with a range in age from 18 to 74. The study results highlighted those consumers who self-report, are older, possess ethical viewpoints, seek approval from significant others of consuming such products have a better tendency to have favourable purchase intentions. The research concluded that the following factors: consumer knowledge, expectations of impressing others, ethical judgments, risk awareness contribute to a consumers' decision making before purchasing a product. The researcher provided an overview into approaches of addressing consumption in the U.S. health, safety, brand advocacy, education and risks were also addressed in this research.(Ofori-Parku and Park, 2022)

Impacts of counterfeit and falsified medicine

Dalton et al (2022) performed an examination on community pharmacists and their perceptions of how the Falsified Medicines Directive impacts their role. The implementation of this directive is aimed at reducing the number of falsified medicines within the supply chain. The research highlighted the gap in research which examines the pharmacists fulfilment of such tasks. 4,727 Irish community pharmacists took part in an online survey. Quantitative data was collected from multiple choice questions and Likert-scale questions. The data was then with the use of descriptive and inferential statistics. Qualitative data was also collected through a free-text box, which enabled the researcher to perform a thematic analysis. With 618 responses being recorded, 82% thought new requirements increased waiting times for patients. Whilst 65% though it decreased time to interact with patients. 28% of pharmacists agreed that the Falsified Medicines Directive enhanced safety to patients. The thematic analysis revealed the demand for medicine authentication was acknowledged. However, pharmacists perceived that the authentication task fell within the line of work of a wholesaler as opposed to a pharmacist. Also, pharmacists stated how the decommissioning of medicines was time-consuming and distracting in the clinical checks which poses an increased risk for error. Pharmacists also highlighted that they did not recover any remuneration for the loss in staff productivity and the additional costs of equipment. Therefore, pharmacists thought the workload is not proportionate to the risk of patients obtaining such products. The study concluded by highlighting how the participation of stakeholders would aid implementation of the procedures associated with the Falsified Medicines Directive within community pharmacies. (Dalton *et al.*, 2022)

Extent of problems associated with counterfeit medicines.

Schwartzman et al (2022) performed a study to determine the extent of the problem associated with dermatology on a worldwide scale. The research involved a cross sectional survey and the use of MEDLINE to source examples of Substandard, Spurious, Falsely labelled, Counterfeit medicines SSFFC. The research aimed at selectively determining examples of each type of dermatology-related SSFFC category. The outcome of the research entailed the identification of a list of approximately 500 indexed papers, although some papers had no relevance to the study. The researchers reviewed 20% of the papers in greater detail.

The study concluded by highlighting how substandard and falsified medical products is an remains problematic on a global scale. Research also placed emphasis on the World Health Organization WHO, who estimate that 10% of medications worldwide are counterfeit however, in regions such as Africa, Asia and Latin America the estimation rises to 30%. The majority of online pharmacies are not in compliance with federal state, or industry standards. As a result, many countries do not have sufficient regulatory agency practices in place. (Schwartzman *et al.*, 2022)

Public purchasing behaviour when purchasing medication online.

Fittler et al (2018) performed cross-sectional explorative research by collecting information from Hungarian outpatients regarding patients purchasing behaviours when purchasing medication online. As online internet platforms is offers an accessible way to purchase products and services, *Fittler et al* performed an analysis on participants sentiments towards the distribution chains, expected advantages and disadvantages of an influenced decision to purchase medication online. With several patient safety risks being correlated to the purchase of medicines online, *Fittler et al* places emphasis on the thousands of internet pharmacies accessible on the internet and that the precise size of the market remains undetected. The research involved 1055 outpatients in Hungary. The questionnaire received a response rate of 77%, with the mean age being 45 years. 456 participants reported suffering of chronic health conditions.82% of the respondents were aware of being able to access medicine through the online market however, 4% of respondents admitted that they previously purchased medication online. The attitudes analysis observed significant differences, with some participants confirming that retail pharmacy units being the most suitable source of medication products and that internet pharmacies were rejected. The demographics reflected how the use of the internet impacts behaviour, and the tendency to purchase medicines online. Participants who were more comfortable with using internet have a greater potential to purchase products through online medicinal distributors. The research concluded that Many patients will purchase medications on the internet in the future. *Fittler et al* also

highlighted the increased risk associated with patients purchasing medicinal products from illicit online websites which dominate the market. In order to reduce risks to public health, the research recommends improving patient-provider communication through promotions by various informative public campaigns.(Fittler *et al.*, 2018)

Extent of counterfeit medicine issue

The majority of counterfeit products are distributed among lower socio-economic groups and in developing regions where the population may not have full access to health and sanitary infrastructure, thereby increasing demand for cheaper but sub-standard medicinal products. They may also be exposed to mis-information around drugs and their sources. The WHO reported "1 in 10 medical products in developing countries is substandard or falsified". (WHO, 2017)

Illicit distribution of counterfeit pharmaceutical products damages many aspects of authorised pharmaceutical trade e.g. sales, revenue and growth of legally compliant manufacturers. This illicit trade hinders stakeholders' contribution and strategy to Research and Development (R&D), which pharmaceutical copyright owners heavily invest in to continue bringing new drugs to market and maintain their footprint in the competitive pharmaceutical arena. This ongoing issue is also depriving global pharmaceutical companies of sales in developing regions where this issue is most prevalent. (European Union Intellectual Property Office, 2022)
In 2019 status report on Intellectual property rights (IPR) Infringement, the European Union reported a loss of 16.5 billion euro as a result of counterfeit pharmaceutical distribution.(European Union Intellectual Property Office, 2019)

Trafficking of counterfeit medication is difficult to trace, as it is produced in clandestine laboratories. Most of the counterfeit trade is conducted on the surface web with the use of social media, which offers a wider target market and a more convenient route for counterfeiters. However, such products are also being sold through the dark web which enables transactions to be completed anonymously.

In 2020, Europol launched operation shield, which combat counterfeit, misused and doping medicines. This operation was also performed by the European Anti-Fraud Office OLAF and 27 countries, 19 of which are European states. The operation uncovered 25 million units of such drugs. 25 criminal networks were identified with 700 criminals being arrested. (European Union Intellectual Property Office, 2022)

Operation Shield II was performed again in 2021 and identified 254,731 tablets and 131,027 vials of various medicines and 278 kg of food supplements. (European Anti-Fraud Office, 2021)

In December 2022, operation Shield III revealed illegal substances holding a market value of €40 million. The operation made 349 arrests with 59 crime groups, 10 underground labs and 89 websites being identified and closed. The operation also discovered that criminal gangs continue to exploit business ventures as a result of the COVID-19 pandemic. However, a decrease was noted in relation to trafficking drugs due to increased law enforcement activity and providing the public with free vaccines.(Wahl, 2023)

Approaches to minimising supply of counterfeit drugs

Baybar (2018), an independent researcher suggests that limitations and intervention variances exist within literature review research around counterfeit medicine. The research highlighted the main drivers of counterfeit medicine decisions associated with finance and profit. Baybar suggested several means of tackling this global issue. Better results can be obtained if analyses are conducted in more detail by each country which would reflect multinational results. A global harmonised and standardised response with tougher law enforcements, penalties and more alignments with a multinational response is also recommended to enhance response to counterfeit medicine. Baybar also recommended that all involved in the supply chain should be encouraged to engage in more effective communication strategies. An example is provided by outlining how the use of internet algorithms could be altered to prioritise authorised sellers who conform to industry standards on search engine results.(Babyar, 2018)

O'Hanlon (2019) Chief Executive Officer and founder of Genesis Automation Healthcare published an article on raising awareness of how to make fake products less available to consumers in the United States. O'Hanlon compares the EU's Falsified Medicines Directive to the current US identification requirements. O'Hanlon therefore recognises the following aspects contributing to need for improvement: need to protect patient safety, access to medication, awareness, affordability, and oversight. O'Hanlon recommends that all US FDA approved drugs being exported into the European Union meet the EU's more stringent requirements. Vice versa, drugs imported to the US would meet criteria.(O'Hanlon, 2019)

International Coalition of Medicines Regulatory Authority ICMRA (2021) places emphasis on how the current traceability systems are designed and implemented to focus on local or regional areas and therefore has little consideration of the exchange of information on a global scale. In 2021, ICMRA published a report outlining recommendations which would aid exchange of information in track and trace systems. The recommendations listed are intended to contribute towards protecting public health and safety by improving communication and sharing of information which would aid responsiveness to common technical denominators. The recommendations also aim to enhance pharmacovigilance, facilitate batch recalls, combat exposure to falsified medicines and product shortage. The first recommendation ICMRA proposes is to use numerical values as opposed to alphabetic letters as product identifiers, this is to address variances in languages globally an example is observed in *Figure.6* below.

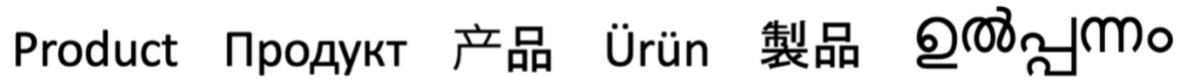

Figure 7 Image showing variances in different languages on product packaging and labelling. (International Coalition of Medicines Regulatory Authorities, 2021)

The second recommendation proposed is to use of widely accepted international standards. whereby medicinal products could be identified globally. ICMRA highlights that this recommendation enhancing sharing of information is only achievable if all countries are consistently correlated to the specifications defined by compatible international standards. This could involve the implementation of using the same product with different batch

numbers in each package of product therefore providing enhanced traceability from the manufacturing process to the global supply chain. As a result, authenticity and unambiguous product identification would be achieved as each package of product would have an individual batch number. ICMRA also recommend for readable information by the human eye to not be replaced with barcodes however, barcodes could be added to product in addition to syntax readable information.(International Coalition of Medicines Regulatory Authorities, 2021)

Yakubu (2020) performed research into the loopholes in the pharmaceutical supply chain and ways of enhancing control of counterfeit medicinal products in Nigeria. The research obtained a response rate of (65%). Research followed a quantitative and qualitative analysis which involved a questionnaire and interviews with distributors and pharmacists. Information collected from the interviews were assessed using a thematic approach. Research highlighted how open illicit distribution markets serve as a facility due to the poverty and want for financial gain. Yakubu concludes research by drawing attention to the cause of Corruption, poor implementation of laws, and how the amount of unskilled people in the distribution supply chain are factors which also facilitate the loophole in the Nigerian supply chain.
Yakubu also recommends the need for regulatory bodies to become more forceful and considerate of who is permitted to trade as a pharmacy. The researcher claims that this recommendation will reduce the operation of open markets contributing to reducing the spread of such products. (Yakubu, 2020)

Lawrence (2020) performed research into the impacts of drug Importation and the regulations enforced on local pharmaceutical manufacturers in Nigeria. Lawrence conducted a questionnaire-based survey and interviews with local Nigerian drug manufacturers and importers which enabled the research to perform an analysis with both a quantitative and qualitative approach. 77 people out of the 117 reached out to participated in the survey questionnaire. Research findings highlighted that 83% of the participants admitted that regulations regarding the import of such products in Nigeria are outdated, not consistent and limit growth of the pharmaceutical industry in Nigeria.
Finally, Nigerian pharmaceutical industry growth is relying on the intervention of the Federal Government of Nigeria to provide funds, enforcement of law. Lawrence concluded research by recommending for further research to be performed into the drug importation and the

regulations currently in place in Nigeria. Lawrence also calls for further positive inputs from the Nigerian government which would contribute to reducing dependency from Contract Manufacturing Organisations. (Chisom Lawrence, 2020)

Case study: example showing collision of cultures in medical care.

Fadiman (2012) As Anne Fadiman's published research in The Spirit Catches You and You Fall Down highlights many issues around the level of ignorance and danger around not understanding minority cultures. Issues include ethical, political, social economic factors. This is captured in the case of Lia Lee who was a member of the Hmong community, Lia was born a normal baby girl, yet ended up severely brain damaged. As documented evidence observes on the one hand, the medical professionals had Lia's best interest in mind, on the other hand Lia's family also had her best interest in mind. However, both parties failed Lia due to their cultural misunderstanding of circumstances encountered by both the Lia's family in their nonconformity of not administering the medication, and the mistrust that her family had in the American health system, this resulted in cultural collision. (Fadiman, 2012)
Lia's life tragically ended after living 30 years of age, Lia lived 26 of those years in a vegetative state. (Fox, 2012)

Fadiman (2012) addresses how the root of the problem may have stemmed around the failures in public policy, as resources were not in place to identify the serious misunderstanding of cultural differences. Firstly, failure on the part of her team of medical staff because they assumed that Lia's family understood what was happening around the baby's medical treatment. Secondly, Lia's doctors were not fully aware of what happened to trigger off her epileptic fits in the beginning, this was since interpreters were not present to help translate very important background information on the lead up to when the fits began. The policy did not adhere to a culture who fell under the framework of the proper support for them. The non-availability of interpreters shines light on the importance of acknowledging and respecting people's beliefs as part of their health care.
Again, Anne Fadiman's research shows how many people in society are deprived of basic things that the rest of society take for granted. Fadiman provides a new perception which examines the situation from a different perspective. In the case study of the Lee family,

findings showed how the family were profoundly disadvantaged. Therefore, concern should raise concern for any moral and political theorist globally. Research also portrays how the many different levels of disadvantages exist in society. The Lee family, and other such cases live in a state of social deprivation. The researcher emphasises how Lia's unfortunate circumstances can call upon society to investigate and address the issues around how their deprivation was a consequence of social structure and social injustice amounting to disability on the grounds of functional limitation.

