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Effects of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County, Kenya.

Bosire, Brian
Strathmore Business School
Strathmore University

EFFECTS OF COUNTERFEITING ON THE FINANCIAL PERFORMANCE OF LOCAL GENERIC DRUG MANUFACTURERS IN NAIROBI COUNTY, KENYA

By

BRIAN BOSIRE

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DEDICATION

Student Declaration

I, the undersigned, declare that this project report and the contents contained therein is my original work and has not been submitted for examination in any other institution. No part of this dissertation may be reproduced without permission of the author and Strathmore University.

Brian Bosire

MBA 82004/2014

Signature: ……

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Supervisor Declaration

This research proposal has been submitted for examination with my approval as the university supervisor.

Signature: ……

Dr. Ben Ngoye

Senior Lecturer

Strathmore Business School

ABSTRACT

Counterfeit drugs pose a serious threat to the credibility and finances of the pharmaceutical industry as a whole, and to drug manufacturing companies in particular. The purpose of this research was to assess the effects of counterfeit drugs on the financial performance of drug manufacturers in Kenya, focusing on the generic drug manufacturers in Nairobi County. In order to achieve the aim of the research, the study sought to meet the following specific objectives: to examine the supply chain systems of counterfeits on the financial performance of local generic drug manufacturers; to examine the effects of pricing strategy of counterfeits on the financial performance on local generic drug manufacturers; to examine the effects of the legal and institutional framework on the financial performance of local generic drug manufacturers. The study was grounded on the Theory of Reasoned Action and the Balanced Score Card. The study employed a cross sectional descriptive research design in order to paint an accurate picture of the impact counterfeit drugs have had on Kenyan generic drug manufacturing companies. There are 15 local generic drug manufacturers operating in Nairobi County registered with the Pharmacy and Poisons Board and the unit of analysis was the heads of departments in the local generic drug manufacturers. The study was based on a sample size of 75 respondents. The study used purposive random sampling to select the respondents in the study. The research adopted a well-structured questionnaire to collect data from Quality Assurance Manager, Quality Control Manager, Regulatory Affairs Manager Sales Manager and Director or C.E.O of all the local generic drug manufacturers in Nairobi County. The collected responses were analyzed in the Statistical Package for Social Sciences (SPSS Version 22.0) using descriptive and inferential techniques. The descriptive analysis findings revealed that respondents agreed with an overall mean of counterfeit drug supply chain systems of 3.86, an overall mean of pricing strategy of counterfeits 3.77, an overall mean of the legal and institutional framework of 4.01 and an overall mean of the effect of counterfeiting on the financial performance of local generic drug manufacturers of 3.72. Multiple regression analysis was run to test if counterfeiting significantly predicts the financial performance of local generic drug manufacturers. Through the consistency of the regression coefficients on the model predicators the study concludes that pricing strategy of counterfeits and the legal and institutional framework are significant factors that influence the financial performance of local generic drug manufacturers. The study recommends the collaboration between drug manufacturers and government to review the existing supply chain, improve transparency in sale and distribution of drugs in Nairobi County and access the effectiveness of the existing drug control laws to positively impact the financial performance of generic drug manufacturers in Nairobi County.

Keywords: Counterfeit Drugs, Pharmaceuticals Industry, Generic Drug Manufacturing Companies

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LIST OF ABBREVIATIONS

WHO- World Health Organisation

IPR- International Property Rights

PWC- Price Waterhouse Coopers & Lybrand

SMEs- Small and Medium Enterprises

MNCs- Multi- National Companies

KAM- Kenya Association of Manufacturers

GDP- Gross Domestic Product

OECD- Organization for Economic Cooperation and Development

PPB- Pharmacy and Poisons Board

KAPI- Kenya Association of Pharmaceutical Industry

MOH- Ministry of Health

UNIDO- United Nations Industrial Development Organization

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DEDICATION

This project is dedicated to my family, for their invaluable support, love and encouragement, prayers and understanding during this study.

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CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

Intellectual property rights play a critical role in any economy, promoting creativity, innovation, research, and product development, and in the process enabling businesses to boost their competitive edge in the global market (Ezell & Cory, 2019). PwC (2020) argues that the protection of intellectual property is the most valuable resource to a pharmaceutical or Biotech Company. A patent is a form of intellectual property rights similar to copyright and trade mark (Maina, 2015). A patent is awarded for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial or commercial application (Saha & Bhattacharya, 2011). In the pharmaceutical industry, the essence of any granted patent is the bargain between the patentee and the public. The patentee is granted the exclusive right to exploit the intervention in return for public disclosure of the invention (Khachigian, 2020). Patent protection provides manufacturers an exclusive right to sell new drug products for up to 20 years from the date of the patent filing (Mutua, 2013). The patent system and marketing power are at the root of the world-wide dominance of the Multi National Companies MNCs as the products patented by the MNCs enjoy a monopoly status (Chaudhuri, 2016, p. 104).

A recent challenge facing the protection of intellectual property has been the balancing of the opposing forces of innovation through IP protection and providing affordable drugs for the developing world (PricewaterhouseCoopers, 2020). One of the major opposing forces is patent expiry. The expiration of patents, a concept referred to as the patent cliff, affects multinational pharmaceutical companies with rival companies' production of generic products (Khalil & Onyango, 2022). Once the patent expires, the drug may be manufactured in generic versions by any number of manufacturers, thus lowering the prices for the drug (Mutua, 2013). A generic drug is a medication that is equivalent to a brand name product in dose, strength, route of administration, quality and intended use, but does not carry the brand name. Generic drugs are typically more economical and more accessible than brand name versions because the Active

Pharmaceutical Ingredient (API) is already known and does not need to be researched and developed again (Toverud et al., 2015).

In Kenya, import-substituting industrialization is a set of economic and trade policies that aim to promote domestic industrialization in order to reduce the country's dependence on manufacturing from abroad. The policies seek to promote the accumulation of skills, capital and knowledge for the local production of manufacturing goods (Simonetti et al., 2016, p. 26). This is in line with KAM (2022) manifesto's goals and ambitions of vision 2030 for Kenya to become a middle-income country with a manufacturing sector that contributes 15% of the GDP and intends to promote the growth and development Kenyan generic drug manufacturers.

The presence of counterfeit medicines in international commerce was initially identified as a problem in 1985 at the World Health Organization Conference of Experts of Rational Drug Use in Nairobi, Kenya (*WHO*, 2022). The conference emphasized the importance of addressing the issue of counterfeit medicines and recognized that counterfeit drugs pose a significant threat to the public health. A counterfeit drug, is a medication that is 'deliberately and fraudulently" mislabelled with respect to identity and/or source.

The OECD/EUIPO (2019) report indicates pharmaceuticals are particularly vulnerable to counterfeiting. According to worldwide custom seizures, pharmaceuticals were the 10th most counterfeited product category out of ninety seven documented product categories. Counterfeit medicine trafficking is one of the world's fastest growing criminal enterprises. Analysts estimate the global counterfeit market to be worth between US$200 and US$432 billion (Ofori-Parku, 2022). Counterfeiting of pharmaceutical products is particularly prevalent in regions as Africa, South America and Asia (Ziavrou et al., 2022). Ozawa et al (2018) estimate that the prevalence of substandard and falsified medicines in low and middle income countries was 13.6%. Among the studies included in the meta-analysis the highest prevalence of the falsified and substandard medicines was registered in Africa 18.7%. This finding underscores the disproportionate burden of counterfeit and falsified medicines on low and middle income countries particularly Africa. A study done by Karungamye (2023) on a review of counterfeit and substandard drugs in Tanzania estimates that 30% of the supplied pharmaceuticals in Africa are

counterfeit or substandard. According to WHO (2022) the vast majority of counterfeit drugs in Africa do not contain the right active ingredients in the correct proportions, and many of these counterfeit drugs contain undeclared active ingredients that may have serious unintended health consequences, ranging from mild to life threatening. Falsifying a medical product is a criminal act that not only involves consumer fraud but also a threat to public health and safety (Ziavrou et al., 2022).

In Kenya, according to a report by Anti Counterfeit Authority (2020), it estimated the value of counterfeit goods including pharmaceuticals was approximately Kshs 560 billion. The report also stated that pharmaceutical products were among the top five goods seized in Kenya, with antibiotics, antimalarials and painkillers being the most counterfeited drugs. According to the KAM (*Kenya Association of Manufacturers*, 2022), the infiltration of counterfeit medications in Kenya's pharmaceutical industry could be as high as 40% and specific to Nairobi County pharmaceutical enterprises contribute up to 12 billion shillings (63%) of Kenya's pharmaceutical counterfeit problem in Kenya.

Counterfeiting of goods by rogue manufacturers is one of the emerging concerns threatening the future of manufacturing enterprises worldwide and particularly in Kenya (Wakhanu, 2020). Original products that are offered under brand names are imitated in product counterfeiting and the trade in counterfeit labels, packaging and goods. For consumers, entrepreneurs and traders in Kenya, counterfeit goods are becoming problematic. These imitations typically consist of clones or altered products, labelling and packaging. Unverified dealers produce, process or provide counterfeit goods by illegally using the ideas and intellectual property of other businesses or people (Munyao, 2022). The detrimental effects of counterfeiting are manifold. They include: economic losses to the creators of genuine goods; governments lose out on revenue from unpaid taxes; governments suffer major losses when implementing intellectual property rights; consumers receive low-quality products, sometimes at exorbitant costs; and counterfeiting helps further criminal activities like terrorism, money laundering and drug trafficking (Fink, Mankus&Qian, 2016). Nomani, Alhalboosi and Rauf (2020) explain that

the entry of a counterfeit drug into any economy is a cost to the individual companies that developed the drug, the consumers (patients and their families), and the general economy.

From a health perspective, fake and counterfeit pharmaceuticals jeopardize medical practitioners' ability to treat diseases, infections and other disorders. These counterfeit medicines lead to patients to believe they are receiving an effective treatment when, in fact, they are receiving ineffective and often deadly treatments that pose a direct threat to their health (Miller & Winegarden, 2020). Poor quality pharmaceuticals may have serious consequences for human health because of treatment failure, development of antimicrobial resistance and dramatic adverse drug reactions (Bottoni & Caroli, 2019). Counterfeit medications are a waste of income of patients, and they often endanger the public's health and safety (Blackstone et al., 2014).

1.1.1 Counterfeiting

The International Anti-Corruption Conference (IACC, 2022) states that counterfeiting is a deceitful collection, modification and dispensation of a product of lesser value than the original product. A counterfeit drug, on its part, is a medication that is "deliberately and fraudulently" mislabelled with respect to identity and/or source (*WHO*, 2022). Counterfeiting is the manufacture, production, packaging, re-packaging, labelling or making of goods that are imitations, identical, or substantially similar to original protected goods (*Kenya Law*, 2023). According to Bian et al (2023), counterfeiting is the illegal imitation of associated legitimate brands distinguishing labels and trademarks without permission from the brand owners. Ofori-Parku (2022) notes that the term counterfeit medicines is not synonymous to low cost generics. Amankwah-Amoah (2022) further defines counterfeiting can apply to both branded and generic products, and counterfeit products may include products: with the correct ingredients; with the wrong ingredients; without the active ingredients; with insufficient active ingredients; or with fake packaging. Counterfeits are always inferior to legitimate pharmaceuticals in terms of quality, safety, and efficacy; they pose a grave danger to the public health and lead to a loss of trust in medications, healthcare professions and health systems (Bottoni & Caroli, 2019).

Schneider & Ho Tu Ham (2020) sought after the dimensions of counterfeiting in seeking to understand the prevalence of counterfeit drugs in Africa. The researchers affirmed that counterfeiting is a deeply rooted challenge in Africa due to the porous supply chain channels and low risk of detection, weak regulatory mechanisms with low risk of prosecution and weak fines, and trusting consumers with low disposable incomes. These sentiments are echoed in the study by Ziavrou et al (2022) who defines the main drivers of counterfeiting are high demand for less expensive drugs (pricing strategy of counterfeits), complex and fragile supply chains with limited technical capacity to monitor products through the supply chain (supply chain systems), lack of law enforcement and weak national regulatory policies on the manufacturing and marketing of medications. Ng'ethe (2017) noted that the key to understanding the effects of counterfeiting within the Kenyan pharmaceutical industry involves the pricing of counterfeits, the supply chain of counterfeits and the regulatory and institutional framework. Ng'ethe (2017) also operationalizes counterfeiting through the pricing of counterfeits, the regulatory and institutional framework and the supply chain systems of counterfeits . This study adopted the pricing strategy of counterfeits, the supply chain systems of counterfeits and the legal and institutional framework since they are most applicable to the study's scope and in relation to financial performance of local generic drug manufacturers. This study sought to understand the impact of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County.

Wijaya (2022) defined the healthcare supply chain as a complicated web of numerous independent businesses, including retailer pharmacies, hospitals, wholesalers, manufacturers, distributors and raw material suppliers. Shashi (2022) defined the pharmaceutical supply chain serves as a conduit for the distribution of pharmaceutical products of the right quality to final consumers at the right time and location. Miller & Winegarden (2020) showed the importance of supply chain in the pharmaceutical industry, noting that fraudulent medicines primarily enter the drug industry when counterfeiters take advantage of alternatives to main stream pharmaceutical manufacturing and distribution pathway. Open markets like the internet provided counterfeiters with a Pandora,s box of opportunities to prey on naïve patients. Chen

et al (2023) asserts that the pharmaceutical supply chains exhibit unprecedented vulnerability due to lack of an integrated supply chain viability system with adaptive structures to survive in a changing environment. Liza et al (2022) characterizes the pharmaceutical supply chain sustainability to the changing environment is dependent on key aspects which include; integrated information systems, manufacturing and distribution channels, open markets with the introduction of the internet and consumer preferences and willingness to pay.

Hemphill & Johnson (2020) define pricing as the process of determining the monetary value of a product or service with the objective of maximizing profits for the seller while providing value to the customer. Safitri (2018) notes that price of a product is the most important factor influencing consumers purchase decisions. Levchuk & Сергеевна (2022) define pricing in the context of counterfeiting drugs as the price at which the imitated drugs are sold to customers. When examining the pricing strategy of counterfeit drugs, it is important to consider not only the pricing of the counterfeit drug itself, but also the costs incurred by the manufacturer in mitigating counterfeiting (Terblanche & Niemann, 2021). In terms of pricing of counterfeit drugs, it is vital to highlight that these drugs are sold at a fraction of the price of their legitimate counterparts making them more appealing to price sensitive consumers and it is also critical to evaluate the costs incurred by legitimate manufacturer in mitigating counterfeiting as these costs drive up the price point of genuine drugs as compared to counterfeit drugs (Gao, 2018).

The legal and institutional framework refers to the set of laws, regulations, policies and institutions that exist to combat the production, distribution and sale of counterfeit pharmaceutical products (Abbott & Reichman, 2020). Lima et al (2018) identify the aspects of the legal and institutional framework as legislation, national regulatory authorities, law enforcement, custom authorities, inter-governmental organizations and public awareness. Schneider & Ho Tu Nam (2020) asserts that the weak link and driving force behind the availability of counterfeit pharmaceutical products in Africa is weak regulation and enforcement frameworks. Ziavrou et al (2022) note that less than 30% of the regulatory agencies in the world can ensure adequacy of medicines and vaccines due to limited resources and skilled workforce. Amankwah-Amoah (2022) affirms that the institutional impediments such as lack of or weak

institutional facilities, poor legal system and weak legal enforcement structures that characterize developing countries often have curtained governments, ability to regulate and monitor pharmaceutical business activities.

1.1.2 Financial Performance of Local Generic Drug Manufacturers

Organizational performance can be measured by financial aims attainment or workers satisfaction (Maaka, 2013). Firm Performance is the calculation of normal or defined measures of production and environmental quality, the cycle of time, profitability, waste minimization and adherence to regulations (Muchira, 2013). Maaka (2013) also opined that the financial performance is a subjective measure of the responsibility of a substance for the consequences of its approaches, operations, and exercises evaluated for a recognized period in budgetary terms. López-Toro et al (2021) notes that financial performance measurement answers questions about a company's health. Rahmawati & Kholilah (2023) state that the goal of measuring financial performance is to assist operational activities in focusing on the company,s target goals and planning at the outset, allocating resources, and assisting in decision making forms of accountability to the company and improvement as company communication. The financial related performance indicators consist of profitability, cost of production, and availability of funds for expansion (Srimarut & Mekhum, 2020).

A more practical indicator of success is the Balanced Score Card which is widely adopted by manufacturing and service companies as it emphasizes a linkage to strategy and the cause and effect linkages (Kaplan, 2001). The balanced scorecard is a performance management tool that provides comprehensive view of an organization's performance. From this framework, a financial perspective can be used to evaluate the performance of an organisation. In this perspective, the focus is on the traditional financial measures of the manufacturer such as revenue growth, profitability and return on investment. Good financial performance of any firm not only plays a role in increasing the market value of that specific firm but also leads towards the growth of the whole industry which ultimately leads towards the overall prosperity of the economy (Banafa et al., 2015). Assessing the determinants of performance of manufacturing

firms have gained the importance in corporate finance literature because as intermediaries, these companies not only provide the mechanism of risk transfer but also helps to channelize the funds appropriated to support the business activities in the economy (Audax, 2018).

Butticè et al (2020) carried out an evaluation on the effect of counterfeiting on the economic performance of Italian companies operationalizes financial performance based on sales, profitability and return on investment. Similarily, Srimarut & Mekhum (2020) in a study on enhancing financial performance through supply chain innovation the main financial related performance indicators consist of sales, profitability and availability of funds for expansion. Cheruto (2021) also considered evaluating the financial performance of retail pharmacies using frequency of sales, profitability and return on investment.

1.1.3 Pharmaceutical Industry in Kenya

Kibwage (2008) notes that the pharmaceutical industry officially began in Kenya over fifty years ago and has grown immensely since then. The pharmaceutical industry in Kenya operates in a liberalized environment that is characterized by stiff competition of the price nature, political factors, and fight against counterfeit medicines, prohibitive and wanting regulation (Kabiru, 2013).The macro and microenvironments in which the pharmaceutical industry operates under is characterized by a myriad of factors and stakeholders that affect its operations. The stakeholders in the Kenyan pharmaceutical industry include manufacturers, distributors, wholesalers, retailers and consumers. The main role of the manufacturer is the production of safe and efficient goods. Distributors' main role in Kenya is to ensure the availability of pharmaceutical products across the country. The fundamental role of the wholesalers is to distribute the pharmaceutical products in the most effective and efficient way. Pharmaceutical retailers are responsible for ensuring that drugs they sale are safe, effective and stored and dispensed according to manufacturer's instructions.

All the Kenyan pharmaceutical businesses from the manufacturing stage to the supply stage are regulated and comply to the Pharmacy and Poisons Board (PPB) of Kenya (Kabiru, 2013). The PPB requires that each business entity that manufactures, distributes, stores, sales and

dispenses pharmaceutical products has a registered and licensed pharmacist or pharmaceutical technologist (Osundwa, 2013). The aim of registering and licensing is to ensure that the businesses dealing in drugs within the country are effectively regulated. However, the exceptionality of this regulation continues to negatively affect several stakeholders in the country especially as relates to the existence of counterfeit drugs in the country.

More specific to the drug manufacturing industry is divided into two; foreign drug manufacturers and the local generic drug manufacturers. The foreign drug manufacturing firms which are active in Africa can be broadly classified between the multinational corporations (MNCs) and the Indian generic companies (Chaudhuri, 2016, p. 103). Local generic drug manufacturers can be classified to generic drug manufacturers (final product), generic active pharmaceutical ingredient production (API) and generic packaging and repackaging of final product. Local generic drug manufacturers hold a significant portion of the drug market share particularly in developing countries. By offering affordable alternatives to expensive brand name drugs, they make healthcare more accessible to the local population. In this study we focus on the local generic drug manufacturers in Nairobi County. According to (KAPI, 2021) there is a total of fifteen licensed local generic companies in Nairobi County making cross sector partnerships and collaborations to support and strengthen the healthcare system in Kenya.

1.2 Statement of the Problem

Kenya has attracted a large amount of counterfeit drugs, and according to the Kenya Associations of Pharmaceutical Industry (KAPI), counterfeit medicines accounted for approximately Kenya Shs.9 billion in sales annually in the year 2011 which corresponded to between 20-25 % of the total legal commercial pharmaceutical market (Ng'ethe, 2017). This has had a direct impact on Kenyan pharmaceutical manufacturers in terms of huge financial losses, as well as a negative impact on the reputation of pharmaceutical manufacturers and the public health systems as a result of counterfeits (*Kenya Association of Manufacturers*, 2022). Kenyan drug manufacturers have continued to incur losses as far as revenues and profits are concerned, which has adversely affected other stakeholders that is; their shareholders (as stock values are reduced); their employees (loss of jobs); their customers (losses are passed on to

them in the form of hiked prices); the government (losses in terms of tax revenues); and public and private sector players who bear the cost of policing and law enforcement (*Anti-Counterfeit Authority (ACA)*, 2020). Specific to the public, the effects of counterfeiting are particularly dangerous as drugs have a direct impact on the wellbeing and health of human beings throughout the world. Counterfeiters have flooded developing nations with contaminated and dangerous drugs, and nearly 10 per cent of prescription drugs in the world market are estimated be counterfeit, causing hundreds of thousands of deaths every year. According to the World Health Organization, 200,000 people die annually from counterfeit and substandard anti-malarial medicines alone; the total human toll of all counterfeit drugs is far greater (*WHO*, 2022).

All this has occurred despite the fact that the problem of counterfeit drugs was first addressed at a conference in Nairobi in 1985 and yet, since then, the counterfeit market has rapidly expanded, largely as a result of the widespread use of the internet to market counterfeit products (O'Hagan & Garlington, 2018). Conducting research on counterfeiting in the pharmaceutical industry, especially within the generic drug manufacturing sector, is necessary because counterfeiting hinders KAM Vision 2030 goals and ambitions to promote domestic industrialization and reduce the country,s dependence on manufacturing from abroad (*Kenya Association of Manufacturers*, 2022)

In the midst of these very real effects that are supported by statistics, there is a widespread perception by many that local generic drug companies are not affected by the counterfeit market, with the perception being that it's only the governments and large pharmaceutical companies in the industry who suffer effects of counterfeits. This perception stems from the idea that the act of counterfeiting is harmless and a victimless offense, since it presents an opportunity to get a branded product at a much lower cost than the original (Ramara& Lamont, 2012). Counterfeiting of generic drugs is more prevalent because they are usually less expensive, less regulated than brand names drugs and more widely available, making it easier for criminal groups to imitate them and sell fake versions at a profit. Additionally, generic drugs often have a simple packaging design and lack of security features, making it easier to produce

fake copies (O'Hagan & Garlington, 2018).This is a research gap that the proposed study will seek to fill by providing empirical evidence to show the dire impact of counterfeit drugs to local generic drug manufacturers in the pharmaceutical industry.

Another research gap that the study seeks to fill is the limited existence of studies that have carried out to measure the cases of counterfeiting in Kenya and their impacts, especially as relates to Kenyan generic drug manufacturers (Wanjau & Muthiani, 2012). Only a few studies have been done in Kenya. In fact, empirical research on the effect of counterfeit drugs on local generic manufacturers in Nairobi County is limited. Some of the previous studies that have been carried out on counterfeit drugs were conducted for different geographical contexts such as Mombasa County while other studies have focused on other stakeholders in the pharmaceutical industry which include wholesalers, retailers and public. The proposed research which will be based on primary data, hence, filling a gap as relates to local generic drug manufacturers in Nairobi County. An example of the few related studies carried was by Ozawa et al. (2018) who conducted a systematic review and meta-analysis on the prevalence, and estimated economic burden, of substandard and falsified medicines in low and middle-income countries. Said (2016) investigated the effect of counterfeit drugs on the distribution of pharmaceutical products in Mombasa County. Kumar & Baldi (2016) did a comprehensive review on prevalence, detection and preventative measures of the counterfeit drugs challenge.(Cheruto, 2021) investigated the anti-counterfeit strategies in retail pharmacies in Nairobi County. Studies specific to local generic drug manufacturing companies are non-existent yet most of the local generic drug manufacturers are mainly found in Nairobi or the outskirts of Nairobi.

Additionally, previous studies have focused on larger manufacturers in the West and countries outside Africa, leaving out the local generic drug manufacturers in Kenya as well as Africa. Examples of these studies include: the study by (Blackstone et al., 2014) which focused on American drug manufacturers in general; (Bansal et al., 2013) which focused on the international pharmaceutical industry as a whole; and (Shukla & Sangal, 2009) and (Kumar et

al., 2019) both of which focused on the manufacturing industry in India. These previous studies have lumped all drug manufacturers together yet the local generic drug manufacturers have unique conditions, and moreover, they have focused on the western world which is characterized by robust health financing systems and social safety nets, whereas Africa and Kenya's situation is markedly different. The intent of this study was to assess the effects of counterfeiting on the performance of local generic drug manufacturers in Nairobi County, Kenya.

Generic drug manufacturers play a critical role in Universal Health Coverage (UHC) by providing affordable and assessable medicines that are equivalent in quality, safety and efficacy to brand name drugs at a lower cost (*Universal Health Coverage (UHC)*, 2022). UHC aims to ensure that all individuals and communities have access to quality health products without suffering financial hardships. The cost effectiveness makes generic drug manufacturers an essential component of UHC programs as generic drugs can help to address the issue of high out of pocket expenses that many patients face when seeking treatment for their illnesses (Wasir et al., 2019). The generic drug industry has increased the accessibility and affordability of essential drugs in the healthcare sector (Birn & Nervi, 2019). Despite the significant contribution of the generic drug industry to the healthcare sector, the industry is plagued by counterfeiting, which has a negative impact on the financial performance of generic drug manufacturers who are often seen as easy targets due to their affordability, accessibility and low prices (Pisani, 2019). Moreover the presence of counterfeit medicines undermines the confidence of patients and healthcare professionals in generic drugs, hindering their adoption and usage. This is especially damaging in low and middle income countries where generic drugs are critical to providing affordable healthcare services to the population (Orubu et al., 2020). The study aims to investigate the extent to which counterfeiting affects the financial performance of local generic drug manufacturers in Nairobi County. The study will examine the effects of counterfeiting on sales volume, revenue, and profit margins as well as costs associated with fighting counterfeiting.

1.3 Purpose of the Study

The purpose of this study was to assess the effects of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County, Kenya.

1.4 Research Objectives

In order to meet this objective, the study had the following specific objectives:

i. To examine the effect of supply chain systems of counterfeit drugs on the financial performance of local generic manufacturers in Nairobi County;
ii. To determine the effect of pricing strategy of counterfeit drugs on the financial performance of local generic drug manufacturers in Nairobi County; and
iii. To establish the effects of the legal and institutional framework of pharmaceutical industry on the financial performance of local generic drug manufacturers in Nairobi County.

1.5 Research Questions

The following research questions was guided the below research questions;

i. What is the effect of supply chain systems of counterfeit drugs on the financial performance of local generic drug manufacturers in Nairobi County?
ii. What is the effect of pricing strategy of counterfeit goods on the financial performance of local generic drug manufacturers in Nairobi County?
iii. What is the effect of the legal and institutional framework on the financial performance of local generic drug manufacturers in Nairobi County?

1.6 Significance of the Study

1.6.1 Kenyan Pharmaceutical and Drug Manufacturers

The findings of this study will be useful to Kenyan pharmaceutical and drug manufacturers in particular, as understanding the financial effects of counterfeit drugs. This is as a result of the negative impact as counterfeit products undercut the prices of legitimate products and this will

give them the urgency to support efforts to curb the influx counterfeit drugs. Nevertheless, contrary to their expectations, counterfeit drugs continue to enter the country illegally as a result of porous borders and weak institutional procedures.

This information can be used to make informed decisions, such as developing new strategies to combat counterfeiting, or investing in the necessary technologies to improve security and traceability of the pharmaceutical products for local generic drug manufacturers.

1.6.2 Government and other Policy Makers

The study will also be useful to law enforcement agencies, the Ministry of Health, the Pharmacy and Poison Board (PPB) and the government as a whole, as it will provide them with important information and innovative strategies that will assist them in their role as law enforcers and regulators in the fight against counterfeit goods in the pharmaceutical industry. The study findings will likewise inform policy formulation for the effective tackling of counterfeiting. The study will additionally be significant for Kenyan anti-counterfeiting agencies as they will be able to use the study's findings to empirically explain the financial effects of counterfeit medicines to Kenyan pharmaceuticals, manufacturers, the public and medical personnel, and this will help galvanise support and cooperation between all stakeholders towards the fight against counterfeit drugs. Finally, the study will be of assistance to academicians and scholars in the field of medicine and pharmacy as it will form the academic basis upon which other similar studies can be founded on.

1.6.3 Future Researchers and Academicians

The study will be significant to future researchers and academicians who would be prompted to explore more about the effect of counterfeiting either in the same field of generic drugs production or the pharmaceutical industry as a whole. In this case, the researchers will be in a position to use these findings to affirm, confirm or relate with their literature review or outcomes.

1.7 Scope of the Study

This study focused on the effects of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County. Currently, the Kenyan pharmaceutical industry consists of 35 manufacturers, the majority of which are in Nairobi and its outskirts (Vugigi, 2020). As such, the proposed study location is Nairobi County. Out of the 35 manufacturers there are 15 licensed and registered local generic drug manufacturers listed in the Pharmacy and Poisons Board (PPB) located in Nairobi County (*Pharmacy and Poisons Board*, 2020). This will make up the population considered for this study. Nairobi County has also been chosen as the study location due to its close proximity to the researcher who resides within Nairobi, which will make data collection easier and cheaper. The study adopted a descriptive cross sectional design to determine the effect of counterfeiting on the financial performance of local generic drug manufacturers. The study was carried out between Nov 2022 and January 2023. Data was collected using closed ended structured questionnaires and analysed through descriptive and inferential statistics.

1.8 Chapter Summary

The first chapter of the research was vital in the presentation of the background of the study which identified the conceptualized variables of the study and the parameters of measurement for individual variables. Further, the chapter outlines the focus of the study, the problem statement and the objectives guiding the survey. The chapter finalized with a presentation of the study scope and significance of the study to various players in the pharmaceutical sector in Kenya.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This particular section presented discussion on the effects of counterfeiting on the financial performance of local generic drug manufacturers. The section mostly presented reviewed literature, reports and assertions by various authors and researchers as well as academicians in the same area. The main areas are the theoretical, empirical and conceptual framework of the study.