Research concludes by providing insights into the major problems for example on the marketing and sale of counterfeit drugs and on research surveys carried out around drugs in general, the question is how patients be assured that the validation of a survey is in any way accurate when data is analysed in issues identified in Lia's case regarding social class problems and the misunderstanding between cultures. (Fadiman, 2012)

Conceptual Framework

The conceptual framework will comprise of the following:

1. Topic introduction, outlining importance and benefits of research findings.
2. Consequences of counterfeit pharmaceutical products to pharmaceutical companies and product stakeholders
3. Looking at distribution of counterfeit pharmaceutical products
4. Reasons why counterfeit pharmaceutical products distribution may exist.
5. Approaches which can minimise supply and demand of counterfeit pharmaceutical products.
6. Challenges and opportunities of minimising counterfeit distribution
7. Conclusion of topic

Conclusion of literature review

The published articles which were discussed chapter 2 all commonly highlight the threat counterfeit medicine poses to public health and the need for increasing the public's level of awareness and knowledge of counterfeit medicine.

Summary table of key papers used in literature review.

Table 2 Summary table of key research papers used in literature review.

Authors	**Study Description and Publication Year**	**Sample Size**	**Key Points**	**Conclusion**
Bashir	Study on community pharmacists awareness, perceptions and practices relating to counterfeit medicine in Egypt. **2020.**	175 Community Pharmacists in Egypt	Need for an implementation of a strategy comprising of a strong legislation on drug distribution	Encourages promotion of partnerships from the leadership team between stakeholders and the collaboration with international organisations.
El-Dahiyat et al	Study performed to the identify the rate of substandard and falsified medications and its association with knowledge amongst the public. **2021.**	320 People from various geographic regions	Highlighted importance behind the need for increasing public awareness of the risks associated with counterfeit medicines	Recommended participation of vigilant healthcare professionals in raising public awareness and by holding educational campaigns.
Yadav et al	Performed study on knowledge and perspective towards counterfeit medicine amongst doctors in tertiary care hospitals. **2018.**	80 medical doctors participated from the Northern region of India	Over 50% of the participants suggested the use of technology and its ability to contain counterfeiting. Research concluded that counterfeit medicine poses health hazard and waste to consumer income.	Recommended that sufficient knowledge, awareness, and the implementation of modern technological approaches has potential to contribute to minimising counterfeit medication
Wagiella et al	Assessed the extent, awareness, and attitude of public in Sudan towards counterfeit medicine.	386 participants.	68% of participants had a fair awareness, 80% displayed good awareness of counterfeit medicine.	Recommended attention and efforts are required from the government, drug manufacturers, health care providers' and

	2020.		The research concluded that the literature includes gaps in knowledge and attitude towards counterfeit medicine.	pharmaceutical analysts to ensure that only drugs of acceptable quality reach the consumer
Sholy et al	Assessed pharmacist awareness and views towards counterfeit medicine in Lebanon. **2018.**	223 pharmacists	All participants' ability to define counterfeit medicine as a bad quality medicine or of unknown source. 43% Pharmacists knew others who dispensed such medicine. Also, participants asserted that pharmacists who dispensed such products were unprofessional and unethical and that it was a simple business yet highly profitable.	Highlighted the requirement for awareness through campaigns especially the key responsibility of pharmacists and the importance their duty is in protecting patients. Research also identified the need for an official definition of counterfeit medicine which mitigates variances.
Ofori-Parku and Park	factors as follows supply chain process, technology, legal mechanisms, consumer judgement and decision-making in relation to counterfeit medicine. **2022.**	427 US consumers	Consumers who self-report, are older, possess ethical viewpoints, seek approval from significant others of consuming such products have a better tendency to have favourable purchase intentions.	The research concluded that the following factors: consumer knowledge, expectations of impressing others, ethical judgments, risk awareness contribute to a consumers' decision making before purchasing a product.

Dalton et al	Examination on community pharmacists and their perceptions of how the Falsified Medicines Directive impacts their role. **2022.**	4,727 Irish community pharmacists	82% thought new requirements increased waiting times for patients. Whilst 65% though it decreased time to interact with patients. 28% of pharmacists agreed that the Falsified Medicines Directive enhanced safety to patients.	Pharmacists thought the workload is not proportionate to the risk of patients obtaining such products. The study highlighted how the participation of stakeholders would aid implementation of the procedures associated with Falsified Medicines Directive within community pharmacies

Chapter 3

Research Methodology

Overview of research methodology

Table 3 Overview of research primary data collection

Section	*Primary Data*	*Survey Questionnaire*	*Interview*
1	Method	Quantitative & Thematic	Qualitative & Thematic
2	Philosophy	Pragmatism	Pragmatism
3	Source	Questionnaire distributed through google forms	Interviews
4	Structure	24 questions *(all reflecting gaps in similar previous research)* Demographics Level of education Purchasing decision factors Counterfeit medicine awareness assessment	20-minute interviews 9 Questions
5	Subjects	Public in Ireland	Pharmacists Health care professionals

In *Table. 3 above*, the reasoning for choosing the methods of collecting primary data will be further explored and discussed below.

Method of primary data collection for survey questionnaire

Method of questionnaire

A quantitative approach was chosen to enhance the visualisation of the data collected form the questionnaire.

A thematic approach was also applied to identify patterns and themes in the data obtained from the questionnaire.

Philosophy of questionnaire

Pragmatism and Saunders research onion was chosen due to the ability of dynamically discovering answers to research objectives and questions. The research philosophy implemented in this paper aided the collection, interpretation, and evaluation of the primary data. (McDeirmid, 2023)

Source of questionnaire

A questionnaire was a chosen method of primary data collection due to the efficiency; larger audience reach, good data representation and participant confidentiality in provides. The design of the questionnaire was aimed towards achieving the aims and objectives of this research. The public were asked questions aligned with assessing public knowledge and awareness of counterfeit medicine. Questions were also based on exploring gaps in previous similar research as participants were voluntarily prompted to answer topics around demographics, consumer purchasing behaviour, level of education and if education has an impact on the public's level of knowledge and awareness.

The questionnaire was distributed through the google forms platform online to make the questionnaire more accessible to the public in Ireland. The questionnaire was populated by the participant with the absence of the researcher. The results of the questionnaire were saved and displayed on a pie chart by google forms.

Structure of questionnaire

The survey questionnaire consisted of twenty-four questions all of which reflected the gaps identified from similar previous research. The questions were also designed to be aligned with reaching the aims and objectives set out in this research paper.

The questionnaire was grouped by types of questions and therefore included the following sections: Demographics, Level of education, Purchasing decision factors and counterfeit medicine awareness assessment.

Subjects targeted in questionnaire.

The public in Ireland were the target subjects for this research. This means contributing to the research aims and objectives. Research subjects were targeted and invited to participate through social media platforms such as WhatsApp, Google Gmail, LinkedIn, and Facebook. Each participant received a link to access the online survey questionnaire. Prior to accessing the questionnaire each participant was prompted to read the participant information Leaflet (PIL). Then confirmation of full awareness of what participation, confidentiality, and ability to withdraw participation was recorded prior to accessing research questions.

Method of data collection for interview

Method of interview

A qualitative method was chosen to aid the understanding and interpretation of the information collected in the interview. A thematic analysis was then applied to the information collected. This enabled the identification of themes and patterns in data. Also, applying both approaches enabled the interpretation of the professional's perception and opinion of public knowledge, awareness and deciding factors a patient considers when purchasing a medicine, all of which contribute to research objectives.

Philosophy of interview

Pragmatism philosophy was applied to this data collection. This enabled the exploration of mixed research methods consisting of both philosophical and methodological methods. This enhanced the interpretation of the information collected from the pharmacist and health care worker.

Source of interviewees

The method of holding interviews was chosen to obtain information from professionals in the primary data collection. Although the research intended to hold interviews online through Microsoft teams, interviewees requested to be interviewed face to face due to time constraints they encountered. As a result, the face-to-face interviews enabled the two interview participants to be more comfortable sharing important information whilst knowing that their image and voice would not have any traces of being retained.

Structure of interview

Prior to engaging in the interview, Interviewees were invited to read the participant information leaflet (PIL) and the Informed Consent Form (ICF). The participants then signed the informed consent form (ICF) which enabled the interview to begin.

The interview comprised of nine questions and took approximately twenty minutes to complete. The questions were guided and linked to gain information aligned with the research gaps, aims and objectives. The interview also explored professional

recommendations for ways of improving public knowledge and awareness of counterfeit medicine.

Subjects

The pharmacists and health care professionals in Ireland were targeted in this research due to the nature of their roles and therefore being in direct contact with pharmaceutical products. Health care professionals and pharmacists were targeted through visiting local general practitioner medical centres and pharmacies in county Galway, Ireland.

Research Purpose

This research proposal is aimed at assessing public awareness of counterfeit medication and understanding if improving public knowledge would play a key role in the minimisation of counterfeit distribution. This paper will perform a study from a public awareness perspective as well as analysing measures that may be taken to reduce supply and demand of counterfeit medication. Research into the chosen topic is being performed as the consumption of counterfeit medicinal products poses a major health and safety risk to public health. This topic holds importance as it is vital that the public have trust in pharmaceutical medicinal products which will enhance patients' access to treatments to aid recovery from illness. Due to the unpredictable health risks associated with counterfeit products, an analysis of public awareness will be performed to identify if improving knowledge can contribute to reduced counterfeit supply and the purchase of those medicines.

Research structure

Primary research will involve a quantitative questionnaire to assess knowledge of the topic. Target participants will be members of the public in Ireland. Participants with professional work experience in relevant roles such as pharmacists and health care workers will be invited to partake in an interview which will be assessed qualitatively. This chosen method of research will enable the assessment of public knowledge, awareness and practices regarding counterfeit medicine it will also allow consideration for the valuable information a professional in this sector could provide.

Secondary research will comprise of searching published reports, academic books, white papers, green papers and journals. In order to answer and reach initial research questions and objectives, a list of relevant terms and words known about counterfeit pharmaceutical products was compiled. In addition, websites such as the World Health Organisation (WHO), the US Food and Drug administration (FDA) and the European Medicines Agency (EMA) will be reviewed for informative guidance. Research will also consist of accessing Griffith College Dublin online library and the EBSCO Host Research Platform database, which will enable the sourcing of relevant academic articles.

Examples of the terms and keywords in the database search include the following: Pharmaceutical product distribution, falsified medicine, illicit distribution strategies, Illegal medication smuggling, falsified medication awareness, out-of-specification medicinal products, serious adverse reactions (SARs) and effects of falsified medicine, illicit medicines and public awareness. Shortlisted words were then inputted into online public search engines such as google scholar.

Possible hypothesis:

The level of public awareness is poor and improving it would help reduce global supply of and access to counterfeit medicine.
The socio-economic class, cultural practice and level of education has an impact on level of awareness.

Approaches of minimising counterfeit medicine supply and demand:

- Avoid purchases through online platforms and or unauthorised retailers.
- Provide information to stakeholders about possible health consequences of taking counterfeit pharmaceutical products.

Methodology for research design and data collection

This research will follow both quantitative and qualitative approach during the collection of information.

Data from the public's participation will be collected through online quantitative surveys. However, information collected from interviews with pharmacists and health professionals will be reviewed using a qualitative approach. A thematic analysis will then be performed on all data collected in this research.

The research findings will be analysed thematically and interpreted in the research analysis.

Outline of Philosophical influences on the approach to the research

Primary research will comprise of a quantitative and qualitative approaches. The research method applied will comprise of individuals participation in a qualitative questionnaire. Participants' answers to the questions will reflect individual perception, experience, and cognitive knowledge regarding this research topic. Although research will include participants, the public and pharmacists, it will be limited as the questionnaire will not reflect few stakeholders for example pharmaceutical manufacturers participation in the survey. Also, data will only reflect Ireland, and the public awareness and level of knowledge of counterfeit medicine.

In conclusion, this research philosophy explores interpretivism of results through using a qualitative approach in the gathering of data from participants.

Research strategy

The research strategy will apply as follows:

1. Identify public awareness of counterfeit pharmaceutical products.
2. Review published documentation and statistical reports to provide clarification on effects of counterfeit pharmaceutical products on shareholders and stakeholders.
3. Identify approaches of minimising distribution of falsified medicine by reviewing published academic articles and interviewing industry professionals.
4. Highlight reasons why counterfeit pharmaceutical products distribution may exist from reviewing published academic articles, qualitative surveys, and journals.
5. Observe challenges and opportunities of minimising counterfeit distribution through research of articles, case studies, documents, and surveys.

The results of this research strategy should meet proposal aims and objectives previously outlined.

Techniques in data analysis

The most vital step in this dissertation is the collection and analysis of data collected. The collection data associated with this research is comprised of two methods primary and secondary.

This research will be performed using a qualitative approach on the questionnaire followed by a qualitative approach on the interview. Then a thematic analysis will be conducted to identify patterns and themes. To minimise risk of biased results, a reflective strategy will be implemented during the interpretation of results.

A study on data, participant observations and interviews will be analysed. (Busetto *et al.*, 2020)

Nature of data

Review of published documents and statistical reports:

- Perform research and data analysis.
- Perform interpretation of data

Interviews will be performed with the following:

- Pharmacists who have direct contact with pharmaceutical product in their day-to-day role.
- Health professionals who are authorised to prescribe and or distribute medication.

Surveys will be performed as follows:

- Participants will include public to enable analysis of public knowledge and awareness of counterfeit medicine.
- Pharmacists and health care professionals who are in direct contact with medicine and who hold valuable experience and knowledge around precautions of minimising counterfeit distribution.