2.2 Theoretical Review

A theoretical framework is a collection of interrelated concepts which guide a researcher to determine what things to measure, and what statistical relationships to look for (Defee et al., 2010). The study adopted the following theories to help explain the reasons why counterfeiting is deeply rooted in generic drug manufacturing industry: Theory of Reasoned Action (TRA) and the Balanced Score Card (BSC). Both Cheruto (2021) and Clemence (2021) who conducted studies on counterfeit medications, incorporated the Theory of Reasoned Action to understand counterfeiting in the context of the attitudes and intentions of the various actors involved in the pharmaceutical supply chain including consumers, healthcare providers, regulators and counterfeiters. Amer et al (2022) and Rahmawati & Kholilah (2023) used the Balanced Score Card model to underpin the financial performance of businesses. Similarly, the financial performance of the local generic drug manufacturers in Nairobi is supported by the Balanced Score Card. The theoretical framework of this study formed the structure that supported the empirical portion of the research work.

2.2.1 Theory of Reasoned Action (TRA)

Theory of Reasoned Action abbreviated as TRA seeks to explain relationships between behaviours and attitudes as seen in human actions (Hale et al., 2002). Based on pre-existing attitudes and behavioural intentions, firms or people are likely to act based on the prior

information and knowledge. The proponents of the theory were Martin Fishbein and Icek Ajzen (1977) where the authors tried to establish the A-B (attitude-behaviour) relationships. The theory was however criticised by Montaño and Kasprzyk (2015) in that attitudes were not the major predictors of actions or resultant behaviours. An entities' intent to perform behaviour acts as the main predictor of whether they actually execute the said behaviour or not. The theory establishes that strong intents (reasons) lead to increased efforts towards performing a certain function or behavior (Khan & Idris, 2019). TRA proponents focused on the subjective norms and attitudes, which formed the reasoning behind certain actions. Attitudes towards a certain action can be positive, negative or neutral.

The theory postulates that there exists direct relationship between attitude and the outcomes. While the theory is critical in explaining the foundation of this study, criticism exists on how outcomes in human behaviour do not necessarily depend on reasoned attitude and behaviours. Through focusing on the norms and attitudes, TRA provides a model for identifying as well as sharing underlying reasons for people's intent to behave in certain ways. Reasoning is key part of the underlying process in making informed decisions on a product or decision.

The TRA model is relevant to the study's objectives because it is crucial in shedding light on the relationship between the causes of the rise in the pharmaceutical sector counterfeiting and why it is still a pervasive and ongoing practice. The TRA model suggests that an individual's intention to engage in counterfeiting is determined by their attitudes towards the behaviour and their perceptions of what is considered appropriate or expected behaviour by others. An individual's attitude towards counterfeiting is influenced by their beliefs about the consequences of the behaviour. As described by the model strong intents by counterfeiters in making huge profits by the imitation and the falsification of pharmaceutical drugs leads to increased efforts in the supply and distribution of counterfeit drugs. The theory thus explains why counterfeiting practices remain common, as players in the pharmaceutical industry might need to focus on profits (by supplying cheap counterfeits) or satisfying market demands of a certain drug.

2.2.2 The Balanced Score Card (BSC)

The Balanced Score Card (BSC) emanated from the works of Kaplan and Norton (1992) who proposed that the tool was developed as a performance measurement framework that added strategic non financial measures to traditional financial metrics (Kaplan, 2001). The BSC was used to evaluate the organization through four perspectives; the financial perspective, the customers' perspective, the learning and growth perspective and the internal processes perspective (Amer et al., 2022). The financial perspective in the BSC focuses on the financial performance measures such as revenue growth or sales volume, profitability and return on investment (Aliakbari Nouri et al., 2018). By including these financial measures as a key dimension in the BSC, businesses can ensure that their financial objectives are aligned with the overall strategic objectives (Malagueño et al., 2018).

The model was used in this study in conceptualizing the measurement of the financial performance of the local generic drug manufacturers in Nairobi County. Based on the model, this study developed three major indicators for evaluating financial performance: sales volume, profitability and return on investment. The non financial perspective of the BSC was not incorporated as the study focused on measuring the financial indicators.

2.3 Empirical Review

This section emphasizes the various conclusions drawn in the body of published work that are relevant to the subject under investigation. As a result the section is separated into three subsections, each of which addresses a certain set of perspectives on how counterfeiting effects the financial performance of local drug manufacturers. This study thus centres on supply chain systems, pricing strategy of counterfeit drugs and the legal and institutional framework. This section is thus subdivided to address each of the variables and will be followed by a summary of the gaps identified and the operationalization of the study variables.

2.3.1 Supply Chain Systems and Financial Performance

The definition of the pharmaceutical industry is "a system of operations, procedures, and organizations engaged in the research, development, and production of pharmaceuticals." (Goodarzian et al., 2020). The pharmaceutical supply chain serves as a conduit for the distribution of pharmaceutical products of the right quality to final consumers at the right time and location (Shashi, 2022).

A study by Isles (2017) on falsified or counterfeit medicines indicated the need for a robust supply chain platform due to the rising tide in criminal activity to manufacture and distribute counterfeit medicine with estimates of the problem vary between US$75 to US$200 billion a year and evidence clearly demonstrates it's on the increase . The study showed that there has been a great infiltration of counterfeit drugs through the "legitimate" supply chains and the "illegitimate" supply chains which can have a negative impact on the sale and profitability of a drug manufacturer. The "illegitimate" supply chain has vastly been brought about by online rogues or internet "pharmacies" that threaten health, lives, privacy and security of internet consumers. These sellers do not operate in compliance with the laws of the jurisdiction in which they are located. Counterfeit drugs are available through the legitimate supply chain, which also includes a small percentage of online pharmacies. The legitimate supply chain has many stages in which counterfeits can enter, starting with providing ingredients for manufacturing of the drug. Subsequent stages for infiltration include storage, transportation, and finally distribution.

Munyao (2022) explored that the infiltration of counterfeit goods is because the industry of counterfeits is increasing and becoming more profitable, the complexity levels of how the offenders are packaging their products keep rising. This has led to the issue of counterfeit pharmaceuticals being such a deeply ingrained problem in the Kenyan pharmaceutical supply chain. The author also proposes the diversification of the e-commerce has led to an influx of falsified drugs and a variety of imitations of prescription medication supplied by illegal distributors. The illegal distributors disrupt the distribution network leading to losses in sales

and revenue from the genuine drug manufacturers as PPB have little or any control over the influx of counterfeit goods in the supply chain.

According to Sahoo et al (2020), the pharmaceutical medicine supply chain has numerous flaws. In the current supply chain scenario, information is either not communicated at all between the parties throughout the hand-off process or is supplied sparingly or irrelevantly, which has encouraged counterfeiting. This has resulted in the legitimate maker of the drug suffering astronomical financial losses in sales and profitability as well as health consequences to the public from the use of counterfeit drugs. The lack of an integrated information system from manufacturer to the end user has led to an increase in drug counterfeiting in India as the information of the movement of pharmaceutical products is not shared between parties in the pharmaceutical supply chain. Sahoo et al (2020) proposes the use of block chain technology, the pharmaceutical supply chain can benefit from traceability, visibility and security. The pharmaceuticals products can be tracked through a planned system from their manufacturer or origin to their final consumer leading to improved sales and profitability.

Kritchanchai (2014) underlines that there is a presence of a logistics and supply chain system in the pharmaceutical industry but the coordination and operations among the players has been neglected. The healthcare supply chains that exist are highly fragmented with each player in the supply chain creating their own data communication language which discourages the player from communicating and sharing the information with other partners in the supply chain. This fragmentation complicates the task of connecting the thousands of partners involved at any stage in the supply chain leading to a lack of integrity in the supply chain which has become a facilitating factor for the growing problem of counterfeiting. A fragmented supply chain leaves gaps for the introduction of counterfeit drugs which can damage the reputation of the manufacturer and lead to a loss in trust among customers, which can impact sales and profitability in the long term.

A study by Kanwar and Rahim (2019) established that social responsibilities of global pharmaceutical companies and their ethical healthcare paradigm envisions a scenario in which every individual in society is assured of availability and accessibility to medical care. However,

there are multiple stakeholders in the pharmaceutical supply chain all have different motives with regards to the ethical health paradigm. The ethical dilemma of acquisition of counterfeits arises from the fact that the sale of counterfeits is seen as morally and legally wrong, yet it provides benefits for both the illegal seller and buyers. From the illegal seller's perspective, counterfeiting is a way to make a profit by illegally producing and selling counterfeit drugs at low cost. From a buyer's perspective, counterfeit drugs provide a way to acquire goods at a lower cost. Generic drug manufacturers have an ethical health motivation to provide affordable and essential medication in the supply chain, but counterfeiters have a motive to imitate drugs to the detriment of the primary stakeholder which is the patient. Thus, an ethical dilemma is brought about by the illegal seller of counterfeit drugs gaining from the sale of their products while the legitimate seller and the patient lose out.

According to Cohn et al (2013) who did a study on the entry of falsified medicines in Kenya noted that Kenya's drug distribution network is currently in a state of disarray since it comprises of open markets, patent drug stores, community pharmacies, private and public hospitals, wholesalers/importers and pharmaceutical manufacturers. Counterfeit drugs are often manufactured in unsanitary facilities, using low quality ingredients or incorrect dosages. This can lead to quality control issues in the supply chain, as these counterfeit drugs are not subject to the same safety and quality standards as legitimate drugs. Additionally, the distribution of counterfeit drugs often involves illegal and unregulated channels, which disrupt the legitimate pharmaceutical supply chain. The presence of counterfeit drugs results in increased regulatory scrutiny and compliance costs which have a negative impact on the return on investment.

According to study conducted by Hidayat, Mizerski and Ogilvie (2013) on the Indonesian consumers' willingness to buy supplied counterfeit products, the increased supply of counterfeit goods was one of the world's fastest growing industries, with actual losses estimated to be excess of $10 trillion." The study concentrated much on supply-side issues, which included product extrinsic cues, that is, brand and price, and product involvement and examined their influence on consumers' willingness to purchase known counterfeit goods." The

study findings provided insights that can be applied to the supply chain systems of counterfeit drugs. The study found that consumers who are more accepting of counterfeit products may be more likely to purchase them even if they are aware that they are not genuine. Similarly, actors in the supply chain of counterfeit drugs may be motivated by financial gain, and may be willing to take advantage of consumers who are more accepting of counterfeit products. This leads to a decrease in demand for the genuine products and cause a decline in sales volume for the genuine manufacturer.

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2.3.2 Pricing Strategy and Financial Performance

Van Baelen et al (2017) discuss the importance of generic drug manufacturers in increasing accessibility of medication in Europe. The authors point out the off-patent industry suffers from a continuous pricing pressure from the payers on one side and increased regulatory costs on the other. Apart from production cost of a medicine of a generic drug there are additional costs in a highly regulated pharmaceutical market. Compliance with all these regulations comes with a significant cost which drives up prices of generic drugs. The costs in production of a generic drug include; the regulatory costs: the sale and marketing of a generic drug can only be accomplished after the submission and approval of a market authorization dossier by the PPB, the pharmacovigilance costs: there are very stringent regulations with regards to pharmacovigilance in production of generic drugs and it requires expensive, skilled staff and capable IT systems and the; quality control costs: these are costs due to a set of procedures to ensure that a manufactured generic product adheres to a defined set of quality and meets the requirements of a customer. Other costs of drug production are; quality assurance costs: costs to keep oversight of supply chains and to guarantee the quality of generic products, distribution costs: relates to supply chain management and patient safety, the Cost of Capital: investors expect a return on their investment and the counterfeit drugs and substandard medication undermine the local generic drug manufacturing as the undercutting costs of counterfeit drugs are looked at as more favourable to the public.

One of the most important elements in the marketing mix is pricing and it is the only mix which generates a turnover for counterfeit firms (Wanjau & Muthiani, 2012). Companies adopt different pricing strategies to assign value to their products. Using different strategies implies that the final prices of products will vary. In the pharmaceutical industry, the drug manufacturers of a product include several aspects such as the cost of production, processing, raw materials, and labour when quantifying the final price of a given drug. However, dealers of counterfeit drugs often bypass most of these costs, hence making their products relatively cheaper. High price sensitivity markets may demonstrate a skewed preference for counterfeit drugs, which are lower-priced when compared to genuine drugs. This not only hurts the financial performance of the producers of genuine drugs, but also exposes patients to health hazards and encourages more smuggling of counterfeit drugs. Pricing strategy promotes counterfeiting in that counterfeits have price advantages of relative to genuine products, because they are typically cheaper than original products. This plays a major role in the continual demand for counterfeit products because consumers typically opt for cheaper products (Schlegelmilch, 2016).

Spink, Moyer, Park, & Heinonen (2014) note that when it comes to counterfeiting, there are two sides of looking at the counterfeit trade exchange: the supply side of counterfeits and the demand side for counterfeits. The supply side of counterfeits relates to the parties and factors responsible for the distribution of counterfeit drugs into the market. It consists of an examination of the 'people factors' in the business environment that permits the production and placement of counterfeit drugs. However, in the examination of the pricing strategy, the primary concern is the demand side of counterfeiting, which includes an examination of consumer perceptions to pharmaceutical counterfeits. The demand side includes the factors and forces in the business environment that motivates patients and their families to express a willingness to pay for counterfeit drugs. Although it has been previously argued that consumers are more sensitive to the quality of drugs than prices, deprived markets characterised by low disposable incomes have a greater affinity towards lowly-priced brands compared to genuine brands that typically come with relatively higher prices.

Rohit & Ranjan (2022) in their study on a goods dominant perspective on counterfeiting show that there are two types of counterfeit products. First, there are deceptive counterfeit products, which are presented to the market as being genuine with the intent to deceive the purchaser. Moreover, there are non-deceptive counterfeit products, which are presented to the market as counterfeit or fraudulent with no intent to deceive the purchaser. Non-deceptive counterfeit products are marketed to consumers who seek counterfeit products such as apparel and luxury goods. Penetration pricing strategic is adopted in deceptive counterfeit products. Penetration pricing strategy is the strategy used to price goods or services artificially low in order to gain market share and once market share is eventually achieved the prices are increased. The core feature of penetration pricing is that products are introduced to markets at the lowest prices compared to all competitor prices. The aim of this pricing strategy is to attract price-sensitive consumers to the product during the introduction stage and as a result the genuine drug manufacturer can experience a decline in sales and market share. Although penetration pricing tends to be followed by a gradual increase in prices, the huge quantities consumed during the period of low pricing tend to increase consumption levels, visibility and some degree of customer loyalty. In deceptive counterfeiting, the strategy is to sell the counterfeit products at the same price as the fast-moving popular brands.

A study by Said (2016) on the effects of counterfeiting on the sale and distribution of pharmaceutical products in Mombasa County. The objective of the study were to find the influence of consumer demand on distribution of counterfeit drugs noted that consumers are more likely to buy counterfeit drugs due to their low prices as compared to high price of a genuine product. This demand and consumption of counterfeit drugs in turn is a great motivator for stakeholders in the supply chain to increase the supply of counterfeit drugs. An increased supply of counterfeit drugs leads to a decline in sales and profitability for the drug manufacturer.

Weru (2018) on a similar view notes that production costs include both direct and indirect costs and that sales of pharmaceutical products must exceed production costs for a pharmaceutical

manufacturing company to be profitable. The pharmaceutical manufacturer in an effort to curb down on counterfeiting has to put in place certain measures which may include improving on pharmaceutical information technology or any other counterfeit detection measures to improve traceability and security of pharmaceutical product. In order to cover any increased production cost, the price of pharmaceutical products must likewise increase. This would guarantee the business's on-going growth and sustainability.