Ethical and GDPR considerations

In compliance with the European General Data Protection Regulation GDPR, an ethics assessment was performed prior to collection primary data. (European Parliament, 2016)
The ethical assessment results showed that this research did not require any further ethical approval. Therefore, an ethics declaration form was submitted to Griffith College. A copy of the Participant Information leaflet (PIL), informed consent form (ICF), questionnaire and interview questions used in the data collection were all submitted in the ethics declaration. The PIL, ICF, questionnaire and interview questions are available for viewing in appendices I, II, III, IV, and V below.

Identification of access and ethical issues

Participants will be provided with a topic introduction. Unbiased questions will be constructed in a questionnaire. Pharmacists and health care professionals will be invited to partake in face to face or zoom interviews to obtain information which will reach project objectives.

The topic will be introduced to each participant verbally and in writing therefore obtaining informed consent to conduct research. Individual approval will be required prior to participation in the research. Participants will be informed that they are permitted to withdraw participation at any time throughout the research.

Possible Outcomes of the Research

This research aims to look at public knowledge of counterfeit pharmaceutical products. Research also seeks to identify popular means of counterfeit distribution and approaches to minimise supply. Therefore, research is focused on identifying means to protect pharmaceutical manufactures revenue and sales as well as patient safety and integrity.

Therefore, findings intend to highlight main distribution links and targets for the global counterfeit pharmaceutical supply chain. Also, findings regarding approaches to the minimization of counterfeit supply will be discussed.

Identification of influences on research

The use of qualitative surveys will provide data reflecting individual opinions and experience. However, consumers may appear to have different answers in contrast with professionals working in the medical sector.

Interviews will be conducted with selected professionals working in the medical industry. By conducting interviews on a selected group of professionals, clarification on counterfeit products, distribution links, opinions and past exposure to counterfeits will be identified.

Conclusion

A pragmatic philosophy approach was implemented in this research. With primary data being collected from two sources, online questionnaire, and interviews 118 people participated in the questionnaire whilst 2 professionals participated in a face-to-face interview. All data obtained throughout the primary and secondary research was analysed thematically in Chapter 4 of this research paper.

Chapter 4

Findings and Analysis

The primary data collected from the respondents' answers to the online questionnaire was analysed using a quantitative approach. This method will allow an analysis of knowledge and awareness to be performed to achieve the objectives set out. Other contributing factors will be analysed which are also linked to gaps in previous similar research.

The questionnaire was made available online through the Google Forms platform. The link was distributed through various social networking platforms such as LinkedIn, WhatsApp, Gmail, and Facebook. The researcher also reached out to personal connections from previous undergraduate studies in similar fields. The survey questionnaire received a total response rate of 116 participants in Ireland. All responses to the questions outlined below will be represented visually and categorically by means of a pie chart. The percentage of each answer will be easily identifiable on each pie chart to enhance visualisation of data.

Overview

In chapter 4 of this research, the data collected from the primary data will be discussed and analysed. The level of public knowledge and awareness in Ireland was assessed using a quantitative approach in the questionnaire. Factors such as level of education, social class, purchase behaviour and methods of reducing supply are evaluated below. The data collected from the interviews enabled the qualitative assessment of experience and opinions on this topic from two professionals who work in Ireland.

Method of Analysis:

Thematic Analysis was implemented in this research. This method aided the identification of patterns and themes in data. Using thematic analysis also offered flexibility in deeper meaningful research.

The questionnaire involved the public in Ireland and was performed to get a view of the general level of public knowledge and awareness of counterfeit medicine in Ireland.

The data collected from the questionnaire was saved on the google forms platform which then automatically displayed the results in a pie chart form. The pie chart offered clear data visualisation in proportions relative to percentages.

Data collected from the interviews were based on professionals' perceptions on counterfeit medicine and assessed other factors and recommendations of what could reduce exposure to counterfeit medicine in Ireland, this contributed to the development of themes within the research.

Primary data collection Response Rate:

The questionnaire was sent to 250 individuals in Ireland.
A total of 116 people from the Irish public participated achieving a response rate of 46.4%
Due to low response rate, out of 25 professionals being invited to participate in the interview, only two professionals participated in the interview. One professional was a pharmacist with 38 years of working experience. The second interview participant had 6 years of work experience in health care. Therefore, a response rate of 8% was obtained in the interview.

Discussion of themes identified.

Although the interview had a poor response rate of two participants, information from the two responses enabled the identification of common themes in the answers.
Common themes from interview responses included the lack of awareness within the public, Impact on purchase decision, education and need for raising awareness.

Lack of public knowledge and awareness

The lack of public knowledge and awareness was a common theme in the primary data collection. Both participants in the interview recognised the lack of knowledge and awareness of counterfeit medicine and recommended that it needs to be improved. The professionals recommended improving awareness through engaging in various government backed activities. This was also a common theme in both the literature review and quantitative data collection.
The quantitative data revealed that females (117) were more aware of counterfeit medicine than males (111)
In the literature review, some previous similar research suggested that pharmacists need to be more precise in their definition of counterfeit medicine.(Sholy *et al.*, 2018) By doing so perhaps this definition could be easily translated in all countries.

The questionnaire observed that 97.3 % were aware of counterfeit medicine and that 77.6% understood the risks associated. When participants were asked if the level of public knowledge and awareness needs to be improved, 98.3% of participants agreed.

Impact on purchase decision

The cost of a medicinal product was also a common theme in both quantitative and qualitative primary data collection.

In the questionnaire, participants were asked if they considered the cost of the medicinal product. 92.2% of participants admitted considering the cost whilst 7.8% do not consider cost. When participants were then asked if they would consider purchasing a cheaper medicinal product from an online pharmacy or website, 69.8% of participants admitted they would and 30.2% of participants do not consider purchasing medicine online from cheaper.

The interview observed similar answers from the professionals. When asked if they thought the public considered any factors before deciding to purchase and/or consume a medicinal product, both interviewees mentioned the impact of decision making was around the price of products.

Demographics

The demographics was also a common theme in the primary data collection.

The area of residence

When participants were asked if purchasing non-branded medicinal products has an impact on social status and reputation, 66.4% of participants agreed whilst 33.6% admitted the purchase of non-branded products did not have an impact.

Similar themes were also identified in the interview. In the interview a question regarding social class and status being impacted by purchasing non branded products, professionals agreed. This is perceived to be as a result of being seen by others in the community and being more conscious when making purchasing decisions.

Level of education

The level of education was also a common theme identified in this research.

When participants in the questionnaire were asked if a person's level of education has an impact on their awareness of counterfeit medicine 87.1% of participants agreed and 7.8 % did not agree and 5.2% neither agree nor disagree.

Data also suggests that people with higher levels of education had higher knowledge and awareness of counterfeit medicine. The question to obtain information on the level of education was segregated into the following levels of education: No formal education (1.7%), Primary education (0%), Lower secondary (2.6%), Upper secondary (11.2%), Diploma (20.7%), Primary degree (30.2%), Postgraduate diploma (18.1%), Postgraduate degree (Masters) (12.9%) and Doctorate (Ph.D.) (2.6%). Most participants in this research have a primary degree as their highest level of education. Another question in the questionnaire asked how long ago the participants completed their highest level of education. This question seeks to assess if the time since completing education has an impact on results. The outcome identified the following (44%) 0 to 5 years, (35.3%) 6 to 11 years and (20.7%) 12 years +.

The findings from the interview with the professionals also identified that education has an impact on a person's level of knowledge and awareness of counterfeit medicine.

Responses to research questions

1. **What is the level of Public knowledge and awareness of counterfeit pharmaceutical products in Ireland?**

   The data collected from the primary research indicates that 87.9% of people are aware of the existence of counterfeit medicine. Although the questionnaire identified that the majority of participants are aware of counterfeit medicine, 22.4% of people did not fully understand risks associated with use when asked. The questionnaire also identified that 98.3% of participants agreed that it is important for public awareness of counterfeit medicine to be improved. However, 1.7% neither agree nor disagree.

   The interview with the pharmacist recognised that more people need to be aware that counterfeit medicine exists and the extent of the problem it causes.

Both professionals who participated in the interview also agreed that the level of public knowledge and awareness of counterfeit medicine in Ireland needs to be improved in efforts to reduce supply.

2. **What is the impact of social class, culture, and level of education on level of awareness of counterfeit medicine?**

   The quantitative data results revealed that the majority of participants view a person's social class, culture and level of education all to have an impact on awareness of counterfeit medicine. The interview also revealed similar responses to these questions.

3. **What are the potential impacts, threats to public health and business caused by counterfeit medicinal products?**

   The consumption of counterfeit drugs poses many detrimental unpredicted risks to public health. With increasing access to the internet and advances in technology, counterfeiting acts have increased therefore becoming more of a public threat. With counterfeit medicine containing different or no Active Pharmaceutical Ingredients, patients will remain ill from the target illness which may cause symptoms to worsen.

   The quantitative results revealed that 77.6% of participants understood risks associated with counterfeit medicine. When asked if they are aware of how such products are distributed, 57.8% of participants confirmed awareness.

4. **What are the approaches that can be taken to minimise supply of counterfeit pharmaceutical products in Ireland?**

   The quantitative data highlighted that 94% of participants think that improving public knowledge and awareness of counterfeit medicine would contribute to reducing the supply. The data collected from the interviews revealed that, in Europe counterfeit drugs are distributed online.

   The data collected from the interview also observes recommendations of spreading awareness of counterfeit medicine and recognising genuine medicine in Ireland. Campaigns and initiatives are also recommended, especially certain successful campaigns which worked well for other organisations.

Comparison of primary and secondary data

Previous similar research in the literature review revealed that the level of awareness needs to be improved (Sholy *et al.*, 2018)
Recommendations of improving awareness of counterfeit drugs through the participation of vigilant healthcare professionals and by holding educational campaign are also observed in research conducted in Egypt. (El-Dahiyat *et al.*, 2021b) This call for the need of increasing public awareness of counterfeit medicines was common through the research in the literature review.

The data gathered from the primary data collection is closely aligned with the evidence from the literature review. The interview revealed similarities in the research performed by *Dalton et al* of which contained participation from 4,727 Irish community pharmacists. Although pharmacists thought the workload is not proportionate to the risk of patients, research highlighted that the participation of stakeholders would aid implementation of the procedures associated with Falsified Medicines Directive within community pharmacies. 25 participants in Dalton et al published researched did not recognise that the Falsified medicine Directive FMD is applicable to their line of work. This paper also recognised that the distribution of falsified medicines should be reduced in Ireland from unlicensed sellers even though the majority of medicine is purchased through legit supply chains. (Dalton *et al.*, 2022)

In *Yadav et al* published research into the public in Sudan's knowledge and perspective towards counterfeit medicine amongst doctors in tertiary care hospitals identified 68% of participants had a fair awareness, 80% displayed good awareness of counterfeit medicine. However, research also concluded that knowledge and attitude towards counterfeit needs to be improved and could be promoted with the implementation of modern technology. (Yadav *et al.*, 2018)

Visual representation of quantitative data

The data collected from the questionnaire is represented in the figures below. This is aimed to aid data visualisation and interpretation.

Understanding of what participation involves

The Participant Information Letter was made available to all participants prior to accessing the questionnaire. This prompted the participant to read what the research entails and what participation involves. The question outlined in *Figure.7* below confirms that 100% participants have read are fully aware of the research and what participating in this research involves.

In *Figure. 8 below*, 100% of participants have read the Participant Information Letter PIL, are fully aware of what participation involves and agree to be involved. Participants are also aware that their participation can be withdrawn at any stage of this research.

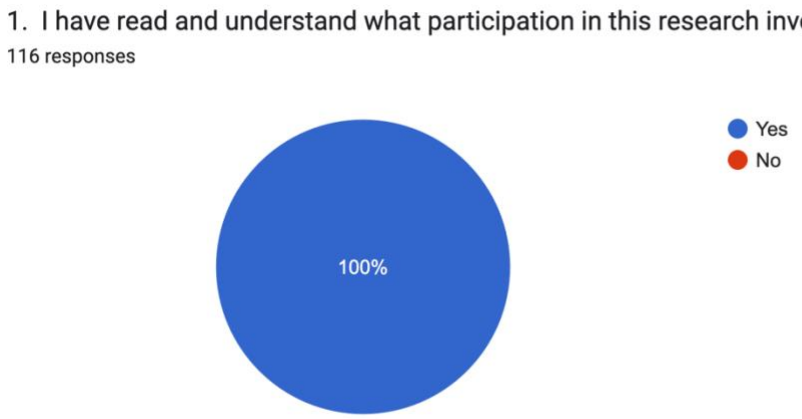

Figure 8 Confirmation of participants' understanding of what research involves.

Figure.9 below, records 100% of participants who display willingness to be involved in the research. It also shows that 100% of participants are fully aware of their right to withdraw from the research.

Figure 9 Participants agree to participate in research and aware of being allowed to withdraw.

General characteristics of quantitative data

Demographics

As 116 people participated in the online survey questionnaire, asking demographic questions enabled the researcher to identify characteristics such as gender, age, area of residence, level of education, time since completion and if the participant ever worked in the health care sector.

Gender of participants

The gender of each participant was recorded. This information enhanced the analysis by identifying if gender has an impact on results and if a gender group is more informed than the other. Participants also had an option to not disclose their gender in the questionnaire if preferred. In *Figure. 9* below, 49.1% of participants were Female and 50.9% were male.