2.3.3 Legal and Institutional Framework and Financial Performance

According to Kenya Law (2023), the Kenyan parliament is the governing body, which is given power by the constitution to make laws in Kenya. There are certain laws that regulate the manufacture, distribution and sale of pharmaceutical drugs in Kenya. These include; the Pharmacy and Poisons Act, Cap 244 of 1989 which regulates the compounding, supply, distribution, sale and dispensing of pharmaceutical drugs and provides various levels of control for different categories of drugs and poisons, the Food, drugs and chemicals Act, Cap 254 of 1992 which the act prohibits the sale of certain foods, drugs, cosmetics, chemicals and other devices as treatments against diseases. The act prohibits the exportation, importation, sale and distribution of certain chemicals. It conveys the power to appoint food and drug analysts. Finally, there is also the Anti-Counterfeit Act, No. 13 of 2008 which Act prohibits the manufacture, production, exportation, importation, distribution and sale of any counterfeit, adulterated, or fake drugs. It also prohibits sell of pharmaceutical drugs in an open market without the permission of the Pharmacy and poisons Board.

Lima et al (2018) remark, in order to generate an extensive look at the legal and institutional framework, that counterfeiting occurs throughout the world, however there are claims it is more common in developing countries with weak regulatory or enforcement regimens. The authors point out that the most obvious and significant appeal of counterfeiting is the profitability of the trade. Counterfeit prescription pharmaceuticals can be ten times as profitable as heroin trafficking. While anecdotal evidence of the correlation between counterfeiting targets and profit is abundant, the clandestine nature of the business, as well as

the secrecy maintained by law enforcement, make it nearly impossible to fully comprehend or quantify the extent of the trade. Governments have been showing concerted efforts towards addressing the detriments of counterfeiting through national security instruments but it seems that counterfeiting is deeply rooted to the extent of being untraceable. The authors also note that a report by OECD states that trade in counterfeit drugs, specifically, is worth a staggering USD 4.4 billion approximately (OECD/EUIPO, 2019). This implies that legitimate manufacturers of drugs are losing billions of dollars in potential revenue.

A study by (Wanjau & Muli Muthiani, 2012) emphasized that, in order for legislation to be effective, law enforcement should equally be up to the task. There is a growing prevalence in developing countries due to their poor regulatory mechanisms and poorly monitored distribution of networks. Minimal fines for the breach of provisions of the decree has encouraged the influx of counterfeit goods in the African market as counterfeit producers can get away with a crime easily. Patients will most likely lose confidence in health care professionals including local drug manufacturers and the Kenyan pharmaceutical industry as a whole (Opiyo, 2006).

Strategies to reduce corruption, criminal activity and promote intersectional cooperation between regulatory authorities, police, customs services and also involve the judiciary to effectively control and enforce the drug market and the drug regulation in the pharmaceutical industry. Public and private entities incur additional expenses to control these illicit counterfeiting activities. The additional cost on the local generic drug manufacturers will minimize the profits and the revenues attained by the business.

According to Ajiffa (2015), in order to spread pharmaceutical products more widely and remove trade and technical hurdles that are impeding global trade, national governments and supra-governmental organizations like the World Health Organization (WHO) and World Trade Organization (WTO) are enforcing regulatory policies through national regulatory authorities. The role of the drug regulatory authority includes, but is not limited to, ensuring that medicines are of the required quality, safety, and efficacy, patients have the necessary information for rational use of medicines, medicines are appropriately manufactured, stored, distributed, and

dispensed, illegal manufacturing and trade are detected and adequately sanctioned, promotion and advertising is fair, balanced, and aimed at a rational drug use, and access to medicines is not restricted by unjustified barriers. The Pharmacy and Poisons Act, Chapter 244 of Kenyan legislation, establishes the Pharmacy and Poisons Board as the regulating body in Kenya. The board controls the manufacture, distribution, and practice of pharmacy as well as the trade in pharmaceuticals and poisons. To ensure the protection of the consumer, it aims to put into place the necessary regulatory measures to achieve the highest standards of safety, efficacy, and quality for all medications, chemical substances, and medical devices that are locally produced, imported, exported, distributed, sold, or otherwise used.

Kirunga (2019) discusses the efficacy of anti-counterfeit laws in Kenya states that the Registrar presides over advisory opinions on registrability of trademarks, assignment of trademarks and searching and screening of trade marks. The registrar is provided for under the Industrial property act to preside under opposition hearings and award any party costs he may consider reasonable. However there are challenges in the enforcement of the Trademark act as infringement actions mare only pursued in the high Court which raises concern as there is a general lack of judicial capacity in handling industrial property law matters. It goes without saying specialization and division of labour which both are fundamental formulae for efficiency and excellence is quite lacking in the regulation and enforcement of IP rights in Kenya (Kirunga, 2019).

Ongola (2014) notes that the National Police Service (NPS) is established under the National Police Act in the Kenyan constitution which provides the police with functions of investigating crime and enforcing laws and regulations in Kenya. The service has a trained set of inspectors and police officers who under the Anti-counterfeit Act play a role in IPR enforcement (Ongola, 2014). The major challenge facing the NPS is the workforce trained in IPR enforcement is limited. The Anti counterfeit Agency has only five inspectors dealing with IPR enforcement hence inhibits their work in the fight against counterfeiting.

2.4 Research Gaps

These studies show a significant influence of the various aspects of counterfeiting. However, these studies failed to investigate the specific context that the current research sought to examine, hence presenting a gap that this research sought to fill. From an empirical perspective, the study assesses the effects of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County. Most of these studies were not carried out in Nairobi county include Said (2016) who conducted the effects of counterfeit drugs in Mombasa County; in India Sahoo et al (2020) conducted the impact and elimination of counterfeiting through a block chain based model.

Cheruto (2021) carried out a study on the analysis of counterfeit drug prevention studies on the financial performance of retail pharmacies in Nairobi County in which the author focused on anti counterfeit strategies in Nairobi County. On the legal and institutional framework studies such as Ajiffa (2015) focused on the competitive analysis of the Kenyan drug regulatory regime while Ongola (2014) focused on the anti-counterfeit laws before e-commerce. Rohit & Ranjan focused on the effectiveness of price strategies of deceptive counterfeit goods. The study did not focus on the impact of pricing strategies on the legitimate manufacturer. Further, the study focused on counterfeit goods and not counterfeit medication in particular. The current study seeks to address the above gaps by examining counterfeiting and how it influences the financial performance of local generic drug manufacturers in Nairobi County.

Table 2.1 Summary of Research Gaps

Author	Title of the study	Findings	Research Gap	Filling the Gaps
Said (2016)	The effect of counterfeiting drugs on the distribution of pharmaceutical	Findings revealed there is a high influence of consumer demand on the	The study was carried out in Mombasa County	The current study investigated the impact of counterfeiting in Nairobi County

	products in Mombasa County	distribution of counterfeit drugs.		
Cheruto (2021)	Analysis of counterfeit drug prevention strategies on the financial performance of retail pharmacies.	Findings indicated that none of the anti counterfeit approaches had a bearing on the financial performance of retail pharmacies.	The study focused on anti counterfeit strategies that are not utilised in Kenya.	The current study assessed the aspects of counterfeiting and financial performance of local generic drug manufacturers.
Ongola (2014)	Efficacy of anti counterfeit laws in Kenya.	The findings indicated that there is a legal framework put forth to curb counterfeit trade.	This study did not explore counterfeiting with the diversification of commerce with the introduction of the internet.	The current study considered the role the internet plays in counterfeit trade of pharmaceuticals.
Ajiffa (2015)	A competitive analysis of the drug regulatory affairs regime in Kenya- using porter,s forces for competence powers	Findings indicate a significant effect for applying the porters forces to create a drug regulatory strategy	This study did not investigate the specific factors that affect the competitive forces within the regulatory affairs industry.	The current study explored the legal and institutional factors in the Kenyan pharmaceutical industry.
Rohit & Ranjan (2022)	A goods dominant – a service dominant perspective of counterfeiting.	The study noted the effectiveness of pricing strategies of counterfeits.	This study did not examine the impact of pricing strategies on legitimate manufacturers.	The current study examined the impact of pricing strategies on the financial performance of generic drug

				manufacturers.

2.5 Conceptual Framework

Developing a conceptual framework is necessary to understand the main aim of the study is to assess the effect of counterfeiting on the financial performance of the local generic drug manufacturers. To achieve this, the study has three independent variables counterfeit supply chain systems, pricing strategy of counterfeits and legal and institutional framework. The indicators for counterfeit supply chain systems are distribution monitoring and online supply chains. The indicators for pricing strategy of counterfeits are price sensitivity and penetration pricing. The indicators for legal and institutional framework is regulatory agencies/bodies, acts and policies, law enforcement agencies and regulatory mechanisms. The dependent variable in the study is the financial performance of local generic drug manufacturers. The indicators for the dependent variable are sales volume, profitability and return on investment.

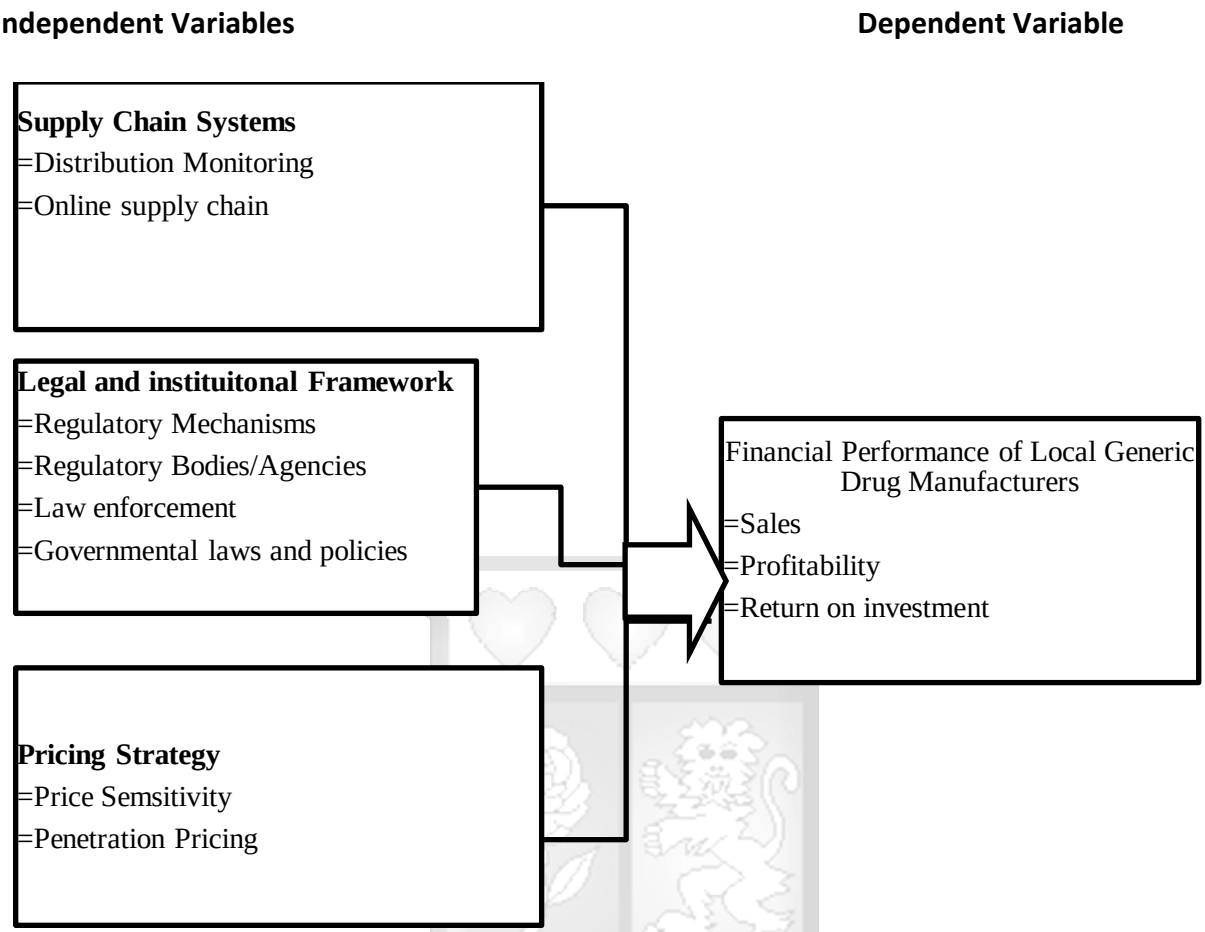

Figure 2.1 Conceptual Framework

Researcher (2023)

From the above framework, the financial performance of the local generic drug manufacturers (the dependent variable) depends on the effects of counterfeiting; pricing strategy of counterfeit drugs, supply chain systems of counterfeit drugs and the legal and institutional framework in place. The three factors are interconnected in that: the pricing strategy drives the penetration of counterfeit drugs since cheaper counterfeit drugs are often more affordable to stakeholders than original drugs; counterfeit drugs can penetrate the supply chain systems and be indistinguishable from legitimate products and disrupting the distribution network; weak legislation coupled with ineffective law enforcement results in a lack of control of the drug

market and poorly enforced drug regulation. All these factors combined result in affecting the financial performance of local generic drug manufacturers. Knowing the effects of the counterfeit drugs in the industry by the people, the government and the industry players can also amount to measures towards reducing the influx of the counterfeit as conceptualized in the framework.

2.6 Operationalization of Study Variables.

The table presents the definition and measurement of the study variables. The variables in the study are; dependent variables, financial performance, the independent variables, pricing strategy, counterfeit supply chain systems and the legal and institutional framework.

Table 2.2 Operationalization of the Study Variables

VARIABLE	CONSTRUCTS	MEASUREMENT	SOURCE
Independent	Counterfeit Drug Supply Chain systems • Integrated Supply Chain • Distribution chain monitoring • Online Supply Chain	5 point Likert Scale	Munyao (2022b), Sahoo et al (2020)
Independent	Pricing Strategy of Counterfeits • Low Pricing of counterfeits • Cost of Production	5 point Likert Scale	Wanjau & Muthaini (2012), Said (2016)
Independent	Legal and Institutional Framework • Regulatory Acts and	5 point Likert Scale	Ajiffa (2015), Kirunga (2019), Ongola (2014)

	Policies • Regulatory Agencies • Law Enforcement Agencies		
Dependent	Financial performance of local generic drug manufacturers • Sales Volume • Profitability • Return on Investment	5 point Likert scale	Kaplan (2001) Srimarut & Mekhum (2020)

2.7 Chapter Summary

Chapter two focused on the review of the extant literature covering both theoretical and empirical aspects of the research. This study was informed by the theory of reasoned action which grounded the aspects of counterfeiting and the Balanced Score Card which anchored the financial performance aspect of local generic drug manufacturers. The study also carried out a critical review of previous researchers' findings on the relationship between the study variables. Further various gaps were pointed out and were presented in the summary of research gaps. Lastly, a conceptualization of the variables and operationalization was presented.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlined the research methodology that will be used in the study and had the following structure: research design, target population, sample size and sample procedures. The study also presented the sections on how piloting of the instruments would be done on validity and reliability, data collection procedures and the data analysis approaches, as well as, the ethical considerations adopted by the researcher in the study.

3.2 Research Philosophy

Research philosophy refers to the set of beliefs, assumptions and values that underpin a research study (Tamminen & Poucher, 2020). It guides the researcher in selecting the research methodology, methods and techniques used to collect and analyze data (H. R. & Aithal, 2022). Positivism is a research philosophy that emphasizes the use of empirical observation, quantitative data and scientific methods to test hypotheses and explain phenomena (Alharahsheh & Pius, 2020). This study therefore applied the positivism philosophy was used because it focuses the researcher's responsibility to data collection and interpretation using objective methodology, and the study outcomes are typically observable and quantifiable.