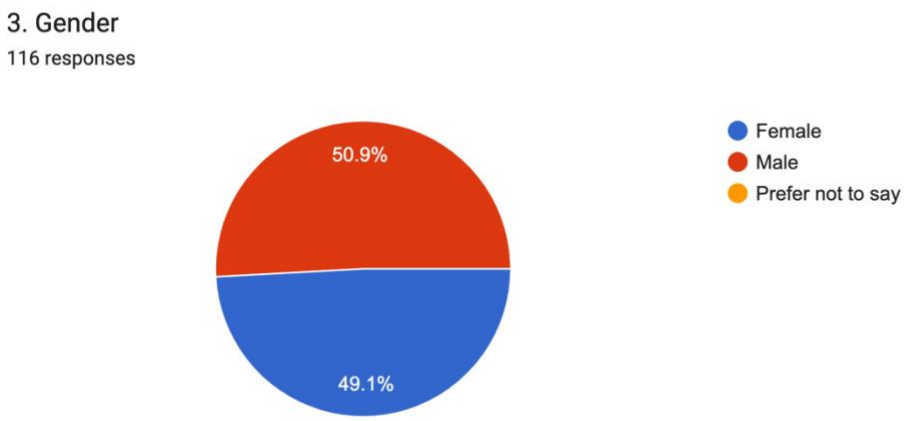

Figure 10 Gender of Participants

Age group of participants

In Figure.10 below, the age group of each respondent was recorded. Participation reflected the following age groups (16.4%) 18 to 24, the majority of participants (57.8%) were associated with the age between 25 to 39, (12.9%) 40 to 60 and (12.9%) 60+. The identification of age groups provides a deeper perspective to analysis.

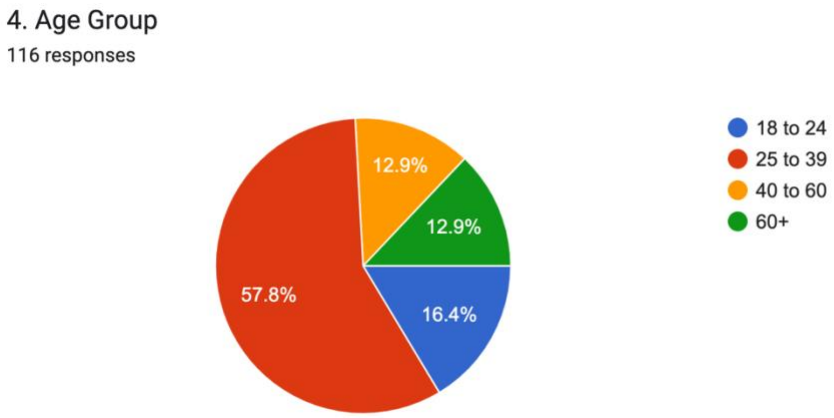

Figure 11 Age group of participants

Area of residence

The area of residence was recorded to identify if it has an impact on participants' responses throughout the questionnaire. As observed in Figure.11 below, this research involved a fair mixture of people residing in the urban region (56.9%) and rural region (43.1%). This also highlights useful information as it provides perspective of the participants awareness of counterfeit medicine-based area of residence.

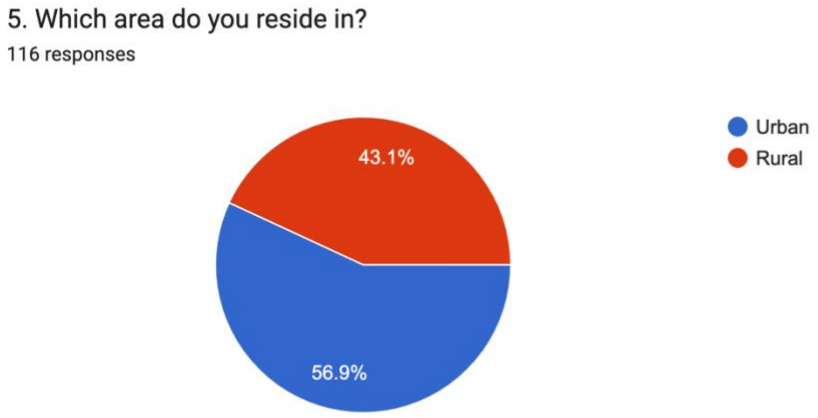

Figure 12 Area of residence (urban or rural)

Level of education

This question also addresses gaps in previous similar research as results can aid the identification of the impact of education on level of knowledge and awareness.

The question was segregated into the following levels of education: No formal education (1.7%), Primary education (0%), Lower secondary (2.6%), Upper secondary (11.2%), Diploma (20.7%), Primary degree (30.2%), Postgraduate diploma (18.1%), Postgraduate degree (Masters) (12.9%) and Doctorate (Ph.D.) (2.6%). The majority of participants in this research have a primary degree as their highest level of education.

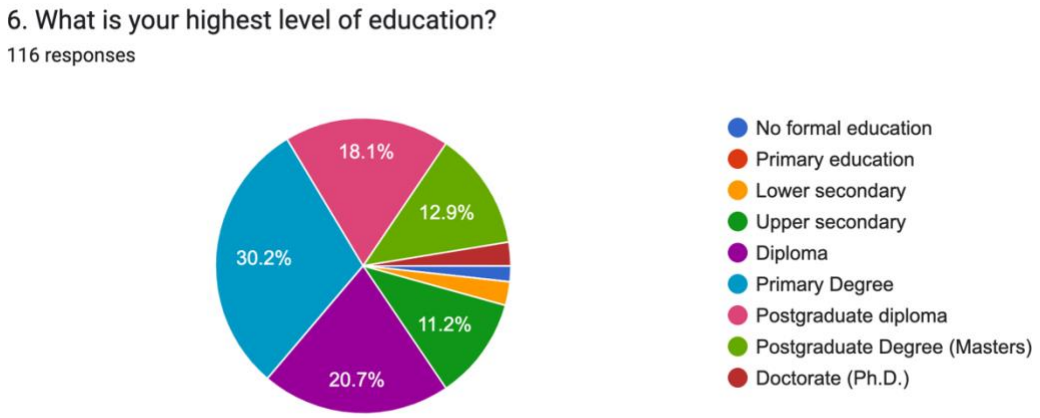

Figure 13 Highest level of education

This question outlined in *Figure.13* below, asks how long ago the participants highest level of education was complete. This aims to assess if the time since completing education has an impact on results.

Results identified the following (44%) 0 to 5 years, (35.3%) 6 to 11 years and (20.7%) 12 years +.

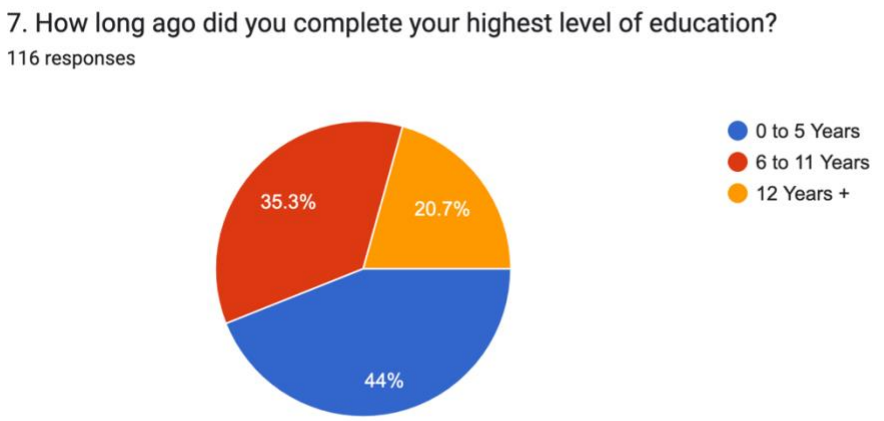

Figure 14 Time since completion of education

Experience

This question observed in *Figure.14* below, assessed the participants current occupation. The question involved the following responses by category: Unemployed (3.4%), Self-employed (6.9%), employed (63.8%), Student (10.3%), and retired (15.5%).

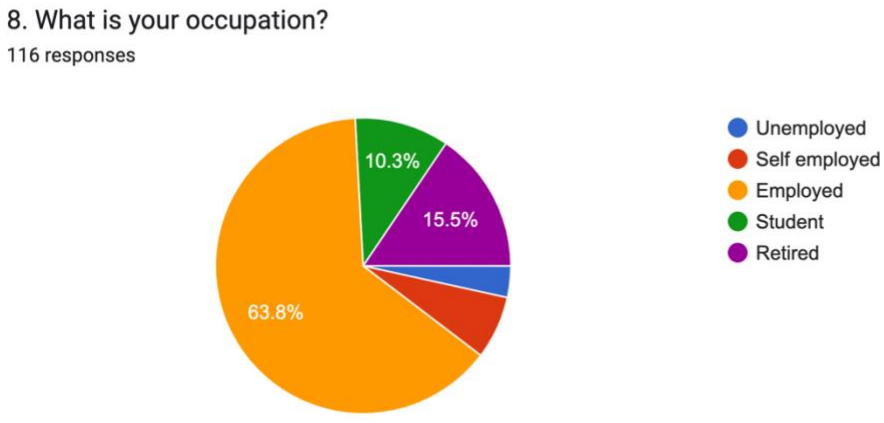

Figure 15 Participants occupation

In figure.16 below, 54.3% of respondents previously worked in the healthcare environment whilst 45.7% of participants did not.

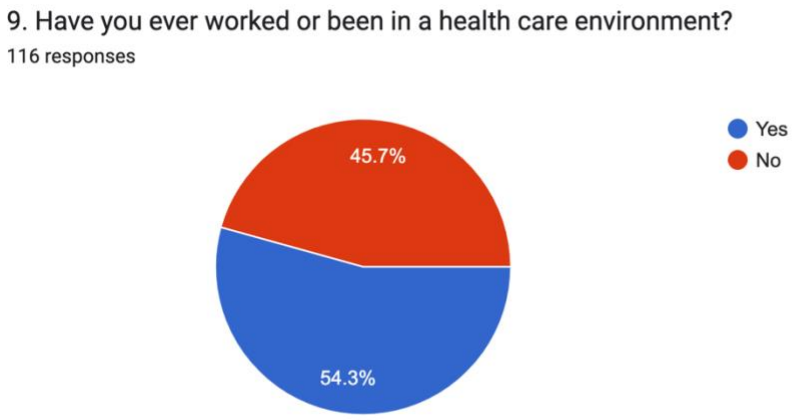

Figure 16 Identification if participant previously worked in the health care sector.

Purchasing decision factors

The questions relating to a participants purchasing decision factors were asked to identify what sort of influences and decisions impact their purchase decision. Data obtained observes that products cost, and appearance are main factors in the purchase decision.

In *figure.17* below, 92.2% of participants consider the cost of the product whilst 7.8% do not consider cost.

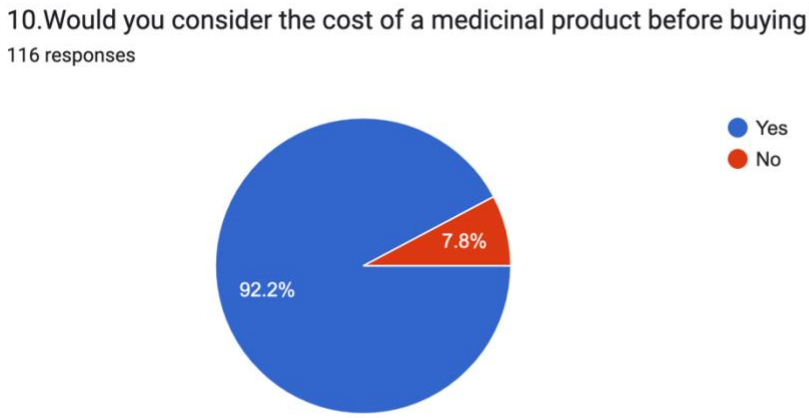

Figure 17 Purchase decision making.

In *figure.18* below, 69.8% of participants would consider purchasing a cheaper medicinal product from an online pharmacy or website. However, 30.2% of participants do not consider purchasing medicine online from cheaper sources.

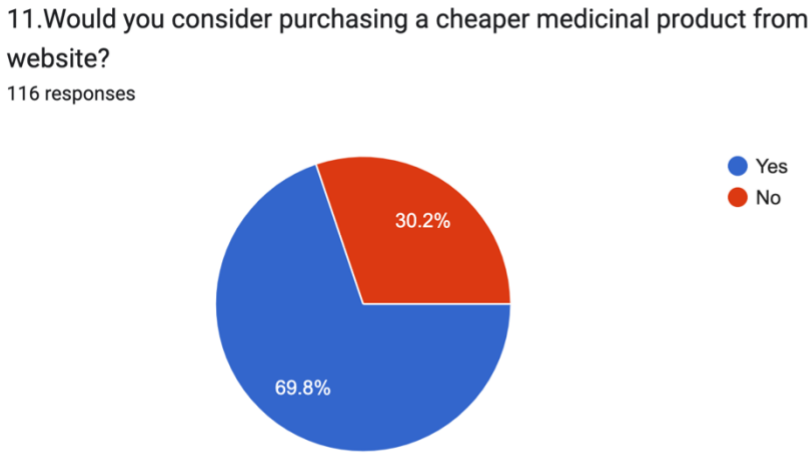

Figure 18 Purchase considerations

In *figure.19* below, 75% of participants admitted to the product's overall appearance, packaging and labelling to have an influence on their decision to purchase the medicinal product. 25% of participants admitted that these considerations do not influence their decision to purchase the product.

Figure 19 Product appearance influence on purchase

In *figure.20* below, 66.4% of participants thought purchasing non-branded medicinal product has an impact on social status and reputation. 33.6% admitted the purchase of non-branded products did not have an impact.