3.3 Research Design

Dul and Hak (2008) indicated that a research design is the methodical framework used for collecting and analyzing data or obtained feedback with the goal of attaining the study's objectives. Mugenda and Mugenda (2010) indicate that a study's design is the structure that must be adhered to when seeking solutions to research questions. This study used the descriptive cross-sectional research design approach to analyze the data which was fully quantitative in nature. The descriptive survey-research-design technique/approach was the best to be used in this investigation. This procedure focuses on the "what" rather than the "why" of the scenario. In this case, the primary focus of this method is the description of the

status about demographic factor, rather than why a particular phenomenon occurs. As a result, it characterizes the subject of the study, conditions, behaviour, or the phenomenon rather than the motives why it happens.

The research was a cross sectional study. Cross sectional studies are distinguished by the collection of pertinent data at a specific point in time. As a result, there is no time dimension in cross sectional studies because all data are collected and mostly refer to the time at or near the time of data collection (Kesmodel, 2018). Quantitative research involves collecting numerical data and analyzing it using statistical methods (Bloomfield & Fisher, 2019). Quantitative research design was used in this study to quantify data, generalize findings, and assess the prevalence of distinct viewpoints and opinions within a selected sample. A descriptive cross sectional design is particularly useful to describe the current status of local generic drug manufacturers in Nairobi County and also identify relationships between variables. The design hence deems fit to assess the effects of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County, Kenya.

3.4 Target Population

There were 35 listed local pharmaceutical manufacturers in Kenya, a majority of which are located around Nairobi City County (UNIDO, 2010). The target population for this study was local generic drug manufacturers in Nairobi County. The choice of the location was that the firms happen to have all their headquarters in Nairobi County. The other fact was due to accessibility and sensitivity of the data needed on counterfeit, the authentic process, as well as, the increase of such local firms and not multinational ones. The inclusivity criteria was that all the 15 local licensed and registered pharmaceutical manufacturers according to PPB, form the sample frame from which the research drew its sample. The exclusivity criteria was that all registered multinational firms were to be excluded from research as the issue of counterfeits is not adequately spelt out compared to the local manufacturing perspective. The study targeted 5 people from each of the 15 registered local generic drug manufacturers in Nairobi County. The 5 people represent the heads of department which the study focused on namely; Quality Assurance Manager, Quality Control Manager, Regulatory Affairs Manager, Sales Manager and

Director or Company Pharmacist or CEO. This formed the unit of analysis of the study where the researcher targeted 1 top manager, 2 middle level managers and 2 lower level managers for these were the ones well versed with the operations of the organizations well placed to give valid responses to the raised research questions. The target population was therefore 75 respondents as distributed in the Table below;

Table 3.1: Target Population

Category	Target population
Top Managers	15
Middle Level Managers	30
Lower Level Managers	30
Total	**75**

Researcher (2023)

3.5 Sampling Design

Cooper & Schindler (2014) state that a sample design is a plan or a framework created before any data is collected to obtain or to define how a sample is drawn from a given population. The sample design consists of the following elements: sample frame, sampling technique and sample size.

3.5.1 Sample Frame

The sample frame is the group of people who are chosen from the target population based on the sampling method used in the study (Martínez-Mesa et al., 2016). In this study, all the elements in the population were used and constitute the sample frame. The sample frame consists of all the 15 licensed and registered local generic drug manufacturers in Nairobi County according to PPB.

3.5.2 Sample Size and Sampling Procedures

Due to the small size of the population all the local generic drug manufacturers in Nairobi County took part in the study. When the population is small, the study includes all the elements of the population (Zikmund et al., 2013). Siegel (2013) defined a sample size as a subdivision

selection group based on targets to provide a clear depiction of the whole population. He also defined sampling as process or a technique used to decide on an articulate sample size on those to take part in a study. Cooper and Schindler (2014) state that a sample size of 50 percent (%) or greater is adequate for a given academic research. This research sought to study a sample of all 15 registered local generic drug manufacturers in Nairobi County. Purposive sampling approach was used to consider all the 75 respondents to take part in the research study in each of the targets population sections. The justification on the heads of department consideration as the sample size is based on the fact that they are assumed to have past and present experience and knowledge on the counterfeits drugs in the pharmaceutical industry and will be able to offer valuable information and also understand more on the operations of the firms. The sample size was therefore 75 possible respondents.

3.6 Data Collection

Cooper and Schindler (2014) state that the process used to gather data from a sample size selected as the study respondents is referred to as data collection. Data collection is critical because it provides the researcher with correct information from which to draw conclusions (Kombo & Tromp, 2006). The only data gathering technique for this study was a questionnaire. According to Creswell and Plano Clark (2011), a questionnaire is legitimate in data collection since it allows the researcher to acquire a great amount of data in a short period of time and also allows respondents to give frank, anonymous answers. Questionnaires are easy to tabulate and analyze and are a cheap method of collecting quantitative data (Patten, 2016). The respondents were given well structured questionnaires with closed ended questions and 5 point Likert scale response options. The questionnaire as the tool was created in basic and unambiguous language so that respondents may answer freely (see the Questionnaire in the Appendix 11).

3.7 Research Quality

A pilot study, according to Donald (2006), is a preliminary investigation conducted on a small scale to analyze feasibility, cost, time and difficulties in some scenarios, as well as to allow for

the enhancement of best tools to use in the actual research. The questionnaire was pre tested on 10% of the target respondents and this group did not participate in the study.

3.7.1 Validity of the Instruments

Mugenda and Mugenda (2010) depicted validity as the point of accuracy of conclusions drawn from research findings. In actuality, it is the extent to which the research tool guarantees its ability to convince the respondent and the same data used to fulfill the intended purpose with ease. Validity comprises of face validity, construct validity and content validity (Heale & Twycross, 2015). To establish face, construct and content validity the researcher sought guidance for the supervisor to ensure the questionnaire was measuring what was intended and designed to capture in the study.

3.7.2 Reliability of the Instruments

Donald (2006) defines dependability as the extent upon which a given research tools/instrument produces consistent results following repeated trials or Cronbach's tests to obtain advising values about how reliable the tool is based on the constructed questions. Respondents constituted 10% of the total sample size of the study who were equally drawn from each of the registered local drug manufacturing firms in Nairobi County. It therefore meant that 8 respondents were requested to participate in the study. These individuals were not obliged to take part in the actual study. This was due to the fact that the personnel working in the outlets share nearly identical characteristics with those working in the headquarters in terms of the management techniques they have implemented. Cronbach's alpha is a measure of internal consistency where authors like Cooper and Schindler (2014) state that an alpha coefficient of 0.70 or higher. The findings are presented in table 3.2.

Table 3.2 Reliability Results

Variables	No. of items	Cronbach's alpha	Recommendations
Supply chain systems	5	0.79	Good

Pricing Strategy	6	0.8	Excellent
Legal and institutional framework	7	0.70	Acceptable
Financial performance	3	0.78	Good

3.8 Data Analysis

The process started with the cleaning of the data obtained from the field. In this case, the researcher differentiated the feedback in the already filled questionnaires to ensure that only the ones containing valid data proceed to the next episode of data entry after coding. Data coding entailed the process of assigning values to the each of the research queries and thereafter followed by data entry which entailed the feeding of responses against the coding. The data obtained in this study was articulately analysed quantitatively and compiled to generate the final findings and conclusions (Cresswell & Plano Clark, 2011).

The main aid statistical tool used for estimating the predicted parameters or measures of central tendency was the Statistical Package for Social Sciences abbreviated as SPSS-Version 22.0. The researcher used descriptive statistics outcome aspects like frequency tables, percentages, charts, graphs to present the results. In addition, inferential statistical approaches such as regression modelling, correlation and ANOVA were used to explain the interaction using various forms of analysis such as Analysis of variance and co – relations.

The inter-relations among any two independent variables is described as the statistical correlation or the relative relationship between two continuous variables (Cooper & Schindler, 2014). This technique has been characterized as the initial step in the construction of predictive methods intended to determine associations or connections between dependent and independent variables. A correlate value of 0 implies that there is no connection between the applied dependent and independent variables. Furthermore, correlation indexes of 1.0 indicate that there is a notable relationship between the variables as explained by the above author.

Results about the readings were be construed between the number line, a negative (-1) and a positive (+1) where a negative -1 means a perfect negative relationship, a 0 suggests a lack of correlation, and a +1 represents a perfect positive association. The correlation values obtained showed the existence of a positive + significant relationship for they were below .005 ($p<.05$).

Besides descriptive analysis, researcher computed a multiple regression analysis to assess whether there is a significant relationship between the variables. A statistical method for identifying the relationship between one or more independent variables and one or more dependent variables is multiple regression analysis (Hair et al., 2010). The independent variables in this study will be pertaining to the effects of counterfeiting and the dependent variable will be the financial performance of registered local generic drug manufacturers in Nairobi County, Kenya.

$\mathbf{Y = \Omega_0 + \Omega_1 X_1 + \Omega_2 X_2 + \Omega_3 X_3 + \varepsilon}$, where,

Y= β_0= Intercept

$\mathbf{H_1}$= Supply Chain Systems

$\mathbf{H_2}$= Pricing Strategy

$\mathbf{H_3}$= Legal and Institutional Framework

Ω 1, Ω 2 and Ω 3 are the coefficients of the regression

ε= the error Term

3.9 Ethical Considerations

Kothari (2014) describes ethics in research as the correct rules of action in any academic research. Three research factors were considered by the researcher: ethical issues concerning the individual researcher, ethical issues concerning research subjects, and ethical issues concerning the study process. To conduct research, the researcher applied for authorized research letter from the National Commission for Science Technology and Innovation (NACOSTI) to accompany the questionnaires, the researcher also obtained an approval from Strathmore University Institutional Scientific and Ethical Review Committee (SU-ISERC).

When working with participants, the researcher adhered to strict ethical and integrity norms. A Participation Information and Consent Form will be handed to all participants and they will be assured that the procedure is voluntary. Consent participants will be educated about the type of feedbacks the researcher requires, why the feedback is being needed, how it was used, how respondents will be asked to take part in giving their opinions in raised queries and finally how the findings would directly or maybe indirectly influenced them. Lastly, the researcher did not misuse any authority he or she has over the participants in this study, whether technical, administrative, and professional by asking them to perform activities that might ostracize them.

The respondents were assured of confidentiality through anonymity and secure information storage, and objectivity in reporting the findings was observed because each respondent's identity was separated from the information required for the study.

3.10 Chapter Summary

Chapter three delineates the methodological steps that were adopted in the conduct of the study. The chapter highlighted the research design and philosophy. Additionally, the population was defined and the sampling technique, sample size and adopted research instruments were presented. Finally, an overview of the data analysis approach was discussed and ethical considerations adhered to in the course of the study.

CHAPTER FOUR: DATA ANALYSIS, INTERPRETATION AND PRESENTATION

4.1 Introduction

This chapter is centered on the presentation of the findings derived from the analysis of the collected data in accordance with the research objectives. The main objective of this study will be to assess the effects of counterfeiting on the financial performance of local generic drug manufacturers in Nairobi County, Kenya. The chapter is divided into 5 sections: response rate, respondents profile, objective 1, objective 2 and objective 3. The specific variables of the study are supply chain systems of counterfeit drugs, pricing strategy of counterfeit drugs and the legal and institutional framework.

4.2 Response Rate

The section below presents the response rate of the study.

Table 4.1: Response Rate

Status	Frequency	Response Rate
Responded	66	88
Not Responded	9	12
Total	75	100

The study targeted a total of 75 possible respondents who constituted the heads of departments of the 15 targeted and sampled local generic drug manufacturers in Nairobi County. Out of the 75 questionnaires administered, 66 questionnaires were properly filled and returned giving the study a response rate of 88%. This is adequate according to Mugenda and Mugenda (2010) who advocates that a response rate of 75% or higher is adequate for an academic research. The high response rate was attributed to early notification of participants, and observation of research ethics including seeking consent and maintaining confidentiality of the data collected and anonymity of the participants.

4.3 Demographic Information of the Respondents

The study aimed at examining the profile of the various respondents who took part in it, with a focus on their gender, age, education and tenure in the pharmaceutical industry.

4.3.1 Gender of Respondents

Table 4.2: Gender of Respondents

Gender	Frequency	Percentage
Male	40	61
Female	26	39
Total	66	100

The study reviewed the gender profile of the respondents. According to the findings displayed in the table 4.4 above, 61% of the respondents were male whereas the rest as shown by 39% were female. The results imply that there are more males than females working in the drug manufacturing industry. This indicates that in the technical nature of the work in the drug manufacturing industry is more preferred by males than by females.

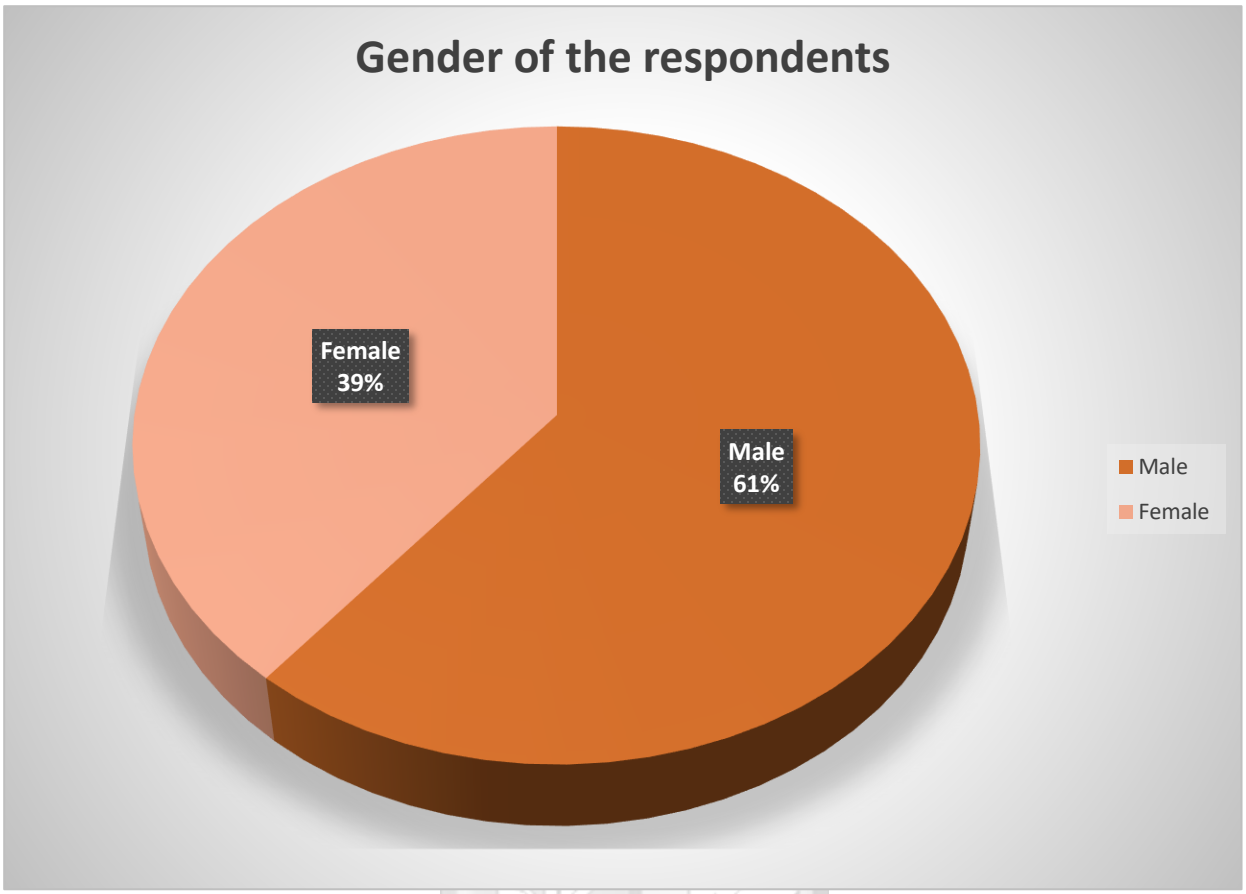

Figure 4.1: Gender of Respondents

4.3.2 Age Bracket of Respondents

The graph below depicts the findings based on the respondent age bracket. According to the findings, 47% of the respondents were between the ages of 21 and 30, 32% were between the ages of 31 and 40, 14% were between the ages of 41 and 50, and 7% were above 50. The findings indicate that the majority of the heads of department in the local generic drug manufacturing sector are aged between 31 and above 50. This finding indicates that majority of the managers in the local generic drug manufacturers are of the middle aged group and are believed to be experienced and established in their careers.