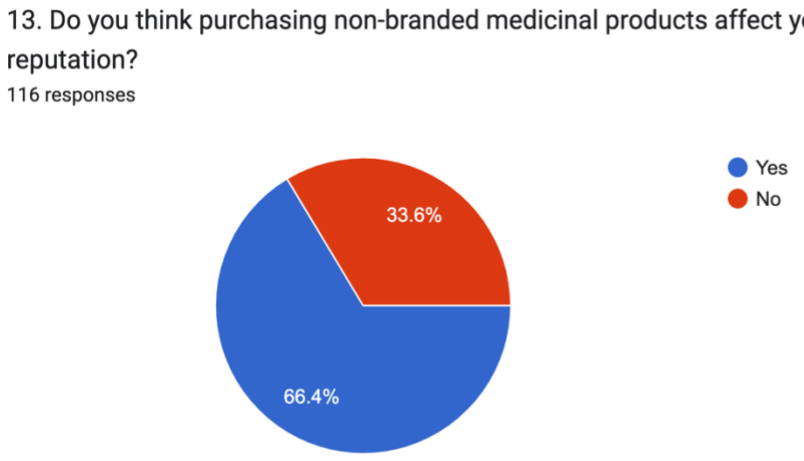

Figure 20 Considerations on social class and reputation

In *figure.21* below, 64.7% participants confirmed that they verify packaging safety features whilst 35.3% did not.

Figure 21 Packaging safety features

In *figure.22* below, 61.2% of participants are not able to identify a genuine medicine from a counterfeit. 38.8% can identify the difference between counterfeit and genuine medicine.

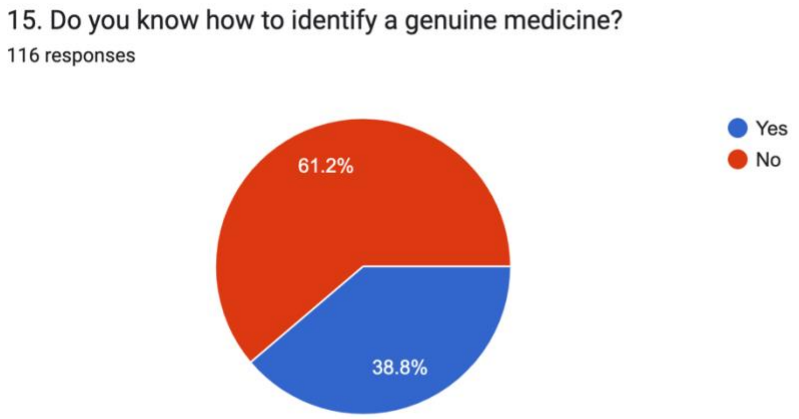

Figure 22 Identification of genuine medication

In *figure.23* below, 87.9% of participants are aware of the existence of counterfeit medicine whilst 12.1% were not aware.

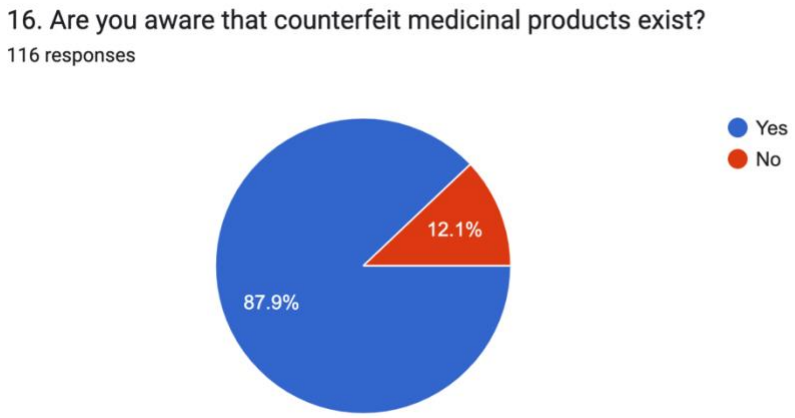

Figure 23 Awareness of counterfeit medicine existence

In *figure.24* below, 92.2% of participants thought counterfeit medicine is a risk to public health and safety. However, 7.8% did not think this caused any risk.

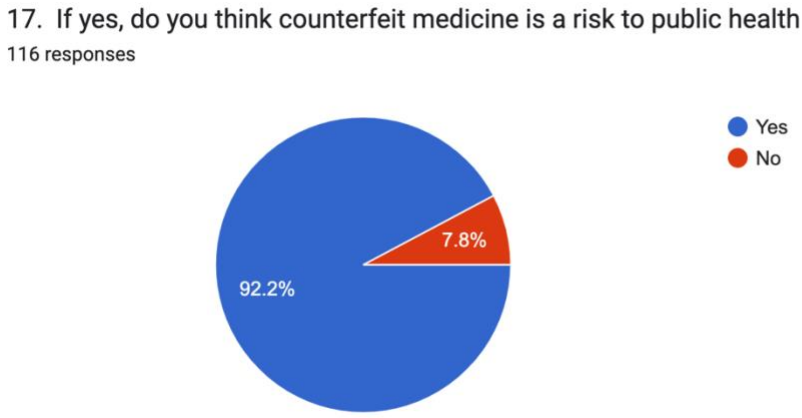

Figure 24 Risk consumption causes to public health

In *figure.25* below, 77.6% of participants understood risks associated with counterfeit medicine and 22.4% did not understand the risks to public health.

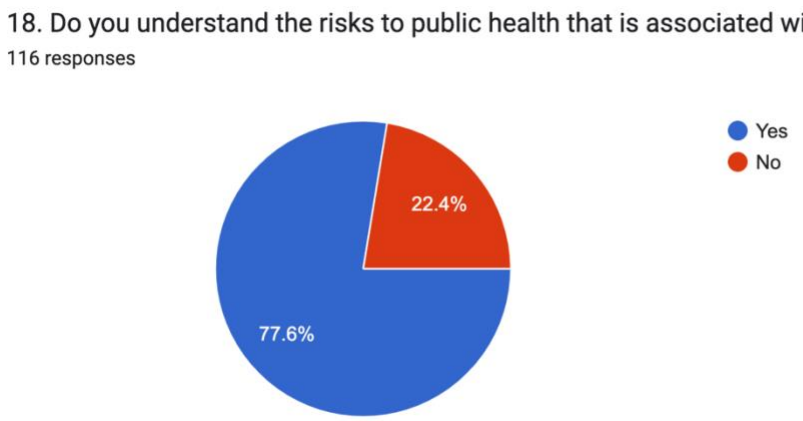

Figure 25 Understanding of risks associated with counterfeit consumption.

In *figure.26* below, 57.8% of participants confirmed that they are aware of how counterfeit medicine may be distributed and 42.2% were not aware.

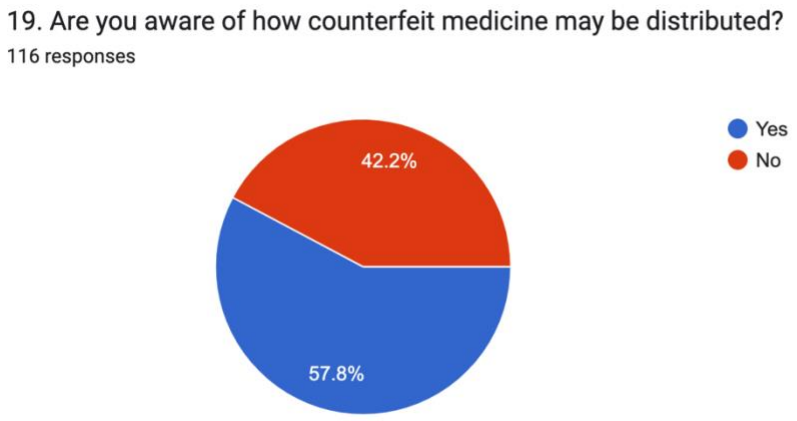

Figure 26 Counterfeit distribution links

In *figure.27* below, the results showed the following sources of awareness,7.8% aware from other sources, 17.2% not aware of counterfeit medicine, 24.1% news or social media, 16.4%

healthcare professionals or health centres, 21.6% learned through education and 12.9% family and/or friends.

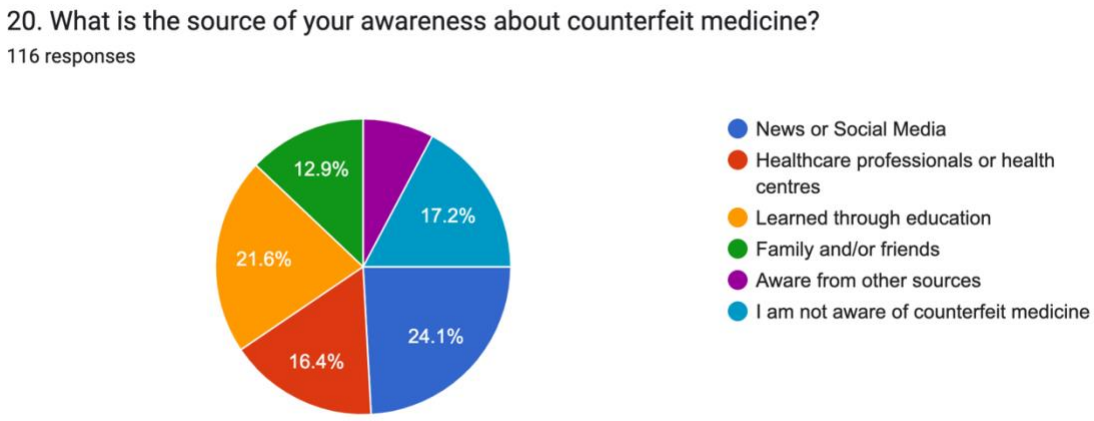

Figure 27 Source of awareness

In *figure.28* below, 38.8% confirmed their ability to identify a counterfeit medicine and 61.2% confirmed that they cannot identify an ingenuine medicine.

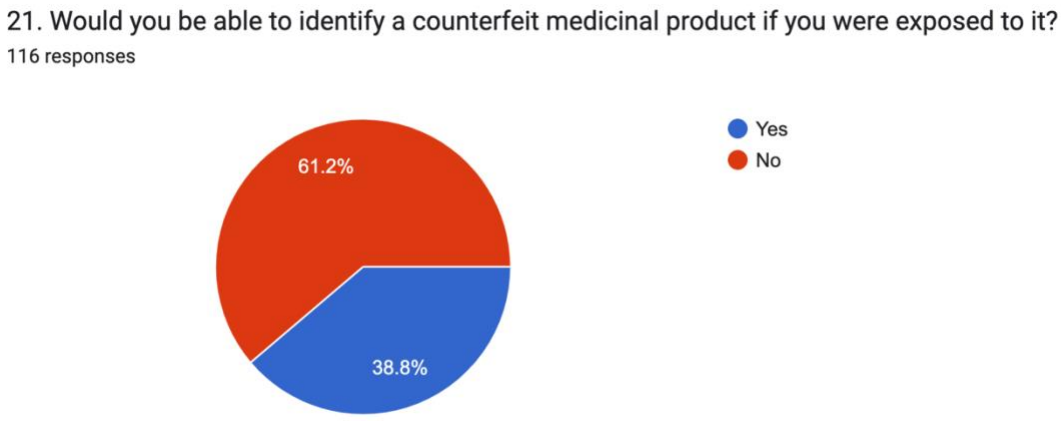

Figure 28 Ability to identify counterfeit medicine.

In *figure.29* below, 94% of participants agree that it is important for the public to be aware of counterfeit medicine and that awareness about it would contribute to reducing the supply, 5.2% of participants neither agreed or disagreed and 0.9% disagreed with this statement.

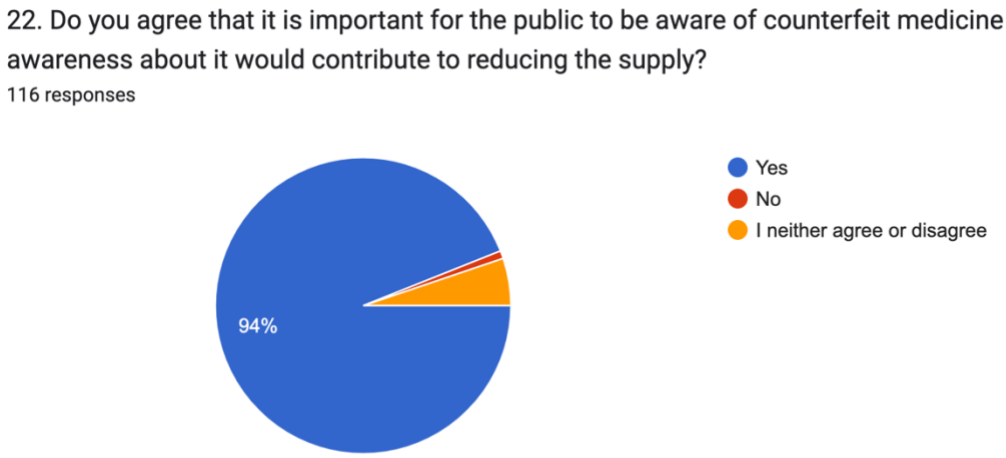

Figure 29 Perception into the need for improving the level of public knowledge and awareness to reduce supply.

In *figure.30* below, 98.3% of participants agreed that it is important for public awareness of counterfeit medicine to be improved. However, 1.7% neither agreed nor disagreed.