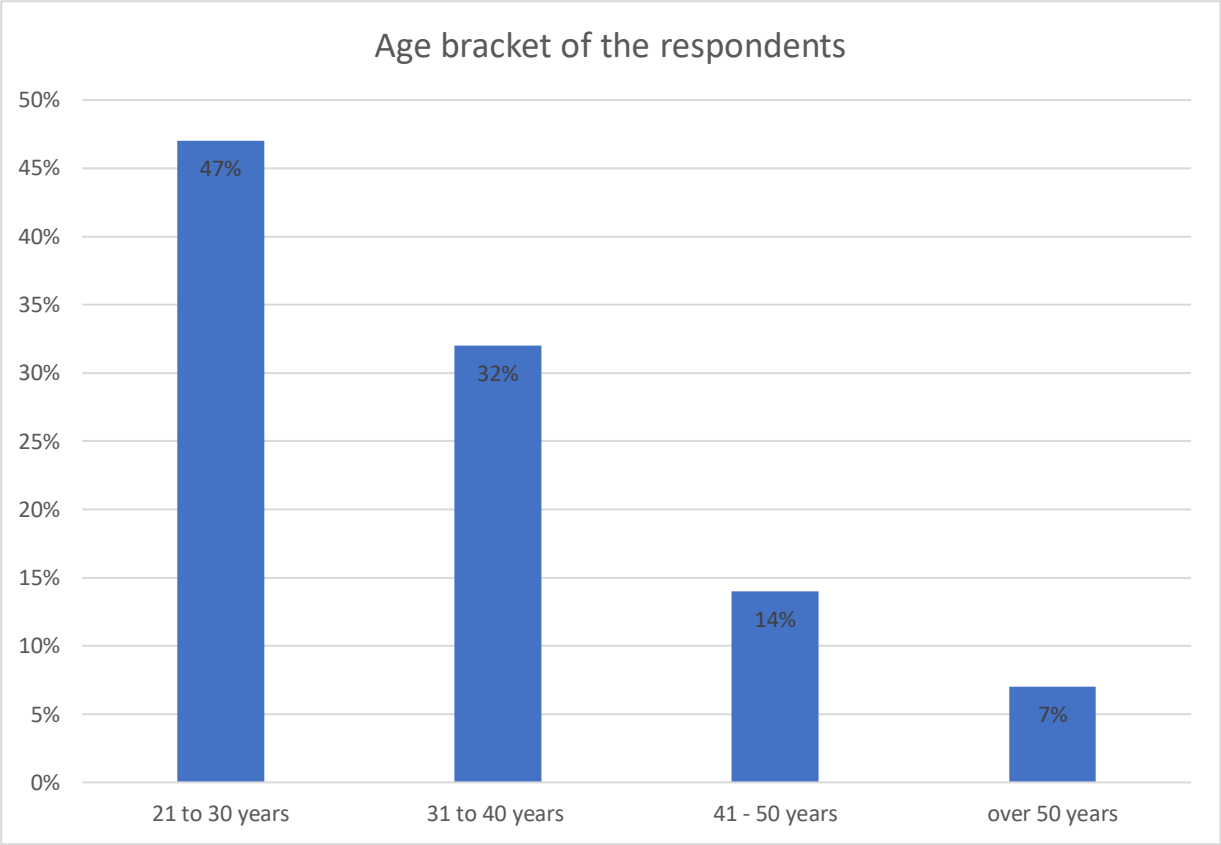

Figure 4.2: Respondents' Age Bracket

4.3.3 Highest Level of Education of the Respondents

The study sought to investigate the educational level of respondents to ascertain the level of understanding of the counterfeit issues relative to the financial performance of local generic drug manufacturers. The study findings indicate that the majority of respondents had degree certificates 54%, 37% had college diploma certificates and only 9% had secondary level qualifications. The results clearly indicate that the respondents were academically educated and understand business and pharmaceutical laws, particularly issues pertaining to counterfeits and how they affect the financial performance.

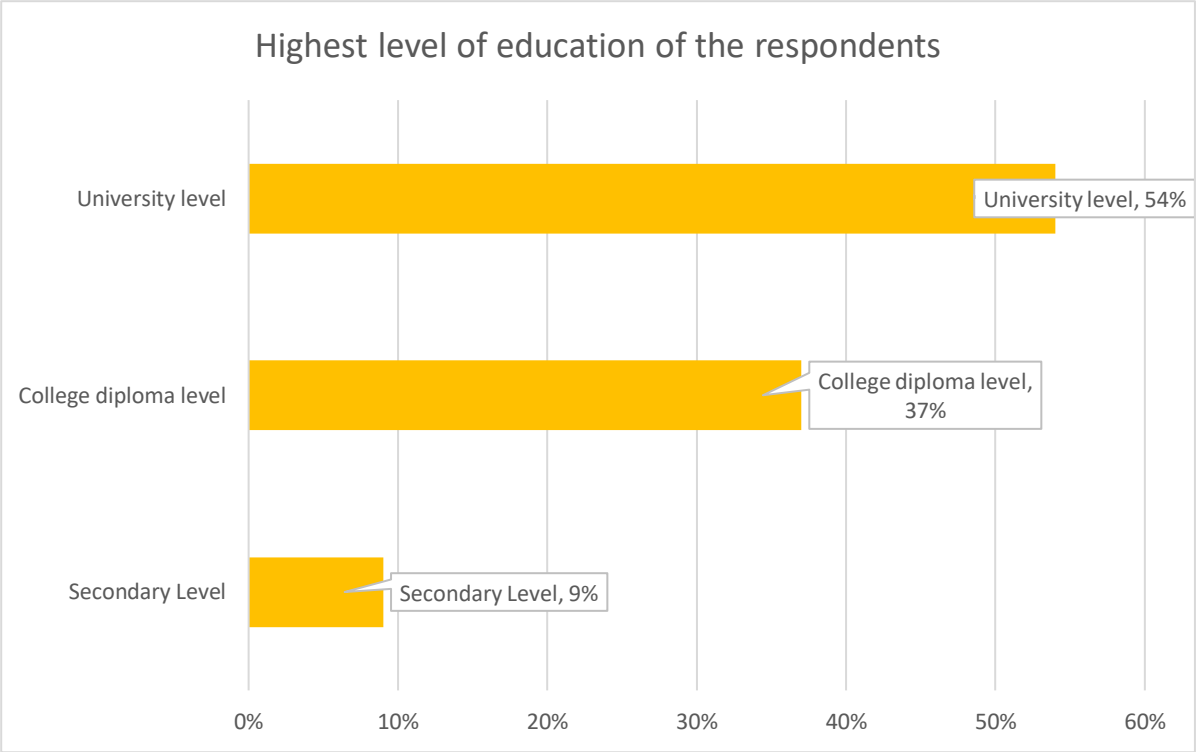

Figure 4.3: Highest level of Education of the Respondents

4.3.4 Duration Respondent Worked at the generic drug Manufacturing Firm

The study queried the respondents on the tenure of service in the pharmaceutical industry. The Figure 4.2 below depicts findings on duration respondents had worked in the pharmaceutical industry. The findings indicate that 47% of the respondents had worked for a duration of less than 5 years, 32% of the respondents worked for 6-10 years, 17% of the respondents had worked for 11-15 years, 3% of the respondents had worked 16-20 years and above whereas a few as shown by 2% said they had worked in the pharmaceutical industry for more than 20 years respectively. The results showed that majority of the respondents have worked more than 6 years in the pharmaceutical industry. The years of experience shows the level of skill and work abilities acquired over time that could be adequate to exploring the research objectives.

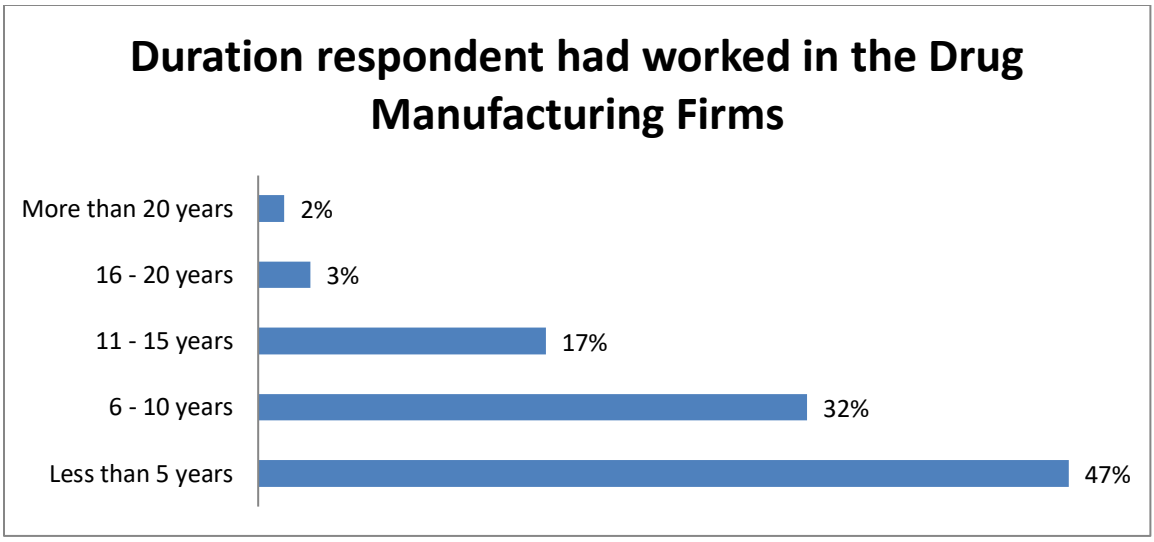

Figure 4.4: Working Period in the local generic drug manufacturing firm in Nairobi County

4.3.5 Job Position of the Respondents in the Organization

Table 4.3: Respondents job position in the Organization

Category		Frequency	Percentage
Heads of Departments		34	52
Top Management		11	17
Employees/representatives		21	32
Total		66	100

The study sought to investigate the job roles of respondents in the organization. According to the findings, 52% of respondents identified as department heads, 17% as top management, and 32% as employees/representatives. This indicates that the study was able to reach the key organization stakeholders who were important in answering the research questions and had the necessary knowledge on local generic drug manufacturing and the impact of counterfeiting on financial performance.

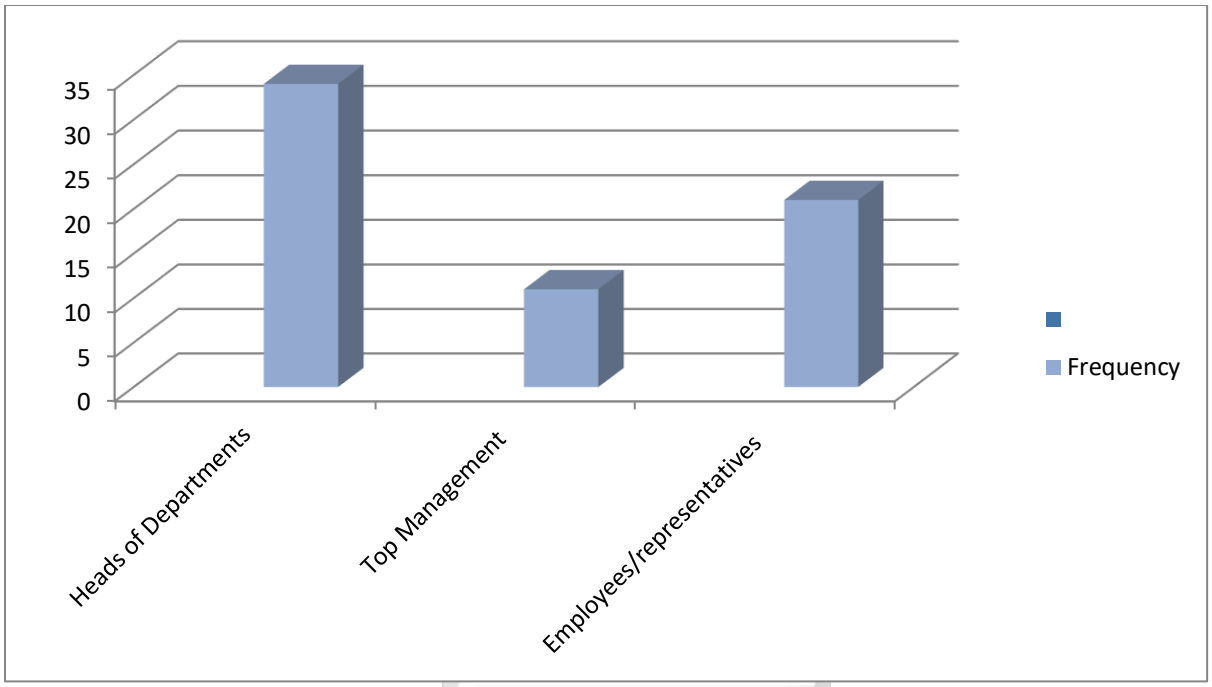

Figure4.2: Respondents job position in the Organization

4.3.6 Company's Position in the Pharmaceutical Value Chain

The researcher wanted the respondents to indicate the company's position in the pharmaceutical value chain generic drug production. On this question, all the sampled respondents indicated that their firms were mostly generic drugs final production oriented while only a few said that they engaged in packaging and repackaging of generic drugs respectively.

Table 4.4: Company's position in the Pharmaceutical Value Chain

Category		**Frequency**	**Percentage**
Generic Final Product Production		57	86.4
Packaging/ Repackaging		9	13.6
Total		**66**	**100**

4.4 Descriptive Analysis

The participant responses were summarized and analysed using descriptive statistical measures such as sum, means and standard deviation. The findings were presented in tables in accordance with the study objectives.

4.4.1 Supply Chain Systems and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

The first objective was to establish the effect of supply chain of counterfeits on financial performance of local generic drug manufacturers and the summary of responses collected is presented in Table 4.5 below.

Table 4.5: Supply Chain Systems

	N	Mean	Std. Deviation
There is an integrated information system that tracks drugs from manufacture to point of use	66	3.6818	.89716
Presence of counterfeit drugs in the distribution chain	66	3.9242	.79053
Many distributors increase the chances of counterfeit prevalence	66	3.7727	.78044
I believe that the acquisition of counterfeits poses an ethical dilemma as it benefits the illegal seller at the cost of the legitimate producer and with fewer taxes being paid throughout the supply chain	66	3.9545	.71105
Counterfeits disrupt the distribution network	66	3.9697	.65562
Valid N (listwise)	66		

The pooled respondents were strongly in agreement that supply chain systems of counterfeit drugs has a negative effect on the financial performance of a local generic drug manufacturer shown by a mean of 3.86 with a variation in responses of 0.77. The results also showed that majority of the respondents agreed that there is an integrated information system that tracks drugs from manufacturer to point of use by a mean response of 3.68 and a standard deviation

of 0.89. Majority of the respondents agreed that there is a presence of counterfeit drugs in the distribution chain, with a mean response of 3.92 and a standard deviation of 0.79. The study also revealed agreement among respondents that many distributors increase the chances of counterfeit prevalence as illustrated by a mean of 3.77 and a standard deviation of 0.78. In regards to the believe of acquisition of counterfeits poses an ethical dilemma as it benefits the buyer and the illegal seller at the cost of a legitimate producer there was a strong agreement by respondents. The respondents also expressed agreements in regard to counterfeits disrupt the distribution network as shown by a mean of 3.96 and a standard deviation of 0.66.