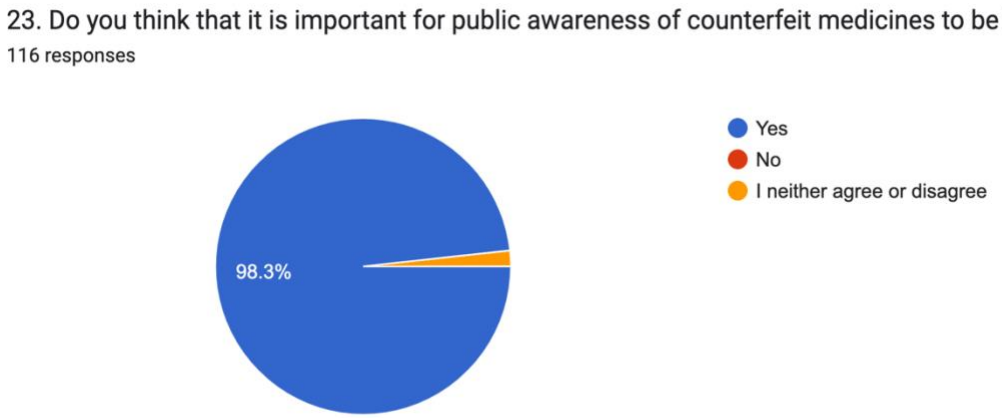

Figure 30 Opinion if improvement of public awareness is needed.

In *figure.31* below, 87.1% of participants thought that a person's level of education has an impact on their awareness of counterfeit medicine, 7.8 % did not agree and 5.2% neither agree nor disagree.

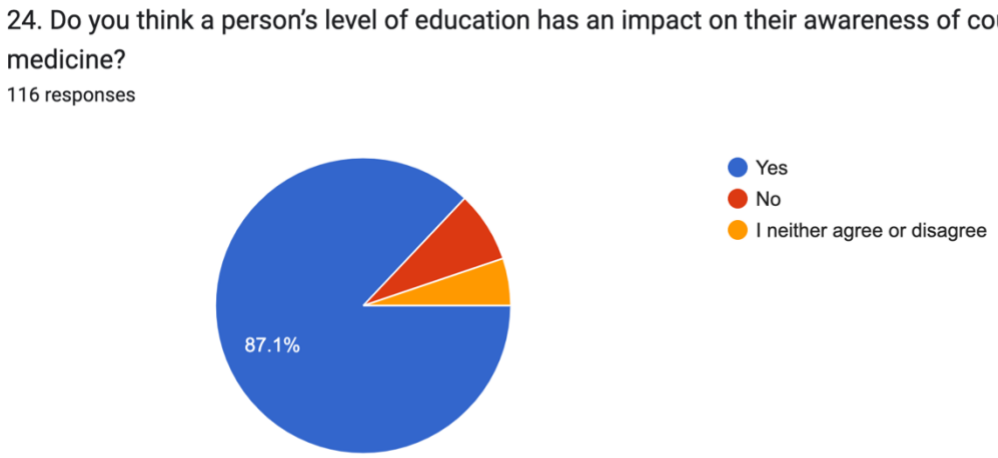

Figure 31 Opinion on the impact the level of education has on level of awareness.

Chapter 5

Conclusion

The distribution and consumption pose major risks to public health and safety. The outcome of this research provides an insight into the level of public knowledge and awareness of counterfeit medicine in Ireland. Research also provides recommended approaches of minimises the availability of counterfeit medicine supply in Ireland through illegitimate distribution links. Increasing the public level of knowledge and awareness is a vital component in combatting exposure to counterfeit medicines in Ireland. Therefore, awareness campaigns and initiatives should be implemented and backed by government organisations to raise awareness levels amongst the public.

Firstly, by hosting various types of awareness campaigns and initiatives the involvement of key stakeholders such as pharmacists, doctors, nurses, and health professionals all could promote the requirement for public knowledge and awareness levels to be improved amongst the public in Ireland. This could also be promoted on social media platforms to increase the reach and target audience. These awareness campaigns should explore many factors, some of which should include information on the risks associated with consumption, how to identify an illegitimate distribution source, where it originates from and highlighting differences between generic and biosimilar drugs to inhibit consumer confusion. By applying this method patients will be aware of counterfeit medicine. Patients could be well informed of these drugs and how they can contain little or no prescribed Active Pharmaceutical Ingredient API which will not treat the target illness and therefore also can cause serious adverse reactions to the patient.

An individual's level of education has an impact on the level of knowledge and awareness they have of counterfeit medicine. If an individual does not have appropriate reading, writing and comprehension skills their ability to be informed of counterfeit medicine may be reduced. Also, depending on how included an individual is in society and class the purchasing behaviours can be affected.

With the current European Union Falsified Medicines Directive (2011/62/EU) being followed in Ireland and the rest of Europe, the exchange of communication and information could be

improved. Although research from (Dalton *et al.*, 2022) highlighted how pharmacists in Ireland thought the workload is not proportionate to the risk of patients obtaining such products their professional input can be a vital part of improving public awareness.
The exchange and sharing of information can be improved by removing QR codes from product packaging and replacing it with numerical identifiers which can be clearly understood and identified from all nationalities around the world. Also, by implementing internet algorithms, authorised sellers who conform to industry standards on search engine result can be prioritised so that it will be primary search results to the user.

Considering the findings of this research, results call for practices to be implemented to contribute to the improvement of the publics level of awareness and knowledge of counterfeit medicine in Ireland. Awareness and knowledge can be improved by implementing various means of campaigns, initiatives, education, and improved exchange of information.

In conclusion, this research has highlighted how many gaps remain within the different levels of knowledge and awareness of counterfeit medicines. Ranging from that of not running enough studies that take in the full assessment of Irish public knowledge, awareness and the understanding of what counterfeit drugs are, what to look out for and the danger that these counterfeit drugs entail. Furthermore, if part of a sample group lacks the required level of education whether it is to do with level of education, social class, cultural practices, or an issue around the participants gender then the hypothesis can fail in achieving a validated on outcome of the research objectives. The importance of collecting the data from the required sample groups is aperitive as gaps will keep persisting in the identification of the key drivers for the continuation of illicit counterfeit medicine distribution. This is proven to be valid as, looking at the work of past researchers who provided us with their published articles, journals, and other research conclusions. This issue has being shown to an ongoing problem in Ireland which is complex, and as technology advances and accessibility to the internet increases, so too is the cunningness of the manufacturers approaches of the counterfeit products.
Other Gaps that this research has highlighted can be seen the lack of concern some organisations due to the fact that the manufacturing and supply of counterfeit drugs is a growing problem on a global scale.

The Irish Medicines Verification Organisation, have highlighted counterfeit medicinal products were detected in Ireland, and were purchased through various online platforms. These issues need to be addressed and policed. (IMVO, 2023)

Contributions and limitations

Prior research into this topic of counterfeit medicine encountered gaps in research. Although similar research primarily involved pharmacists as participants, no research has been found which involves assessing public knowledge and awareness of counterfeit medicine amongst the Irish public. However, academic articles which were discussed in the literature review all call for the level of awareness of counterfeit medicine to be improved globally.

The international Coalition of Medicines Regulatory Authorities highlight how current traceability systems in supply chain focus on local areas and therefore requires improving of the sharing and exchange of information on a global scale to contribute towards protecting public health and safety. (International Coalition of Medicines Regulatory Authorities, 2021)

The data collected from this research had a total response of 116 participants with 2 professional participants being involved in the interview.

Research findings will contribute to improving public knowledge and awareness of counterfeit medicine and precautions to minimise supply in Ireland. The participants who partook in the online questionnaire were prompted to answer questions relating to demographics, level of education, experience, purchase decision factors and assessment of knowledge and awareness.

This research will also prompt stakeholders in Ireland to practice precautions to minimise supply of counterfeit medicine. Research findings encourage consumers to avoid purchasing medicine online. However, if purchasing the medicine online is preferred, consumers are encouraged to verify the seller on the public register which is maintained by The Pharmaceutical Society of Ireland (PSI).

The survey questionnaire received 116 responses from the public in Ireland. The interview received 2 responses 1 being a pharmacist and the other being a care provider. In future research, a larger target of audience would achieve a higher response rate which could be promoted by local health centres would enhance the ability to assess public knowledge and awareness of counterfeit medicine.

The participants who were invited to an interview requested a face-to-face method of interviewing. Although an online recorded interview was preferred in the research plan, this alternative method enhanced the collection of data. The observation of body language, importance of the research topic, credibility and confidentiality deepened using the face-to-face method. Due to the nature of the demanding careers of pharmacists and health care workers, a low response rate to the interview was obtained.

Recommendation for further studies

To obtain a wider reach of participants and obtain a more accurate analysis, further research could involve more participants in both questionnaires and interviews. To achieve a larger response rate, research could be promoted by stakeholders such as the Irish government, local pharmacies, and health care centres through holding events such days of raising awareness. This may enhance the analysis and may lead to the reduction of counterfeit medicine in Ireland. Also, further research could be performed into how the exchange and sharing of information could be improved and if it contributes to reducing supply of counterfeit medicine in Ireland.

Considering how The Health Products Regulatory Authority (HPRA) detained 1,604,589 million units of illegal medicines in 2021, counterfeit medicine proves to be a prevalent public health threat in Ireland. (HPRA, 2022a) Therefore, this research highlights the requirement for public awareness and knowledge of counterfeit medicine to be improved and for precautions for minimising supply to be implemented and practised. However due to limitations encountered with low responsive rates to participation, further research may address these gaps.

Bibliography

Administration (TGA), T.G. (2022) *How to Spot a Counterfeit Medicine*. *Therapeutic Goods Administration (TGA)*. Available at: https://www.tga.gov.au/news/blog/how-spot-counterfeit-medicine (Accessed: 5 April 2023).

An Garda Siochana. (2022) *Operation Thor - Seven Arrested - Dublin and Meath - 19th October 2022*. *Garda*. Available at: https://www.garda.ie/en/about-us/our-departments/office-of-corporate-communications/press-releases/2022/october/operation-thor-seven-arrested-dublin-and-meath-19th-october-2022.html (Accessed: 18 May 2023).

Babyar, J. (2018) 'All the Players in the Game: Driving Home the Global Commitment for Legitimate Drugs'. *Drug Development & Industrial Pharmacy*, 44(11), pp. 1868–1870. DOI: 10.1080/03639045.2018.1504962.

Bashir, A. *et al.* (2020) 'Community Pharmacists' Perceptions, Awareness and Practices Regarding Counterfeit Medicines: A Cross-Sectional Survey in Alexandria, Egypt'. *Eastern Mediterranean Health Journal*, 26(5), pp. 556–564. DOI: 10.26719/emhj.19.058.

Busetto, L., Wick, W. and Gumbinger, C. (2020) 'How to Use and Assess Qualitative Research Methods'. *Neurological Research and Practice*, 2(1), p. 14. DOI: 10.1186/s42466-020-00059-z.

Campbell, N. *et al.* (2012) 'Internet-Ordered Viagra (Sildenafil Citrate) Is Rarely Genuine'. *The Journal of Sexual Medicine*, 9(11), pp. 2943–2951. DOI: 10.1111/j.1743-6109.2012.02877.x.

Chisom Lawrence, O. (2020) 'The Impacts of Drug Importation Regulation on Local Pharmaceutical Manufacturers in Lagos Nigeria'. Available at: https://repository.innoskills.com/handle/20.500.14136/23 (Accessed: 15 March 2023).

Dalton, K. *et al.* (2022) 'Pharmacists' Views on the Impact of the Falsified Medicines Directive on Community Pharmacies: A Cross-Sectional Survey'. *Exploratory Research in Clinical and Social Pharmacy*, 5, p. 100127. DOI: 10.1016/j.rcsop.2022.100127.

Dr. Jarvas, S. (2020) *The Dangers of Counterfeit Medications*. *The dangers of fake drugs*. Available at: https://patient.info/news-and-features/the-dangers-of-fake-drugs (Accessed: 23 April 2023).

Drug and Alcohol Information and Support in Ireland. (2023) *New Benzodiazepines - Drug and Alcohol Information and Support in Ireland - Drugs.Ie*. Available at: https://drugs.ie/newbenzos (Accessed: 17 April 2023).

El-Dahiyat, F. *et al.* (2021a) 'Combatting Substandard and Falsified Medicines: Public Awareness and Identification of Counterfeit Medications'. *Frontiers in Public Health*, 9, p. 754279. DOI: 10.3389/fpubh.2021.754279.

El-Dahiyat, F. *et al.* (2021b) 'Combatting Substandard and Falsified Medicines: Public Awareness and Identification of Counterfeit Medications'. *Frontiers in Public Health*, 9, p. 754279. DOI: 10.3389/fpubh.2021.754279.

EMA. (2023a) *Counterfeit Medicine*. *European Medicines Agency*. Available at: https://www.ema.europa.eu/en/glossary/counterfeit-medicine (Accessed: 6 March 2023).

EMA. (2023b) *Falsified Medicine*. *European Medicines Agency*. Available at: https://www.ema.europa.eu/en/glossary/falsified-medicine (Accessed: 6 March 2023).

EMA. (2023c) *Generic Medicine*. *European Medicines Agency*. Available at: https://www.ema.europa.eu/en/glossary/generic-medicine (Accessed: 6 March 2023).

EMA. (2023d) *Medicinal Product*. *European Medicines Agency*. Available at: https://www.ema.europa.eu/en/glossary/medicinal-product (Accessed: 6 March 2023).

European Anti-Fraud Office. (2021) *OLAF in Operation against Counterfeit Medicines*. Available at: https://anti-fraud.ec.europa.eu/media-corner/news/olaf-operation-against-counterfeit-medicines-2021-12-14_en (Accessed: 25 April 2023).