4.4.2 Pricing Strategy of Counterfeit Drugs and Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

The second objective sought to determine the effect of pricing strategy of counterfeit drugs on the financial performance of local generic drug manufacturers in Nairobi County. The summary of collected responses is presented in table 4.6

Table 4.6: Pricing Strategy of Counterfeit Drugs

	N	Mean	Std. Deviation
There is an infiltration of counterfeit drugs in Kenya	66	4.0000	.70165
The low price of counterfeit drugs is a motivator for increased supply, demand and consumption of counterfeit drugs	66	3.6515	.75432
Counterfeit drugs reduce sales in the pharmaceutical Industry	66	3.6970	.76399
The company incurs additional cost of production due to anti-counterfeit measures	66	3.6667	.95003
Additional costs due to anti-counterfeit measures increases price of a pharma-product	66	3.8485	.70694
Valid N (listwise)	66		

The table above depicts findings on respondents' level of agreement with statements that regard about the effects of pricing strategy of counterfeits on the financial performance of local

generic drug manufacturers. According to the results, majority of the respondents agreed that; There is an infiltration of counterfeit drugs in Kenya, the low price of counterfeit drugs is a motivator for increased supply, demand and consumption of counterfeit drugs, counterfeit drugs reduce sales in the pharmaceutical Industry, the company incurs additional cost due to anti-counterfeit measures, additional costs due to anti-counterfeit measures increases price of a pharma-product, as shown by the mean scores of 4.0, 3.65, 3.69, 3.67 and 3.85 respectively. The overall mean for pricing strategy of counterfeits was 3.77 indicating that most of the respondents agreed that pricing strategy has an impact on the financial performance of local generic drug manufacturers.

4.4.3 Legal and Institutional Framework and Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

The third objective sought to determine the effect of the legal and institutional framework on the financial performance of local generic companies. The summary of collected responses is presented in table 4.7

Table 4.7: Legal and Institutional Framework

	N	Mean	Std. Deviation
A pharmacist is enrolled in the regulatory affairs of the company	66	3.8485	.76946
Company faces many constraints with regulation of pharmaceutical products	66	3.9242	.63997
Regulatory Agencies do not play an effective role in curbing down counterfeit drugs	66	3.8636	.62969
I believe there is a weak policy that prohibits the manufacture, production, exportation, importation, distribution and sale of any counterfeit, adulterated drug	66	4.0000	.58177
Law enforcement agencies are not doing enough to curb down on counterfeiting	66	3.9545	.66638

Government is doing not enough to curb down on counterfeiting	66	3.6667	.90014
I believe the government should strongly prohibit the sale of pharmaceutical products in an open market without the permission of the Pharmacy and Poisons Board.	66	4.0152	.73364
Valid N (listwise)	66		

The table above depicts findings on the respondents' level of agreement with statements that regard to effects of the legal and institutional framework in the pharmaceutical industry on the performance of local generic manufacturers in Nairobi city county, Kenya. According to the findings, majority of the respondents agreed that; a pharmacist is enrolled in the regulatory affairs of the company, a company faces many constraints with regulation of pharmaceutical products, regulatory Agencies play an effective role in curbing down counterfeit drugs, government is doing enough to curb down on counterfeiting, they believe there is a weak policy that prohibits the manufacture, production, exportation, importation, distribution and sale of any counterfeit, adulterated, or fake drugs and that; they believe the government should strongly prohibits the sale of pharmaceutical drugs in an open market without the permission of the PPB as shown by the mean scores of 3.85, 4.92, 3.86, 4.0, 3.95, 3.67 and 4.01 respectively.

4.4.4 Financial Performance of Local Generic Manufacturers in Nairobi City County

The study dependent variable was aligned to an assessment of the financial performance of local generic drug manufacturers in Nairobi County.

Table 4.8: Financial Performance

	N	Mean	Std. Deviation
Counterfeiting reduces sales volume	66	3.7121	.79933
Counterfeiting reduces profitability	66	3.8182	.74233
Counterfeiting affects investors investment	66	3.6515	.79406

Valid N (listwise)	66		

According to the findings, majority of the respondents agreed that; Counterfeiting reduces sales volume, Counterfeiting reduces profitability and that Counterfeiting affects investors investment termed as the effects of counterfeiting influencing financial performance of their local generic drug manufacturer as shown by the mean scores of 3.71, 3.82 and 3.65 respectively. Based on the aggregate mean response of 3.72 and a standard deviation of 0.78 it can be concluded that respondents strongly agreed that counterfeiting has a negative effect on the financial performance of local generic drug manufacturers in Nairobi County.

4.5 Pearson Correlation Analysis

Correlation analysis measures the relationship that exists between the variables. The Pearson Correlation coefficient (r) was employed to investigate if there is significant association between the supply chain systems of counterfeits and financial performance of generic drug manufacturers, the pricing strategy of counterfeits and the financial performance of generic drug manufacturer, the legal and institutional framework and the financial performance of local generic drug manufacturers in Nairobi County. A correlation of 1 shows a perfect positive correlation while correlation of 0 or value close to zero shows no relationship or weak relationship respectively. -1 value, shows a negative perfect relationship and values close to it have strong negative relationship. . The table 4.7 shows the value of Pearson correlations for the variables.

Table 4.9 Pearson Correlation Coefficients Matrix

		Financial Performance	Supply Chain Systems	Pricing Strategy	Legal and Institutional Framework
Financial Performance	Pearson Correlation	1	.938**	.960**	.936**
	Sig. (2-tailed)		.000	.000	.000
	N	66	66	66	66
Supply Chain Systems	Pearson Correlation	.938**	1	.973**	.969**
	Sig. (2-tailed)	.000		.000	.000
	N	66	66	66	66
Pricing strategy	Pearson Correlation	.960**	.973**	1	.950**
	Sig. (2-tailed)	.000	.000		.000
	N	66	66	66	66
Legal and Institutional Framework	Pearson Correlation	.936**	.969**	.950**	1
	Sig. (2-tailed)	.000	.000	.000	
	N	66	66	66	66

**. Correlation is significant at the 0.01 level (2-tailed).

From the above table of correlation, the results show that there is a strong and positive association between supply chain systems of counterfeits and the financial performance of local generic drug manufacturers in Nairobi County with a correlation of 0.938 and a significant level of 0.000 less than p value of 0.05.

The correlation results also revealed a strong and positive association between the pricing strategy of counterfeits and the financial performance of local generic drug manufacturers in Nairobi County with a correlation of 0.960 and a significance value of 0.000<0.05.

Lastly, the legal and institutional framework had a strong relationship with the financial performance of local generic drug manufacturers in Nairobi with a correlation of 0.936 and a significance value of 0.000<0.05. The findings noted a strong influence on the financial performance of local generic drug manufacturers in Nairobi County.

4.6 Regression Analysis

Multi regression model was estimated to determine the effect of the supply chain systems of counterfeit drugs, pricing strategy of counterfeit drugs and the legal and institutional framework on the financial performance of local generic drug manufacturers in Nairobi County. Multiple linear regression was computed at 95 percent confidence interval to establish the relationship between independent variables and dependent variables. The relationship between the variables was tested at the 5% level where the R-square (coefficient of determination) was used to show the percentage of the changes in performance of local generic drug manufacturer as explained by the independent variables; Supply chain systems of counterfeit drugs, pricing strategy of counterfeits and the legal and institutional framework. Table 4.10 gives the regression model summary.

Table 4.10 Model Summary

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.964[a]	.929	.926	.20556

a. Predictors: (Constant), Legal and Institutional Framework, Pricing Strategy, Supply Chain Systems

Coefficient of determination shows the degree to which changes in the dependent variable financial performance can be explained by the change in the independent variables or the percentage of variation in the dependent variable that is explained by independent variables supply chain systems, pricing strategy and the legal and institutional framework.

Findings as illustrated in Table 4.10 reveal that the coefficient of determination (R square) equals 0.929. This shows that holding other factors constant, the predictor variables in this study explains 92.9% of the variation in financial performance. This indicates that there is a 92.9% chance that the financial performance of local generic drug manufacturers is influenced by the predictor variables being supply chain systems, pricing strategy and the legal and institutional framework. Thus, the variation due to other factors that were not considered in the study is 7.1% implying that the variables used command a significant variation in the financial performance of local generic drug manufacturers in Nairobi County. Table 4.11 gives the results of analysis of variance (ANOVA).

Table 4.11 Analysis of Variance

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	34.471	3	11.490	271.943	.000[b]
	Residual	2.620	62	.042		
	Total	37.091	65			

a. Dependent Variable: Financial Performance of local Generic Drug Manufacturers in Nairobi County

b. Predictors: (Constant), Legal and Institutional Framework, Pricing Strategy, Supply Chain Systems

From the Table, the significance value is 0.000 which is less than 0.05 the critical value at the 5% level in a 2-tailed test. This therefore shows that the model is statistically significant in predicting the financial performance of local generic drug manufacturers in Nairobi County with the use of the variables under study. The F calculated at 95% Level of confidence level was 271.94. Since F calculated is greater than the F critical (value = 5.34), this shows that the overall model was significant i.e. there is a significant relationship between counterfeiting and the performance of local generic drug manufacturer. The regression coefficient table is presented in table 4.12.

Table 4.12 Regression of the coefficient

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	-.290	.161		-1.798	.077
	Supply Chain Systems	-.230	.192	-.223	-1.197	.236
	Pricing Strategy	.893	.155	.851	5.761	.000
	Legal and Institutional Framework	.395	.159	.343	2.487	.016

a. Dependent Variable: Financial Performance of Local Generic drug Manufacturers in Nairobi County

The coefficients in Table 4.10 answer the regression equation relating the dependent and the independent variables. Testing the significance of the coefficients at 95% significance level, the table indicates that pricing strategy and the legal and institutional framework had a significance value less than 0.05 thus confirming the significance of the results, supply chain systems was found to be insignificant at 0.236 which is greater than p value=0.05. In addition, the independent variables indicated a positive coefficient indicating a positive relationship between the dependent and independent variables, only supply chain systems were negatively related to the performance of local generic drug manufacturers.

The regression equation model for the study was of the form; $\mathbf{Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \varepsilon)}$ where Y = Dependent variable (financial performance of registered local generic drug manufacturers in Nairobi County, Kenya.), β_0 = Constant (The intercept of the model), β= Coefficient of the X variables (independent variables), X_1=Supply chain systems, X_2= Pricing strategy of counterfeit drugs and X_3= Legal & Institutional framework. The resulting beta

coefficients of the regression model predicting the financial performance of local generic drug manufacturers in Nairobi County is presented as;

$$\mathbf{Y = -0.23X_1 + 0.893X_2 + 0.395X_3 + -0.29}$$

The constant was $\beta_{0=}$ -0.29 implying that the financial performance of local generic drug manufacturers decreases when all the independent variables are absent. The composite multiple regression model yielded a coefficient for supply chain systems $\beta_{1=}$ -0.23. From the findings, it can be indicated that while holding all other factors constant, a unit increase supply chain systems of counterfeit drugs would reduce the financial performance of local generic drug manufacturers by (-0.230).

In regard to the second objective, the findings revealed a coefficient for pricing strategy of counterfeit drugs $\beta_{2=}$ 0.893. Also, holding all other factors constant, a single unit increase in pricing strategy would increase the performance of drug manufacturers by 0.893.

Lastly, on the third objective the findings revealed coefficient for the legal and institutional framework $\beta_{3=}$ 0.395. The regression of coefficient implies that a single unit increase in legal and institutional framework while holding other factors constant would increase the performance of local generic drug manufacturers by 0.395. Strengthening the law by reforming of legislation and upholding the enforcements of laws against counterfeiting will lead to an increase in financial performance of the local generic drug manufacturers in Nairobi County.

4.7 Chapter Summary

This chapter aimed to present the research findings. The study included 66 respondents from all the registered local generic drug manufacturers in Nairobi County. The study was able to obtain sufficient response adequate for statistical analysis. The descriptive results, Pearson correlation analysis and regression analyses were conducted as guided by the study objectives.

CHAPTER FIVE: SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the summary of findings, conclusions, recommendations and recommendations for further studies as well.

5.2 Discussion of the Findings

The presentation is based on the purpose of this study which was to assess the effects of counterfeiting on the performance of local generic drug manufacturers in Nairobi County, Kenya. The discussion of findings is presented in sections in accordance with the study's objectives. The specific objectives of the study were; to examine the effect of supply chain systems of counterfeit drugs on the financial performance of local generic manufacturers in Nairobi County; to find out what effect the pricing strategy of counterfeit drugs has on the financial performance of local generic drug manufacturers in Nairobi County; and to establish the effects of the legal and institutional framework of pharmaceutical industry on the financial performance of local generic manufacturers in Nairobi County. The discussion of findings sought to review the study results in line with previously reviewed empirical evidence.

5.2.1 Supply Chain Systems and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

The findings in the study show that majority of the respondents agree that there is an integrated information system that tracks drugs from manufacture to point of use. The findings contradict Sahoo et al (2020) who showed that there is need of an integrated information system in the pharmaceutical supply chain to ensure traceability and security of the legitimate supply chain products. To explain the findings, we can use Kritchanchai (2014) whose study agrees with the findings of presence of a integrated information system from manufacture to

point of use but its fragmented with each player creating their own data communication language.

The results indicate agreement that there is presence of counterfeit drugs in the distribution network. The findings is in consensus with Munyao (2022b) who revealed that counterfeit drugs are a deeply rooted problem in the Kenyan pharmaceutical industry. The study revealed that many distributors increase counterfeit prevalence. This is in line with Kritchanchai (2014) who posits that the fragmentation of data communication language between the many players in the supply chain leads to a lack of integrity in the supply chain. The findings in this study also revealed that many respondents agreed that acquisition of counterfeits poses an ethical dilemma as it benefits the buyer and illegal seller at the cost of legitimate producer. The findings in this study are consistent with Kanwar & Rahim (2019) who posits that multiple stakeholders in the supply chain have multiple motives with regards to ethical health paradigm and an ethical dilemma arises the sale of counterfeit drugs is seen as legally wrong but it provides benefits to the illegal seller. This explains why counterfeit drugs make it into the supply chain because the illegal seller has a financial motive of making profits from the sale of counterfeit drugs although it is an unlawful activity.

5.2.2 Pricing Strategy of Counterfeit Drugs and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

According to the descriptive results, the study established that majority of the respondents were in agreement that the low price of counterfeit drugs is a motivator for increased supply, demand and consumption of counterfeit drugs. The findings indicated that dealers of counterfeit drugs often bypass most of these costs, hence making their products relatively cheaper. Similar sentiments were established in the study by Said (2016) in her objective to find influence of consumer demand found that consumers are more likely to buy counterfeit drugs due to their low price compared to high price of a genuine product. This leads to a demand on the counterfeit drugs and this is a great motivator for the increased in supply and distribution of counterfeit drugs. The findings indicate agreement that counterfeit drugs reduce sales of

legitimate products in the pharmaceutical industry. This finding is in consensus with Wanjau & Muthiani (2012) who stated that in high price sensitive markets the price advantages of counterfeit drugs reduces the sale of genuine drugs as consumers will always opt for the cheaper option. The reduction in sales therefore, has a negative impact on the financial performance of the drug manufacturer.