European Commission. (2019) *New Safety Features for Medicines Sold in the EU - Questions & Answers*. *European Commission - European Commission*. Available at: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_19_802 (Accessed: 14 April 2023).

European Parliament. (2016) *EUR-Lex - 32016R0679 - EN - EUR-Lex*. Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj (Accessed: 20 May 2023).

European Union Intellectual Property Office. (2019) *2019 Status Report on IPR Infringement*. 1st Edition. Spain: European Union Intellectual Property Office Available at: https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/docs/2019_Status_Report_on_IPR_infringement/2019_Status_Report_on_IPR_infringement_en.pdf.

European Union Intellectual Property Office. (2020) *2020 Status Report on IPR Infringement*. European Union Intellectual Property Office Available at: https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2020_Status_Report_on_IPR_infringement/2020_Status_Report_on_IPR_infringement_en.pdf.

European Union Intellectual Property Office. (2022) *EUIPO - Trade in Counterfeit and Pirated Goods Increased during the Pandemic [R*. Available at: https://euipo.europa.eu/ohimportal/en/web/guest/-/news/trade-in-counterfeit-and-pirated-goods-increased-during-the-pandemic-report-?inheritRedirect=true&redirect=https%3A%2F%2Feuipo.europa.eu%2Fohimportal%2Fen%2Fweb%2Fguest%2Fsearch%3Fp_p_id%3Dcom_liferay_portal_search_web_portlet_SearchPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26_com_liferay_portal_search_web_portlet_SearchPortlet_mvcPath%3D%252Fsearch.jsp%26_com_liferay_portal_search_web_portlet_SearchPortlet_assetCategoryIds%3D%26_com_liferay_port

al_search_web_portlet_SearchPortlet_keywords%3Dcounterfeit%26_com_liferay_portal_search_web_portlet_SearchPortlet_groupId%3D10162 (Accessed: 24 April 2023).

Europol. (2022) *9 million Fake Sedative Pills Removed from Circulation by Hungarian and Norwegian Police*. *Europol*. Available at: https://www.europol.europa.eu/media-press/newsroom/news/9-million-fake-sedative-pills-removed-circulation-hungarian-and-norwegian-police (Accessed: 17 April 2023).

Fadiman, A. (2012) 'The Spirit Catches You and You Fall Down'. In *The Spirit Catches You and You Fall Down*. D&M Publishers, p. 355.

Fittler, A. *et al.* (2018) 'Consumers Turning to the Internet Pharmacy Market: Cross-Sectional Study on the Frequency and Attitudes of Hungarian Patients Purchasing Medications Online'. *Journal of Medical Internet Research*, 20(8), p. e11115. DOI: 10.2196/11115.

Fox, M. (2012) *Lia Lee Dies; Life Went on Around Her, Redefining Care - The New York Times*. Available at: https://www.nytimes.com/2012/09/15/us/life-went-on-around-her-redefining-care-by-bridging-a-divide.html (Accessed: 4 April 2023).

Health Products Regulatory Authority. (2023) *Generic Medicines*. *Generic Medicines*. Available at: https://www.hpra.ie/homepage/medicines/safety-information/consumer-advice/generic-medicines (Accessed: 18 April 2023).

HPRA. (2023a) *Dangers of Buying Prescription Medicines Online*. Available at: https://www.hpra.ie/homepage/medicines/safety-information/consumer-advice/dangers-of-buying-prescription-medicines-online (Accessed: 18 May 2023).

HPRA. (2023b) *Falsified Medicines Legislation*. Available at: http://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation (Accessed: 15 April 2023).

HPRA. (2023c) 'Master List of All Interchangeable Lists'. *Master List of All Interchangeable Lists*.

HPRA. (2022a) *Over 1.6 million Units of Illegal Medicines Detained by HPRA*. Available at: https://www.hpra.ie/homepage/medicines/news-events/item?t=/over-1.6-million-units-of-illegal-medicines-detained-by-hpra&id=612b1126-9782-6eee-9b55-ff00008c97d0 (Accessed: 15 April 2023).

HPRA. (2022b) *Over 1.6 million Units of Illegal Medicines Detained by HPRA.* Available at: https://www.hpra.ie/homepage/medicines/news-events/item?t=/over-1.6-million-units-of-illegal-medicines-detained-by-hpra&id=612b1126-9782-6eee-9b55-ff00008c97d0 (Accessed: 22 March 2023).

HSE. (2023) *Generic Medicines*. *HSE.ie*. Available at: https://www.hse.ie/eng/health/hl/generics/generics.html (Accessed: 20 May 2023).

IMVO. (2023) *Falsified Medicines*. *IMVO*. Available at: https://www.imvo.ie/falsified-medicines/ (Accessed: 15 April 2023).

International Coalition of Medicines Regulatory Authorities. (2021) *Supply Chain Integrity | International Coalition of Medicines Regulatory Authorities (ICMRA)*. *Supply Chain Integrity*. Available at: https://icmra.info/drupal/strategicinitatives/supplychainintegrity (Accessed: 10 March 2023).

Interpol. (2022) *USD 11 Million in Illicit Medicines Seized in INTERPOL Operation Targeting Illicit Global Health Products*. Available at: https://www.interpol.int/News-and-Events/News/2022/USD-11-million-in-illicit-medicines-seized-in-global-INTERPOL-operation (Accessed: 15 April 2023).

Kowalewicz, R. (2022) *Council Post: How Social Media Impacts Consumer Buying*. *Forbes*. Available at: https://www.forbes.com/sites/forbesagencycouncil/2022/04/28/how-social-media-impacts-consumer-buying/ (Accessed: 15 April 2023).

Lloyds Pharmacy UK. (2022) *Risks of Buying Fake Viagra | LloydsPharmacy Online Doctor UK*. Available at: https://onlinedoctor.lloydspharmacy.com/uk/mens-health-advice/fake-viagra-health-risks (Accessed: 23 April 2023).

Louisiana, L.W., PharmD, MSPH Drug Information Specialist Xavier University of Louisiana College of Pharmacy New Orleans, Louisiana Ellen McKnight PharmD Candidate, 2017 Xavier University of Louisiana College of Pharmacy New Orleans. (2014) *The Real Impact of Counterfeit Medications*. Available at: https://www.uspharmacist.com/article/counterfeit-meds (Accessed: 20 February 2023).

Lynch, P. (2018) *The Doctor Will See You (Online) Now: How Safe Are Online Medical Services? The Irish Times*. Available at: https://www.irishtimes.com/life-and-style/health-family/the-doctor-will-see-you-online-now-how-safe-are-online-medical-services-1.3504608 (Accessed: 15 April 2023).

McDeirmid, D. (2023) 'Pragmatism | Internet Encyclopaedia of Philosophy'. *Pragmatism*. Available at: https://iep.utm.edu/pragmati/ (Accessed: 20 May 2023).

Nayyar, G.M.L. *et al.* (2019) 'Falsified and Substandard Drugs: Stopping the Pandemic'. *The American Journal of Tropical Medicine and Hygiene*, 100(5), pp. 1058–1065. DOI: 10.4269/ajtmh.18-0981.

OECD and European Union Intellectual Property Office (2020) *Trade in Counterfeit Pharmaceutical Products*. OECD DOI: 10.1787/a7c7e054-en.

Ofori-Parku, S.S. (2022) 'Fighting the Global Counterfeit Medicines Challenge: A Consumer-Facing Communication Strategy in the US Is an Imperative'. *Journal of Global Health*, 12, p. 03018. DOI: 10.7189/jogh.12.03018.

Ofori-Parku, S.S. and Park, S.E. (2022) 'I (Don't) Want to Consume Counterfeit Medicines: Exploratory Study on the Antecedents of Consumer Attitudes toward Counterfeit Medicines'. *BMC Public Health*, 22(1), p. 1094. DOI: 10.1186/s12889-022-13529-7.

O'Hanlon, N. (2019) 'Make Fakes Harder to Take: Is a Global Approach to Combatting Counterfeit Medications Too Much to Ask?' *Healthcare Purchasing News*, 43(6), pp. 72–73.

Available at:
https://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=136677267&site=ehost-live (Accessed: 9 March 2023).

Pfizer. (2022) *Biologics vs. Biosimilars: Understanding the Difference | Pfizer*. Available at: https://www.pfizer.com/news/articles/biologics_vs_biosimilars_understanding_the_differences (Accessed: 17 April 2023).

Pfizer. (2023a) *Counterfeit Awareness Campaign | Pfizer*. Available at: https://www.pfizer.com/counterfeiting/counterfeitawarenesscampaign (Accessed: 18 May 2023).

Pfizer. (2023b) *Fake Drugs 101: Facts on Illegal, Counterfeit Drugs | Pfizer*. Available at: https://www.pfizer.com/news/articles/fake_drugs_101_facts_on_illegal_counterfeit_drugs (Accessed: 18 May 2023).

Rahman, M.S. *et al.* (2018) 'The Health Consequences of Falsified Medicines- A Study of the Published Literature'. *Tropical Medicine & International Health: TM & IH*, 23(12), pp. 1294–1303. DOI: 10.1111/tmi.13161.

Ramey, J.W. and C. (2022) *WSJ News Exclusive | Drugmaker Gilead Alleges Counterfeiting Ring Sold Its HIV Drugs*. *WSJ*. Available at: https://www.wsj.com/articles/drugmaker-gilead-alleges-counterfeiting-ring-sold-its-hiv-drugs-11642526471 (Accessed: 20 February 2023).

Research Centre for Drug and Evaluation. (2023) 'Biosimilar Basics for Patients'. *FDA*. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients (Accessed: 18 April 2023).

Ryan, V. (2020) *'Fake' Benzos Potency Fears Rise*. *Irish Medical Times*. Available at: https://www.imt.ie/news/fake-benzos-potency-fears-rise-31-08-2020/ (Accessed: 24 April 2023).

Schwartzman, G.H. *et al.* (2022) 'Dermatologic Consequences of Substandard, Spurious, Falsely Labelled, Falsified, and Counterfeit Medications'. *Dermatologic Clinics*, 40(2), pp. 227–236. DOI: 10.1016/j.det.2021.12.008.

Sholy, L. *et al.* (2018) 'Pharmacist Awareness and Views towards Counterfeit Medicine in Lebanon'. *International Journal of Pharmacy Practice*, 26(3), pp. 273–280. DOI: 10.1111/ijpp.12388.

The Irish Medicines Verification Organisation. (2023) *Counterfeit Medicines*. *IPHA*. Available at: https://www.ipha.ie/code-of-practice-clinical-trials-and-regulatory/counterfeit-medicines-2/ (Accessed: 12 April 2023).

The Pharmacy Regulator. (2023) *Inspection and Enforcement-Pharmacy-PSI*. Available at: https://www.thepsi.ie/gns/inspection-enforcement/overview.aspx (Accessed: 14 April 2023).

Viatris. (2022) *Avoid Counterfeits*. Available at: https://www.viagra.com/Avoid-counterfeits (Accessed: 23 April 2023).

Wagiella, W.W., Shantier, S.W. and Gadkariem, E.A. (2020) DOI: 10.1101/2020.09.28.20201400.

Wahl, T. (2023) *Results of Operation Shield III against Illicit Medicine Trafficking and Doping Substances*. *Eucrim*. Available at: https://eucrim.eu/news/results-of-operation-shield-iii-against-illicit-medicine-trafficking-and-doping-substances/ (Accessed: 24 April 2023).

WHO. (2017) *1 in 10 Medical Products in Developing Countries Is Substandard or Falsified*. Available at: https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified (Accessed: 11 December 2022).

WHO. (2018) *Substandard and Falsified Medical Products*. *Substandard and falsified medical products*. Available at: https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products (Accessed: 11 December 2022).

Yadav, V. *et al.* (2018) 'A Questionnaire-Based Study on Knowledge and Attitude towards Counterfeit Medication among the Doctors in Tertiary Care Hospital'. *International Journal of Basic & Clinical Pharmacology*, 7(4), pp. 802–806. DOI: 10.18203/2319-2003.ijbcp20181190.

Yakubu, O.P. (2020) 'An Analysis of Loopholes in the Pharmaceutical Supply Chain, and Methods for Improving Control of Counterfeit Drugs in Nigeria'. Available at: https://repository.innoskills.com/handle/20.500.14136/36 (Accessed: 14 February 2023).

Ziavrou, K.S., Noguera, S. and Boumba, V.A. (2022) 'Trends in Counterfeit Drugs and Pharmaceuticals before and during COVID-19 Pandemic'. *Forensic Science International*, 338, p. 111382. DOI: 10.1016/j.forsciint.2022.111382.

Appendices

Appendix I

Questionnaire

RESEARCH

Survey Questionnaire

Research Title

An analysis of public knowledge and awareness of counterfeit medicine and approaches to minimize its supply in Ireland.

Stacey Curran
stacey.curran@student.griffith.ie

Research Summary:

This research proposal is aimed at assessing public awareness of counterfeit medication and understanding if improving public knowledge would play a key role in the minimisation of counterfeit distribution. This paper will perform a study from a public awareness perspective as well as analysing measures that may be taken to reduce supply and demand of counterfeit medication.

Research Objectives:

- To assess public awareness of counterfeit pharmaceutical products
- To identify if level of education and social class has an impact on level of awareness.
- To highlight counterfeit supply chain of medicinal products
- To identify potential impacts, threats to public health and business due to counterfeit medicinal products.
- To assess approaches to minimizing supply of counterfeit pharmaceutical products

1. **I have read and understand what participation in this research involves**

   ☐ Yes ☐ No

2. I agree to participate in this research study. I am aware that I can withdraw permission at any time without any consequences.

   ☐ Yes ☐ No

Demographics

3. **Gender**

   ☐ Female ☐ Male ☐ Prefer not to respond

4. **Age group**

   ☐ 18 to 24 ☐ 25 to 39 ☐ 40 to 60 ☐ 60 +

5. **Which area do you reside in?**

☐ Urban ☐ Rural

Level of Education

6. **What is your highest level of education?**

☐ No formal education ☐ Primary education

Second Level

☐ Lower secondary ☐ Upper secondary

Third Level

☐ Diploma ☐ Primary Degree ☐ Postgraduate diploma

☐ Postgraduate Degree (Masters) ☐ Doctorate (Ph.D.)

7. **How long ago did you complete your highest level of education?**

☐ 0 to 5 Years ☐ 6 to 11 Years ☐ 12 Years +

Experience

8. **What is your occupation?**

☐ Unemployed ☐ Self-employed ☐ Employed ☐ Student

9. **Have you ever worked or been in a health care environment?**

☐ Yes ☐ No

Purchasing decision factors

10. **Would you consider the cost of a medicinal product before buying it?**

☐ Yes ☐ No

11. Would you consider purchasing a cheaper medicinal product from an online pharmacy or website?

☐ Yes ☐ No

12. Would a medicinal product's packaging, labelling and overall appearance influence your decision to purchase a medicinal product?

☐ Yes ☐ No

13. Do you think purchasing non-branded medicinal products affect your social status or personal reputation?

☐ Yes ☐ No

14. Would you check packaging safety features on the medicinal product such as anti-tamper device, bar code and safety information leaflet?

☐ Yes ☐ No

Counterfeit medicine awareness assessment

15. Do you know how to identify a genuine medicine?

☐ Yes ☐ No

16. Are you aware that counterfeit medicinal products exist?

☐ Yes ☐ No

17. If yes, do you think counterfeit medicine is a risk to public health and safety?

☐ Yes ☐ No

18. Do you understand the risks to public health that is associated with counterfeit medication?

☐ Yes ☐ No

19. Are you aware of how counterfeit medicine may be distributed?

☐ Yes ☐ No

20. What is the source of your awareness about counterfeit medicine?

☐ News or Social Media ☐ Healthcare professionals or health centres

☐ Learned through education ☐ Family and/or friends

☐ Aware from other sources ☐ I am not aware of counterfeit medicine

21. Would you be able to identify a counterfeit medicinal product if you were exposed to it?

☐ Yes ☐ No

22. Do you agree that it is important for the public to be aware of counterfeit medicine and that awareness about it would contribute to reducing the supply?

☐ Yes ☐ No ☐ I neither agree or disagree

23. Do you think that it is important for public awareness of counterfeit medicines should be improved?

☐ Yes ☐ No ☐ I neither agree or disagree

24. Do you think a person's level of education has an impact on their awareness of counterfeit medicine?

☐ Yes ☐ No ☐ I neither agree or disagree

Appendix II

Interview questions

RESEARCH

Interview Questions for pharmacists and health care professionals

Research Title

An analysis of public knowledge and awareness of counterfeit medicine and approaches to minimize its supply in Ireland.

Stacey Curran
stacey.curran@student.griffith.ie

Interview Questions for Pharmacists and health care professionals

1. Is your profession in pharmacy or health care?

2. How long have you worked in your profession?

3. Have you ever worked directly and/or indirectly with a medicinal product?

4. Do you think the quality and standard of medication is good in Ireland?

5. Do you think distribution of medicinal product is adequately monitored in Ireland?

6. Have you ever performed supplier quality reviews? If so, how often do you perform the supplier review and what factors do you consider?

7. What is your opinion on counterfeit medicine and how it is distributed?

8. Do you think the general public consider any factors before deciding to purchase and/or consume a medicinal product?

9. In you experience, would you think a person's social status would a decision to purchase a medicinal product?

10. Do you practice any precautions to reduce exposure to counterfeit medicine; if so what do you do?

11. Have you ever been in contact with a counterfeit medicinal product and if so what procedure or actions did you follow?

12. Do you inform people or customers of packaging safety features associated with genuine medicine?

13. Are you aware of any drivers which would contribute to influencing a person's decision to purchase a counterfeit medicinal product?

14. Do you think education has an impact on the level of awareness about counterfeit medicine?
15. Do you think the general public awareness around counterfeit medicine needs to be improved?

16. Do you have any effective recommendations of ways to raise awareness around counterfeit medicine within the public?

Appendix III

Interview data collection

Interview Data collection

Method of interview was face to face.

Participant 1 is a pharmacist.
Interview conducted on: 27 March 2023

Participant 2 is a carer.
Interview conducted on: 06 May 2023

1. **Is your profession in pharmacy or health care?**

Participant 1	Pharmacist
Participant 2	Carer

2. **How long have you worked in your profession?**

Participant 1	38 Years
Participant 2	6 Years

3. **Have you ever worked directly and/or indirectly with a medicinal product?**

Participant 1	Yes
Participant 2	Yes

4. **Do you think the quality and standard of medication is good in Ireland?**

Participant 1	Yes medication meets European standards
Participant 2	Yes, I never saw a product that was not of a good quality.

5. **Do you think distribution of medicinal product is adequately monitored in Ireland?**

Participant 1	Yes
Participant 2	Yes

6. **Have you ever performed supplier quality reviews? If so, how often do you perform the supplier review and what factors do you consider?**

Participant 1	In retail community pharmacies, we are only required to test if product is genuine or not. We do not have the capability of performing a chemical examination in our facility. However, we do scan the QR code of every box before dispensing to the patient. Once the we scan each box, the website confirms if it is genuine or not. A green tick appears on the screen if the product QR code is confirmed to be genuine. In my experience, I have never seen red cross appear on screen which flags a fake product. I bought products through regular wholesale genuine retailer which I am aware of.
Participant 2	No

7. **What is your opinion on counterfeit medicine and how it is distributed?**

Participant 1	In Europe it is distributed online through online suppliers. Usually its sensitive medication consisting of products which not easy to get. Also, people want to get products without doctors' advice. I strongly recommend patients to visit their doctor. Viagra and Cialias are examples of drugs which I am aware people have a tendency to purchase online.
Participant 2	Online or through the black market

8. **Do you think the general public consider any factors before deciding to purchase and/or consume a medicinal product?**

Participant 1	Price. Shopping for medication online can also be cheap and simple to patients who are more comfortable shopping that way.
Participant 2	Packaging, sometimes people prefer to buy products with more attractive packaging as we can see in pink or colourful products. Cost of medicine.

9. **In you experience, would you think a person's social status would a decision to purchase a medicinal product?**

Participant 1	Yes, price and education would contribute to making a decision whether to purchase the products. In my experience, if a person is well seen by others in the community and well educated they tend to be more suspicions of what they purchase. I also remind patients that generic products are fine if come from genuine source that is well controlled and maintained.
Participant 2	Yes, medicine is not like purchasing luxury items for show. Some people cut corners when thinking about how much money they could save buy purchasing a cheaper product.

	You also find people who are more health conscious and would rather paying knowing that they can trust the product.

10. Do you practice any precautions to reduce exposure to counterfeit medicine; if so what do you do?

Participant 1	We Scan QR Code of each medicinal product before dispensing to the consumer.
Participant 2	I check if the packaging is intact, sealed and has no visible signs of being tampered with or damaged. I also check the expiry dates printed on the labels.

11. Have you ever been in contact with a counterfeit medicinal product and if so what procedure or actions did you follow?

Participant 1	No. We Scan QR Code of each medicinal product before dispensing to the consumer. The only I encountered a counterfeit product was when concern was raised over a cosmetic product. An inspector had visited my pharmacy after being encountered with fake cosmetics from a supplier in Ireland. The cosmetic products were recalled.
Participant 2	No.

12. Do you inform people or customers of packaging safety features associated with genuine medicine?

Participant 1	No. In my working experience, patients never asked me directly. However, I always tell people not to buy any medicinal products online accept from a known authorised online pharmacy. If a consumer decides to purchase from an authorised online pharmacy, I advise to check The pharmacy regulator search register.
Participant 2	Yes, I tell people to check that the packet is sealed.

13. Are you aware of any drivers which would contribute to influencing a person's decision to purchase a counterfeit medicinal product?

Participant 1	Yes Price is a key main driver. Consumers are always considering cheaper products that work the same way, especially with rising costs and living expenses. Also patients may encounter difficulty to get certain products. The requirement of having to go to doctor, making appointments or getting time of work, paying for doctor are all considerations which can be raised. I have also experienced men who are ashamed to ask doctor or pharmacists about a medical condition they may be suffering from.
Participant 2	Cost, burden, shipping time, discrete shipping

14. Do you think education has an impact on the level of awareness about counterfeit medicine?

Participant 1	Yes . First of all people need to be aware that counterfeit medicine exists. If you don't know there is counterfeit medicine you can buy anything just like how counterfeit money can be used in fraud.
Participant 2	Yes.

15. Do you think the general public awareness around counterfeit medicine needs to be improved?

Participant 1	Yes
Participant 2	Yes

16. Do you have any effective recommendations of ways to raise awareness around counterfeit medicine within the public?

Participant 1	Yes. The first step could involve telling people that there is counterfeit medicine and that it exists within Ireland. Also it is important to inform people of the way of recognising the QR code on the products packaging. Informing people might remind people to think about the existence of counterfeit medicine. If a person wants to buy medication, reminders to purchase it from a pharmacy may help. If someone is buying products from an online pharmacy, check if it is a real shop, check the address especially when you don't know the online pharmacy.
Participant 2	Yes. There are many ways to raise awareness perhaps it would be ideal to see how other organisations tackling issues in public raise awareness.

Appendix IV

Participant Information Leaflet (PIL)

PIL consists of 3 pages

Participant Information Letter

An analysis of public knowledge and awareness of counterfeit medicine and approaches to minimize its supply in Ireland.

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

My name is Stacey Curran, I am a student of the Innopharma faculty of science and Griffith College Dublin. The aim of this research is to assess public awareness of counterfeit medication in Ireland and to determine approaches of minimising supply. This research forms a partial fulfilment of award of a Master's of Science in Pharmaceutical Business and Technology.

WHAT WOULD TAKING PART INVOLVE?

As counterfeit medication causes major unpredictable health risks to public health, improving public knowledge could help prevent this issue. If you decide to participate in this research, you will be invited to complete an online survey which aims to assess public awareness of counterfeit medicine. By participating, you will provide answers to the questions which will be analysed to assess public knowledge.

If you are invited to partake in an interview and you decide to participate, your answers will be collected and audio-recorded for the purpose of transcribing. Knowledge and precautions that you may already practice will be evaluated to further assess knowledge. No audio recordings will be taken during the interview.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You are being invited to partake as public involvement is required in this research. As exposure to counterfeit medicine is associated with detrimental unpredicted risks to public health, your participation enables research to perform an assessment of public awareness about this topic.

Pharmacists and care givers will be invited to participate in a further interview due to the valuable professional experience and knowledge gained through the nature of their business which includes being in direct contact with pharmaceutical products

DO YOU HAVE TO TAKE PART?

No. Participation is entirely voluntary however, should you decide to partake your contribution will be highly valued as you will create a greater awareness of counterfeit medicine and the unpredictable risks associated with exposure. If you decide to change your mind consent can be withdrawn at any stage without a requiring a reason. If you decide not to partake there will be no adverse consequences suffered.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Participation could benefit you and your community, as your awareness of counterfeit medicinal products could improve which could help prevent any unpredictable risks of exposure to counterfeit medicine.

There is no harm, psychological or confidentiality risk linked to participation of this research. However, the allocation of time to participate in this research could be a potential burden.

WILL TAKING PART BE CONFIDENTIAL?

Yes. Confidentiality and anonymity for all participants and data or audio recording provided will be strictly maintained. Although you are required to sign the participant informed consent form, your name will not be recorded ensuring your identification remains anonymous.

Confidentiality may require to be broken if there is a serious risk of harm or danger to either the participant or another individual.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms will be retained in Griffith College Dublin library until after my degree has been conferred. The interviews audio-recordings and transcript will have all identifying information removed and will be retained for a further two years after this. Under freedom of information legalisation you are entitled to access the information you have provided at any time.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of this research will be submitted for a dissertation in partial fulfilment of a Masters award. The research content will be stored in Griffith College Dublin library and could may be made accessible in online e-journals or repository. By following the GDPR published laws, the integrity of participants data will be maintained.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

If you require any further information please contact the researcher, Stacey Curran by sending an email with your query to stacey.curran@student.griffith.ie

THANK YOU

Appendix V

Informed Consent Form (ICF)

ICF consists of 2 pages

Consent to take part in research

An analysis of public knowledge and awareness of counterfeit medicine and approaches to minimize its supply in Ireland.

- 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 survey and/or 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 accessing an online survey which will assess knowledge of counterfeit medicine. If I am invited to participate in an interview, my experience and practices which I may implement will be collected and audio-recorded for transcribing purposes.
- 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 disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I understand that disguised extracts from my interview may be quoted in this dissertation and will be stored in Griffith College Dublin library and therefore could may be made accessible in online e-journals or repository.
- 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 Griffith College Dublin Library until the exam board confirms the results of this dissertation
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for 2 years after the date of the exam board.
- 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: Stacey Curran
Degree Programme: Master of Science Pharmaceutical Business and Technology
College Details: Griffith College Dublin
Contact number: +353 87 968 5835
Contact mail: stacey.curran@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