The findings revealed that majority of the participants were in agreement that the manufacturer incurs additional costs due to anti counterfeit measures and that additional cost due to these measures increases the price of a pharmaceutical product. The results are supported by Weru (2018) who stated that there are direct and indirect costs during production of a pharmaceutical product. Technologies and infrastructure need to be put in place to effectively run the manufacturing plant. With regards to counterfeiting, manufacturers face additional costs to add anti counterfeit measures to their products to safeguard their products from manipulation as it is distributed from one stakeholder to another. The author further states that in order to have sustainable growth of the drug manufacturer, the additional cost to production needs to be covered. In order to cover for the increased expenses the price must likewise increase to fulfil the company's goal of making profits.

5.2.3 Legal and Institutional Framework and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

The results denoted that the respondents agreed that a pharmacist is required in to deal with the regulatory affairs of the manufacturing company. This is in line with PPB (2020) which requires a licensed pharmacist to handle the legal affairs of the manufacturer. The aim of registering and licensing of a pharmacist is to ensure that the business is dealing in drugs within the country which are regulated. The respondents agreed that a company faces many constraints with regulation of pharmaceutical products. The results share same opinion with Ajiffa (2015) who suggested that regulatory bodies should collaborate with WHO to ease and lessen trade and technical hurdles to allow stakeholders in the pharmaceutical field to grow and expand their market.

The analysis revealed an agreement among participants that the regulatory agencies and the government in general are not doing enough to curb down on counterfeiting in the pharmaceutical industry. Similar sentiments are shared by Ongola (2014) and Kirunga (2019) who are critical on the ability of regulatory agencies to prevent counterfeiting due to the limited resources and infrastructure available in the fight against counterfeiting. The authors also criticises the limitation of skilled workforce and manpower to handle matters relating to IPRs.

The results revealed that many of the respondents agreed that the Anti Counterfeit Act is a weak act that prohibits manufacture, production, exportation,, importation distribution and sale of counterfeit drugs. This has been argued by Ongola (2014) who suggested the Act needs to be amended to deal with current environmental factors. According to the descriptive results majority of the respondents agreed that the government should strongly prohibit sale of pharmaceutical drugs in an open market without the permission of Pharmacy and Poisons Board. This finding is emphasized by Isles (2017) who noted the rise in 'online pharmacies' where in a click of a button a consumer can buy pharmaceutical drugs in the comfort of their home. The sale of pharmaceuticals through the internet is hardly regulated and this increases the chances of counterfeit drugs getting into the pharmaceutical market.

The general objective of the study was to determine the effect of counterfeiting on the financial performance of the local generic drug manufacturer. According to descriptive results, majority of the respondents agreed that counterfeiting reduces the sales volume of pharmaceutical products by the manufacturer. This is as a result of counterfeit products being in direct competition with legitimate pharmaceutical products. With every sale of a counterfeit product along the supply chain means there is a loss of sales for the legitimate manufacture. The findings also revealed counterfeiting reduces profitability. The argument behind the statement is, with a reduction in sales of legitimate pharmaceutical product leads to reduction of revenue to cater for the expenses of manufacturing. Furthermore, the manufacturer will incur additional costs in prevention and suppression of counterfeit drugs which additionally reduces revenue. The participants in the study agreed that counterfeiting affects investors' investment. Investors

are less likely to invest in legitimate manufacturers if they believe that their products are at risk of being counterfeited and this limits the growth and expansion of local drug manufacturers

5.3 Conclusions

5.3.1 Supply Chain Systems and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

On the supply chain systems the study concluded that the supply chain plays an integral part in the influx of counterfeit drugs in the pharmaceutical industry. A fragmented information system and availability of many distributors and other stake holders makes an ideal environment for influx of counterfeit drugs. This has a negative impact on the financial performance of a local generic drug manufacturer as reduced profitability as more resources and time is utilised in the suppression of counterfeit drugs.

Based on the study findings the study concluded that the presence of counterfeit drugs in the supply chain can create uncertainty and risk for legitimate manufacturers, making it more difficult for them to plan and operate effectively. With the uncertainty and risk investors are less likely to invest in the drug manufacturing sector if they believe that their products are at risk of being counterfeited.

For the local generic drug manufacturers, it is very evident that specific interventions, from repression to prevention are absolutely necessary. Stopping counterfeit goods from entering the supply chain is the first crucial step. Should that not be fulfilled, actions must be taken to effectively detect any circulating counterfeit drugs in the pharmaceutical supply chain.

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5.3.2 Pricing Strategy of Counterfeit Drugs and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

The study concludes that the low pricing of counterfeit drugs has a negative impact on the financial performance of a local generic drug manufacturer. Counterfeit drugs reduce the sale

volumes of legitimate drugs by stealing the market share of the legitimate drugs. Moreover, counterfeiting increases cost for legitimate manufacturers as they have to spend more on measures to prevent counterfeiting resulting in reduction in profitability of the drug manufacturer.

5.3.3 The Legal and Institutional Framework and Financial Performance of Local Generic Drug Manufacturers in Nairobi County, Kenya

According to the study, the regulatory framework plays a critical role in the influx of counterfeit drugs in the pharmaceutical industry. The presence of a weak regulatory framework as a result of limited resources to the regulatory and law enforcement agencies, lack of infrastructure to effectively combat counterfeiting, a small workforce and a lack of specialization and division of labour has a negative impact on the financial performance of local generic drug manufacturers. To strengthen regulatory capacity, robust legislative measures must be implemented.

5.4 Recommendations

The issue on the presence of a weak supply chain of locally manufactured drugs raises concerns as the respondents agreed to some aspects. This study recommends that the government and other policy actors as well as the managers in the sampled firms to collaborate and review the existing chain so as to help identify loopholes therein so as to protect the very market from circulation of unwanted counterfeited drugs.

Having an effective regulatory and enforcement regime in place is one of the most effective tools for combating counterfeit drugs. Collaboration between regulatory and law enforcement agencies is critical, particularly when exchanging criminal intelligence about organized crime groups engaged in counterfeit activities.

Local drug manufacturers and government should be proactive and collaborate closely, either by increasing infrastructure and investment capital to encourage local generic drug manufacturers to meet international standards, or by assisting producers in developing techniques to improve product tracing and tracking.

Transparency is required to maintain a robust and secure supply chain. That is, regulators should indeed monitor the drug manufacturing sites of pharmaceutical products and track the path through the supply chain to ensure that the quality of pharmaceutical products is not jeopardized.

Raising public awareness about the quality of medicine and the risks associated with using counterfeit health products through educational campaigns is an important tool in combating counterfeiting. This in turn improves consumer vigilance when purchasing medication and there is a greater demand for safety measures with regards to pharmaceutical goods.

Local drug manufacturers can curb down on counterfeiting by investing in anti counterfeit technologies. Developing new technologies to detect and prevent counterfeiting can be effective in combating counterfeiting. This may include developing new packing, labelling and authentication technologies and utilizing block chain technology to improve traceability and supply chain security.

From the study, it is essential that the country assesses the effectiveness of its existing drug control laws in preventing the trafficking of counterfeit drugs. With the rise of internet users and rise of online platforms for sale of pharmaceutical drugs existing regulations need to amended to cater for same. If the laws are inadequate, they must be quickly strengthened to aid in the detection and eradication of counterfeit pharmaceuticals and the criminal organizations behind them.

5.5 Suggestions for Further Studies

The researcher recommends longitudinal studies which will track the performance of drug manufacturers over time, this would provide a more comprehensive understanding on the effects of counterfeiting on financial performance of local generic drug manufacturers.

The researcher suggests that a study be conducted in which other counties besides Nairobi are studied to find out if there will be similar outcomes as in this research and if the results can be generalized.

Further research work should be conducted in investigating the role of online market places and social media in the distribution of counterfeit drugs in Nairobi County. This can include analysing the online presence of counterfeiters and identifying online platforms used to sell counterfeit drugs.

5.6 Limitations of the Study

One of the limitations presenting in the study is data availability. Due to the complexity and sensitivity of the data the researcher did not find studies with comprehensive financial analysis of local drug manufacturers where revenue, profit margins and other financial metrics before and after counterfeiting are analysed. Collaboration between researchers, drug manufacturers and government agencies would be beneficial in order to gather more accurate data on impact of counterfeiting on local drug manufacturers.

Another limitation presenting in the study is resources. The study focused on local generic drug manufacturers in Nairobi County, as looking at local drug manufacturers in Kenya would be expensive and time consuming. The scope of the study was on local generic drug manufacturers hence the findings in the study cannot be generalized drug manufacturers in Kenya. Subsequent studies should be done in other counties so the findings can be generalized.

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APPENDICES

Appendix Ⅰ: Letter of Introduction

Brian Bosire

P.O Box 60113

Nairobi,

Date.....

Company Manager,

.....

Nairobi, Kenya.

Dear Sir/ Madam,

RE: PERMISSION TO CONDUCT A RESEARCH STUDY IN YOUR PREMISES

I am a post-graduate student at **Strathmore Business School**. I wish to conduct my research in your firm. My research is on the effects of counterfeiting on the performance of local generic drug manufacturers in Nairobi County. I thus request that the Sales, Regulatory and Company Managers of the pharmaceutical company to take part in the study.

The findings in the research will be shared with you and will remain confidential.

The survey will take no more than **15 minutes** to complete. Any facilitation and assistance you give in the study will be highly appreciated. Please advise if I can proceed with this by writing back to the address above. For any further inquiries or clarifications about the research you can contact me on 0725651581.

Yours Sincerely,

Dr. Brian Bosire

Appendix II : Questionnaire

PART A: Demographic/ Company Characteristics

The Survey Questions will take no more than **15 minutes** to complete. Any facilitation and assistance you give in the study will be highly appreciated. Kindly take part and tick where possible.

PART A: BACKGOUND INFORMATION OF RESPONDENTS

1. Indicate your Gender
   a) Male [ ]
   b) Female [ ]
2. Highest level of education
   a) Secondary level [ ]
   b) College level [ ]
   c) University level [ ]
   d) Others specify ……
3. Kindly indicate your age bracket
   a) 21 to 30 years [ ]
   b) 31 to 40 years [ ]
   c) 41 - 50 years [ ]
   d) over 50 years [ ]
4. Kindly indicate how long have you been working in this organization
   a) 1 - 2 years [ ]
   b) 2 – 3 years [ ]
   c) 3 – 4 years [ ]
   d) 5 years and above [ ]
5. Position/ Job Title within the organization:
   ……
   ……
6. What is your company's position in the pharmaceutical value chain? (Can Select/Tick More Than One)
   a) Generic drug production [ ]
   b) Generic drugs raw materials production [ ]
   c) Production of generic bio-similar products [ ]
   d) Packaging of Generic drugs [ ]
   e) Others [ ]

PART B: SUPPLY CHAIN SYSTEMS

This section we assess the effect of supply chain systems on the performance of local generic drug manufacturers.

7. Kindly indicate by ticking your level of agreement with the following statements.

Statements	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
There is an integrated information system that tracks drugs from manufacture to point of use.					
Presence of counterfeit drugs in the distribution chain,					
Many distributors increase the chances of counterfeit prevalence.					
I believe that acquisition of counterfeits poses an ethical dilemma as it benefits the buyer and illegal seller at the cost of the legitimate producer and with fewer taxes being paid throughout the supply chain					
Counterfeits disrupt the distribution network.					

PART C: PRICING STRATEGY OF COUNTERFEIT DRUGS

This section we assess the effect of pricing of counterfeits on the performance of local generic drug manufacturers.

8. Kindly indicate by ticking your level of agreement with the following statements.

Statements	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
There is an infiltration of counterfeit drugs in Kenya.					
The low price of counterfeit drugs is a motivator for increased supply, demand and consumption of counterfeit drugs.					
Counterfeit drugs reduce sales in the pharmaceutical Industry.					
The company incurs additional cost due to anti-counterfeit measures.					
Additional costs due to anti-counterfeit measures increases price of a pharma-product					
I believe that pricing strategy promotes counterfeiting in that counterfeits have price advantages of relative to genuine products					

9. **PART D: LEGAL AND INSTITUTIONAL FRAMEWORK**

This section we assess the effects of legal and institutional framework in the pharmaceutical industry on the performance of local generic manufacturers.

2) Kindly indicate by ticking the level of agreement to these statements.

Statements	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
A pharmacist is enrolled in the regulatory affairs of the company.					
Company faces many constraints with regulation of					

pharmaceutical products.					
Regulatory Agencies play an effective role in curbing down counterfeit drugs.					
Government is doing enough to curb down on counterfeiting.					
I believe there is a weak act that prohibits the manufacture, production, exportation, importation, distribution and sale of any counterfeit, adulterated, or fake drugs					
I believe the government should strongly prohibits the sale of pharmaceutical drugs in an open market without the permission of the Pharmacy and poisons Board.					

PART E: PERFORMANCE OF LOCAL GENERIC MANUFACTURERS

This section shows the effect of counterfeiting on the financial performance of local generic drug manufacturer.

10. Kindly indicate by ticking the level of agreement to these statements.

Statements	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
Counterfeiting reduces sales volume					
Counterfeiting reduces profitability					
Counterfeiting affects investors investment					

THANK YOU FOR YOUR PARTICIPATION AND TIME!

Appendix 111: Ethical Research Permit from Strathmore University

Strathmore UNIVERSITY

14th November 2022

Dr Bosire Brian,
drbbosire@gmail.com

Dear Dr Bosire,

RE: Effects of Counterfeiting on the Performance of Local Drug Manufacturers

This is to inform you that SU-ISERC has reviewed and **approved** your above **SU- master's** research proposal. Your application reference number is **SU-ISERC1506/22.** The approval period is from **14th November 2022 to 13th November 2023.**

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, and MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-ISERC.
iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-ISERC within 48 hours of notification
iv. Any changes, anticipated or otherwise, that may increase the risks or affect the safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-ISERC within 48 hours
v. Clearance for the export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days before the expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days of completion of the study to SU-ISERC.

Before commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology, and Innovation (NACOSTI) https://research-portal.nacosti.go.ke/ and obtain other clearances needed.

Yours sincerely,

for: Dr Ben Ngoye,
Secretary; SU-ISERC

Cc: Prof Fred Were,
Chairperson; SU-ISERC

STRATHMORE UNIVERSITY INSTITUTIONAL SCIENTIFIC AND ETHICAL REVIEW COMMITTEE
(SU-ISERC)
14-Nov-2022
Email:ethicsreview@strathmore.edu
P.O BOX 59857-00200
NAIROBI-KENYA

Ole Sangale Rd, Madaraka Estate. PO Box 59857-00200, Nairobi, Kenya. Tel +254 (0)703 034000
Email admissions@strathmore.edu www.strathmore.edu

Appendix IV: Research Permit from NACOSTI

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **200738**

Date of Issue: **06/December/2022**

RESEARCH LICENSE

This is to Certify that Dr.. Brian Bosire of Strathmore University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: EFFECTS OF COUNTERFEITING ON THE PERFORMANCE OF LOCAL GENERIC DRUG MANUFACTURERS IN NAIROBI COUNTY for the period ending : 06/December/2023.

License No: **NACOSTI/P/22/22351**

200738

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions