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ANALYSIS OF COUNTERFEIT- DRUG-PREVENTION STRATEGIES ON FINANCIAL PERFORMANCE OF NAIROBI'S DRUG RETAILING PHARMACIES

MOLLY CHERUTO

MBA2018/111867

A THESIS PROPOSAL SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF BUSINESS ADMINISTRATION AT STRATHMORE UNIVERSITY BUSINESS SCHOOL

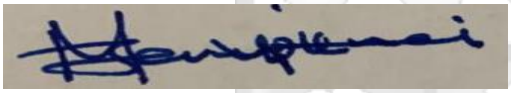
JULY 2021

DECLARATION

This research project is my original work and has not been presented for a degree in any other University.

MOLLY CHERUTO

MBA2018/111867

Signed:  **Date:** 2nd July 2021

This research proposal has been submitted for examination with my approval as the University Supervisor.

Dr. Joseph Onyango

Senior Lecturer

Strathmore University Business School

Signed:  **Date:** 2nd July 2021

ABSTRACT

Kenya Association of Manufacturers indicates that up to 40% of the medications in circulation are falsified. The main implications of this high proportion are the ineffective treatment of the population and disruptions in the pricing mechanism of medicines in the country. These concerns are of pertinence to private pharmacies seeking to avail medication to the population; inefficacious medication results in a loss of trust by patients. This reduces customer flow whereas ineffective pricing results in unjustifiably low costs by competitors sourcing products from competitors' falsified outlets. Both these concerns have implications for the financial performance of pharmacies. The study is guided by Reasoned Action and Planned Behaviour's theory with the assertion that an understanding of the merits of the anticounterfeiting approaches would inspire action towards proper implementation. Implementation of the approaches would serve to improve the performance of the pharmacies. The general thrust of extant empirical findings was that anticounterfeiting approaches positively impact the performance of pharmacies. The central objective of the research was to examine the anti-counterfeiting strategies employed by retail pharmacies in Nairobi County and their impact on the financial performance of the retail pharmacies. The population of the study consists of pharmacies in Nairobi County. Therefore, the specific objectives were to establish the effect of chemical-physical anti-falsified strategies on the performance of pharmaceutical retail pharmacies in Nairobi. To establish the effect of tracking anti-falsified strategies on the performance of pharmaceutical retail pharmacies in Nairobi. To establish the effect of supply chain integration anti-falsified strategies on the performance of pharmaceutical retail pharmacies in Nairobi. Data was collected from retail pharmacies in Nairobi County through the use of questionnaires. An Ordinary Least Square regression model was then used to address the objectives of the study. Findings indicated that none of the approaches had a bearing on the financial performance of pharmacies in Nairobi. Therefore, the conclusion was that current anti-counterfeiting approaches were inefficacious in impacting the performance of pharmacies. The recommendation forthcoming from the finding is that pharmacies should assess their rigor in implementing anticounterfeiting approaches as extant literature indicates that there is a link between proper utilization of the approaches and performance of pharmacies.

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LIST OF ABBREVIATIONS

COMESA – Common Market for Eastern and Southern Africa

FDA – Food and Drug Administration

GPHF – Global Pharma Health Fund

HIV/AIDS – Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome

IACC – The International Anti-Counterfeiting Coalition

IMPACT - The International Medical Products Anti-Counterfeiting Taskforce

LMICs – Lower- and Middle-Income Countries

RFID - radio frequency identification tags (RFID)

TRIPS – Trade-Related Aspects of Intellectual Property Rights

UNICJRI – United Nations Interregional Crime and Justice Research Institute

US – United Sates

WHO – World Health Organization

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I acknowledge the Almighty God for his abundance and blessings that have been my pillar in this research journey. I acknowledge the great support of my supervisor Dr. Joseph Onyango for his continuous support and encouragement. Lastly, I acknowledge my Strathmore family and friends for their overwhelming support.

DEDICATION

I dedicate this research project to my Family especially my Son's Bill and Antony. You have been my steadfast support throughout the journey.

CHAPTER ONE
INTRODUCTION

1.1 Introduction

This chapter introduces the concept of drug counterfeiting and the entails of the study. The section further presents an overview of the constructs upon which the study is founded. Thus, the constructs discussed are counterfeits, strategy, anticounterfeiting strategies, and the variables considered in the study. Discussed in this section as well are the overview of the pharmaceutical industry in Nairobi. After the discussion on the industry are outlines of the problem statement, objectives, research questions, scope, and significance for the study. It is noteworthy that the term falsified medicines, as used in the Kenyan context in the study, is interchangeable with the term counterfeit medicines as used in mainstream literature.

1.2 Background of the Study

The World Health Organization (WHO), in an exposition on substandard and falsified medical products, defines substandard medicine as entailing 'out of specification' medical products that do not meet the required stipulations of the products or that are of subpar quality in comparison to the originals. WHO defines falsified medicines as those that intentionally misrepresent the composition and identity of the original products (World Health Organization, 2018). In Kenya, from a legal perspective, counterfeiting is defined as the manufacture, production, packaging, re-packaging, labeling or making, of any goods in such ways as to result in goods that are considerably similar to the protected goods (GOK, 2015).

A notable mention of counterfeiting of drugs as an issue or threat to pharmaceuticals and, in extension, human health was mentioned at the WHO conference of experts on the Rational Use of Drugs; this was held in 1985 in Nairobi, Kenya (WHO, 2017). The United Nations Interregional Crime and Justice Research Institute (UNICJRI) deems counterfeiting the crime of the 21st century as trafficking of falsified pharma kinetics (drugs) is now the most notable proliferating criminal enterprise. The International Anti-Counterfeiting Coalition (IACC) estimates a value of more than US$ 900 billion is lost annually, with Kenya contributing over US$1.87 billion (Stevenson & Busby, 2015).

In a comparative evaluation of the magnitude of counterfeiting by region, El-Jardali, Akl, Fadlallah, Oliver, Saleh, El-Bawab, and Hamra (2015) point out that whereas up to 10% of global medication consist of falsified drugs, only 1% of the same is viewed in the United States and Western Europe countries; a figure that contrasts with that in African, Asia, and Middle Eastern Countries where up to 30% of medicines are counterfeit. The WHO (2016) estimates that this figure can rise to 50%, and the effects of counterfeit drugs are mostly impactful on low-and-middle-income countries. Among the tenets of sustainable development, to be achieved by the year 2030, are such aspects as safe, high quality, and affordable (United Nations, 2015). However, the attainment of this sustainable development goal is hampered by compromised quality as fully counterfeit drugs present an issue of concern to the public. This threat is most apparent in Africa, Latin America, and South-East Asia (Wirtz, Hogerzeil, Gray, Bigdeli de Joncheere & Ewen, 2017). In Kenya, drug counterfeiting had become such a grievous health hazard that in 2008 Act number 13 on Anti- Counterfeit was enacted by parliament.

As pertains to the prevalence of counterfeit drugs, the situation in Kenya is dire (Marete, 2014). Therefore, establishing an anti-counterfeiting strategy is of value to all stakeholders in the nation's pharmaceutical industry. The Kenya Association of Manufacturers (KAM, 2018) estimated that the infiltration of counterfeit drugs in Kenya's pharmaceutical industry may be as high as 40%. Wafula et al. (2017) place the estimate at 17%, whereas Ndwigah, Stergachis, Abuga, Mugo, and Kibwage (2018) conducted a related study in Embu County where they observed that none of the sampled medications were counterfeit. The significance of falsified medicine penetration is corroborated by the Pharmacy and Poisons Board (PPB), which reports that counterfeits cost the Kenyan pharmaceutical industry over 50 billion shillings ($650 million) and the government 19 billion shillings ($250 million) in annual taxes.

The Nairobi county pharmaceutical companies' operations contribute up to 12 billion shillings (63%) of the falsified pharmaceutical damage in Kenya. KAM (2018) estimates that the losses incurred by pharmaceutical manufacturers in the country are as high as 30 percent in revenue. Further impact is experienced in that 27 percent of jobs are also lost to annual counterfeiting endeavors. The earliest falsified medicines/drugs encountered in Kenya were skin ointments (GOK, 2015). Other recently clear cases were reported in anti-malarial drugs with the specific drugs in question, including Duo-Cotexcin (dihydroartemisinic-piperaquine tablets that lacked

piperaquine), common antibiotics, and fast-moving analgesics. Other commonly targeted drugs are lifestyle medicines, hormones, antibiotics, steroids, and antihistamines (PPB, 2018; Muthiani & Wanjau, 2012). Mehta (2006) further reveals that common brand names and easily manufactured drugs also present as targeted entities for counterfeiters. Likewise, as Mehta (2006) observes over-the-counter medications and government-supplied medicines present as prime counterfeiting targets.

As expected, the costs to the pharmaceutical industry are high as deaths, disabilities, injury, and other perils are visited upon the consumers of the falsified drugs (PPB, 2018). As posited by Kessy and Haule (2010), other consequences of this loss present in the loss of confidence in the pharmaceutical industry as professionals relying on the drugs and patients cannot reap the anticipated benefits of prescribed medications.

Extant literature primarily focuses on the control of supply factors of falsified drugs, with few exploring the influencing factors behind the upsurge of the practice. Among the commonly identified influencers of counterfeiting, as posited by Kessy and Haule (2010), are weak legal frameworks, costly importation charges, and consumers' attitude to counterfeiting. As reported by the World Health Organization (2015), the falsified drug proportion rose to 25% in 2015, among developing nations, as the figure could be as high as 50% for some nations in the region. From a local perspective, about 30% of the drugs sold to unsuspecting patients may be counterfeit; the losses resulting from this estimation could be as high as 10 billion shillings (Rajab, 2016).

From a manufacturer’s vantage point, counterfeits erode brand value (Muthiani & Wanjau, 2012). Additionally, the volume of sales, prices, and royalties are generally affected due to the menace. As Marete (2014) further observes, the level of investment and costs associated with operating businesses also increases with counterfeiting incidences. It is, therefore in the best interest of stakeholders to ensure that counterfeiting is curbed. Removing falsified medicines from the marketplace can only be achieved by implementing productive and innovative approaches to ensure maximum impact in preventing incidences of counterfeiting; this assertion motivates the current study.

1.2.1 Pharmaceutical industry

Counterfeiting is the deliberate infringement of protected Intellectual Property Rights to make profits (Grossman & Sharpiro, 2008). Falsified drugs are those that are manufactured below established drug and pharmaceutical standards of quality. The Kenya Anti-Counterfeit Act (2008) defines counterfeit goods as those products that have been manufactured, produced, packed, re-packed, and labeled as under an original name that has already been verified as safe for use. This is done to confuse the consumer into purchasing medications under false representation. They are dangerous to patients' health and ineffective for treating diseases and making some resistant to drugs and treatment. Counterfeits are purposely and deceptively mislabeled with bigger brand names but does not discriminate between Branded and generic drugs.

According to Nayyar, Breman, and Herrington (2015), counterfeiting as a practice entails the contravention of patent rights via developing similar or subpar quality products. Physical mimicry of goods, for example, through using the same color of the product, also constitutes counterfeiting as the intent of the individuals perpetrating the act is to fool the final consumer (Nsimba, 2008). Dahiya (2008), Ndwigah, Stergachis, Abuga, Mugo and Kibwage (2018) notes that antibiotics, antiretroviral drugs, anti-malarial drugs, anti-cancer and anti-viral drugs are the most falsified medicines in the health sector of developing economies. Muthiani (2012) reported that over-the-counter drugs (OCT) are among the most falsified medicines. Their presence in the local market threatens pharmacies' ability to deliver quality health services to the community and is a serious hindrance to their overall performance. Since falsification is dependent on the brand name of established pharmaceutical manufacturing companies, their prevalence also affects their brand reputation (Ozawa, 2018). Counterfeiting affects sales volume, pricing strategies, brand value and reputation of the affected pharmacies, investment in quality healthcare delivery, and operational cost, especially in instances with legal consequences. Further, some counterfeiting strategies are costly, impacting the capital available for investment (Miller & Winegarden, 2020).

1.2.2 The concept of strategy as applied to pharmaceutical counterfeiting

Strategy is an articulated procedure in decision-making. The main aim of strategy is to ensure that the current situation is well known and that the direction, courses of action, environment, and relative competitiveness of a firm are known to those affected (Rumelt & Richards, 2015). Thus,

it is apparent that strategies are pivotal in gaining a competitive advantage (Sloan, 2015). Cetinkaya (2014) posits that a company's strategy determines its direction. The direction, as posited, entails the vision, perspectives, and goals of the firm in light of the environment, corporate fabric, and scope. This assertion implies that a company's survivability would be determined in light of pressure from its environment (Adeleke, 2015).

In light of the conceptualization of strategies as courses of action (Rumelt & Richards, 2015) and as a reaction to a business's environment (Cetinkaya, 2014), the author of the study considers the approaches taken by pharmacies to combat the menace of counterfeiting (an external environment concern) as comprising the strategies constituting the independent variables under consideration. As Habyalimana et al. (2015) observe, a wide range of approaches have been taken to this end, involving the placement of gatekeeps and technologies that address different aspects of counterfeiting. The United States Pharmacopoeia (USP) and World Health Organization (WHO) (2018) identity, assay, disintegration, and dissolution as some of the tests required to evaluate the quality of medicines. Ndegwa et al. (2018) incorporated identity, assay, dissolution, and microbial load as measures of medicine purity. QIAN (2014) identified quality differentiation and price signaling as indicators of product quality. Petersen, Held, and Heide (2017) noted that Physical inspection, thin-layer chromatography (TLC), color reaction testing, and disintegration testing are among the standard tests for testing of substandard and falsified medical products. The study notes that cheaper methods for the surveillance of medicine quality included the use of portable Raman spectroscopy instruments, such as the hand-held TruScan RM and supply chain partnering.

Khan et al. (2013), in their study on purity levels of pharmaceuticals in the Indian market, applied random sampling and hypothesized testing in terms of Visual examination, HPLC, UV, and dissolution. Marete (2014) noted overt, covert and tracked, and trace technologies were among the most common strategies used to curb counterfeiting. Ozawa (2018), in his meta-analysis noted that some counterfeit strategies are too expensive and require a lot of unavailable technical skills and resources that may not be available in developing economies. The most prevalent strategies in these regions are the cheapest and more accessible strategies, including chemical analyses such as HPLC, dissolution, disintegration, TLC, GPHF-Minilab, UV spectrometry, colorimetry, mass

spectrometry, physical confirmation strategies, tracking strategies and supply chain integration strategies.

As applied to the current study, the foregoing discussion on strategies center on the specific counterfeiting approaches taken by pharmacies in Nairobi County. This study will consider these three strategies – chemico-physical strategies, tracking strategies, and supply chain integration strategies; these are subsequently discussed. This is because these are the cheapest strategies adopted in analyzing pharmaceutical medicines' purity and the ones that most health facilities in developing economies employ (Kovacs et al., 2014).

1.2.3 Chemico-physical strategies

Chemico-physical strategies generally leverage drugs' immediate chemical and physical attributes to assess their authenticity (Habyalimana et al., 2015). Approaches applied to this end involve visual cues, tests based on the uniformity of mass, friability of tablets, disintegration, and fluorescence (Habyalimana et al., 2015). These approaches are predominantly used in the distribution of drugs in LMICs as they offer cheaper options by which to assess the authenticity of medication (Kovacs et al., 2014). In the current study, chemico-physical strategies are assessed through the sub-variables visual packaging cues, solubility tests, uniformity tests, friability tests, and florescence tests (Habyalimana et al., 2015; Bajema, Barstis and Lieberman, 2013; Deisingh, 2005).

1.2.4 Tracking strategies

Tracking approaches involve using specific markers input into medications to verify their authenticity (Hamid & Asher, 2014). A wide range of markers have been investigated, and these offer varying utility in the bid to ensure a clandestine supply chain that is free from exploitation by counterfeiting entities; these technologies include – bar codes, radio frequency identification tags (RFID) technology, physical unclonable functions (PUF), Nanoguardian and biodegradable drug-laden code labels among others (Arppe & Sørensen, 2017; Hamid and Asher; 2014; Arppe and Sørensen, 2017; Hall, 2012; Fei & Liu, 2016). In the current study, tracking strategies applicable to the population under study include – bar code technology, Quick response codes (QR codes), RFID codes, biodegradable labels, and unclonable tags (Hamid and Asher, 2014; Fei & Liu, 2016; Bansal et al., 2012).

1.2.5 Supply chain integration strategies

According to Dégardin, Roggo and Margot (2014), medical counterfeits take different forms and operate in varied manners – a factor that leads to complex anti-falsified mechanisms. Efficacious addressing of the challenge of falsified medication would require a synergized approach in identifying and addressing loopholes and bottlenecks in the supply mechanism by integrating the supply function from manufacturer to final consumer (Dégardin, Roggo and Margot, 2014). The main approaches in ensuring this end thus involve intergovernmental collaboration, integrated information systems, training of personnel, education of consumers, and establishment of fraud-reporting mechanisms, among other functions (Liberman, 2012; Kumar, Dieveney & Dieveney, 2009; Dégardin, Roggo & Margot, 2014). In the current study, supply chain integration strategies are addressed through consideration of the sub-variables integration of information systems, adequate staff training on protocols, customer sensitization and empowerment, affiliation with anticounterfeiting programs/initiatives, sourcing from similar suppliers (Said, 2010; Stevenson & Busby, 2015; Fadlallah et al. 2016; Kumar, Dieveney & Dieveney, 2009).

1.2.6 Anti-Counterfeiting vis-à-vis financial performance

Counterfeiting may be difficult to eliminate permanently. The purpose of anti-counterfeiting strategies is to make it unattractive and costly for criminals to target its products. This can be achieved by using safeguards that combine anti-falsified policy, technologies, robust quality assurance processes, and legal enforcement (OECD, 1998). The integration of anti-counterfeiting strategies in quality management initiatives is shown by Wilcock and Boys (2014) to reduce risk in the supply chain. Anticounterfeiting approaches work as a proactive and effective deterrent in preventing future attacks. Different approaches that are easily understood by all and more so the consumers should be commonly used and traced and recorded for effectiveness.

The technology employed in counterfeiting needs to be combined with other measures such as tough legislation and regulations against counterfeiting, rigorous enforcement, stiffer penalties, transparency, and diligent surveillance Fadlallah et al., 2016). As Wafula (2013) notes, the legislative landscape pertaining to retail pharmacies remains underdeveloped despite the first-

response role served by such establishments in Kenya (Wafula, Abuya, Amin & Goodman, 2014). Ziance (2008) highlights that the strategies applied by the pharma industry in addressing falsified medicines are often associated with increased expense and changes to the general structuring of business processes. These factors affect the efficiency and financial productivity of the companies involved. It is therefore evident that the role of strategy implementation in anti-counterfeiting measures involve a financial aspect; hence the current study explores, as an objective, the implications of various strategies on the financial performance of the manufacturing and distribution companies involved as assessed through sales volumes, revenue, and frequency of sales (Davidson, 2011).

1.2.7 Pharmaceutical companies in Nairobi

Forty-three companies comprise the Pharmaceutical industry in Nairobi (KAM, 2018); Kenya Pharmacy Board, (2017). The main roles performed by pharmacies are facilitated by pharmacists and pharmaceutical technologists. Up to 8% of Kenya's GDP goes to healthcare, with half of this allocation spent within Nairobi (Marete, 2014).

The Kenya Medical Suppliers Agency (KEMSA) is responsible for delivering pharmaceutical products to public facilities; this function is performed under the auspice of the government (Kabiru, 2013). Dloch, Bush, and Campbell (1993) report that the industry is the fastest growing region. The opportunities that present in the industry's growth provide lucrative prospects for importers, manufacturers firms, retailers of drugs, and those involved in the distribution of products. Kenya presents as the largest pharmaceutical product producer in Common Market for Eastern and Southern Africa (COMESA). The country supplies about 50% of pharmaceutical products in the COMESA market. This contribution is valued at more than $500 million, and by 2020, the contribution is likely to expand at a compound growth rate of 11 percent annually 2020 (Muthiani & Wanjau, 2012).

1.3 Problem Statement

Achieving universal healthcare is one of the world goals and one of the key components of achieving these goals is ensuring increased access to essential medicines. While access to health services and health outcomes has improved significantly in the last few decades, there has also been an increase in the volume of substandard and falsified medicines, making it a serious obstacle

to realizing these goals. According to the World Health Organization, falsified drugs contribute to thousands of deaths annually; WHO's launching of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) intended to curb the trade of falsified drugs indicates that the issue presents as a matter meriting international attention owing to the impact of the practice on the wellness of populations. As Fadlallah et al. (2016) highlighted, although a global problem, African, Middle Eastern and Asian countries bear the brunt of the problem as over 30% of the medications issued in the regions are falsified in nature. Counterfeiting affects multiple aspects of the drug manufacturing and distribution process. Among the consequences of counterfeiting in Kenya are compromised healthcare, reduction of taxes, and brand discrediting (Marete, 2014). The current situation further undermines Kenya's goal of achieving Universal Health Coverage compliance.

The challenge of drug-falsification takes on a central role in Kenya and broader Africa as retail pharmacies serve as the first point of care for non-complicated ailments (Wafula, Miriti, & Goodman, 2012). WHO (2010) established the presence of poor quality medicines in the Kenyan market. Aside from the public health implications, private sector manufacturers experience losses of up to 50 million shillings (KAM, 2018). This, therefore, indicates that falsified drugs are of debilitating consequence to multiple stakeholders of the health industry; these include patients, the government, drug manufacturers, and retail pharmacies. Kenyans get access to their medicines primarily through the 4557 distributors and retailers spread across the country. Being the biggest pharmaceutical producer in the Common Market for Eastern and Southern Africa (COMESA) region it is important to ensure the integrity and quality of the pharmaceuticals (Marete, 2014). With an estimated annual value of more than Ksh 10 billion, counterfeits reduce income from legitimate businesses, deny government revenue through taxation, and harms the government's credibility on assurance of the provision of safety products.

Fatokun (2016) highlighted that addressing the challenge of falsified drugs requires a concerted effort from the multiple stakeholders involved in producing and distributing drugs to patients. As the author further observes, most of the medication in Africa is imported, with the figure standing at over 70% in Nigeria. Therefore, curbing the issue of counterfeiting drugs involves manufacturers, regulators, distributors, retailers, and consumers of the medicines (Fatokun, 2016). Each stakeholder must put in place measures to address the menace of falsified drugs, and such

efforts should be complementary to ensure effective impact. Although falsified medicines present as a public health concern, there are no operationalized anti-falsified strategies employed within the industry (Merete, 2014). A recent implementation of a strategic approach to addressing the issue is highlighted by (Omulo, 2019) pointing to the recent government initiative aimed at issuing unique identifier numbers to drugs. These numbers are intended to be used by patients to verify the authenticity of issued drugs. The study specifically focuses on the plight of retail pharmacies as it pertains to their financial performance. Implementing anti-counterfeiting strategies would be a useful intervention to minimize incidences of wrong treatment of ailments and financial losses; this study assesses the effectiveness of various anti-counterfeiting strategies vis-à-vis the financial performance of retail pharmacies.

Multiple studies have tried to explore counterfeit prevention strategies, including Habyalimana *et al.* (2015), who used uniformity of mass, friability of tablets, disintegration, and fluorescence. Kovacs *et al.* (2014) studied the impact of the WHO checklist, paper chromatography, PharmaCheck, Counterfeit Device, and chemico-physical tests. Bajema, Barstis, and Lieberman (2013) assessed the effect of screening tools such as high-performance liquid chromatography, mass spectrometry, and infrared spectroscopy. Deisingh (2005) noted that solubility and viscosity measuring, colorimetry, and thin-layer chromatography are among the adopted strategies to reduce counterfeit pharmaceutical products. Arppe and Sørensen (2017), Hamid and Asher (2014) highlight the efficacy of radio frequency identification tags (RFID) technologies. The volume of counterfeit medicines is a critical strategic management issue that could lead to catastrophic impacts on society and businesses operating in the health industry without proper attention. Hall (2012) identified five emergent technologies that have been employed in assessing the authenticity of medicines; GPHF-Minilab, TruScan, TruTag, Nanoguardian and AuthentiTrack. Stevenson and Busby (2015) proposed a four-item categorization of counterfeiting approaches – extraction strategies, production strategies, distribution strategies, and infiltration strategies. While these studies all assess counterfeit detection strategies, most do not assess the relationship between counterfeit products and profitability in the pharmaceutical industry in Kenya. This presents a research gap that this study sought to fill.

The purpose of this study was to address counterfeit medication strategies from the vantage point of distributors of medicines in Nairobi County. Specifically, the researcher intends to investigate

the strategies currently employed by retail pharmacies - chemico-physical strategies, tracking approaches, and supply chain integration strategies in relation to the performance of retail pharmacies. This study thus serves to provide a focused elucidation of the problem as it pertains to retailers and the efficacy or lack thereof of current strategies in light of the performance of the companies.

1.4 Research Objectives

The main objective of this study was to analyze counterfeit- drug-prevention strategies on the financial performance of retailing drug pharmacies in Nairobi County.

The specific objectives of the study were:

i. To establish the effect of chemico-physical anti-counterfeit strategies on the financial performance of pharmaceutical retail pharmacies in Nairobi.
ii. To establish the effect of tracking anti-counterfeit strategies on the performance of financial, pharmaceutical retail pharmacies in Nairobi.
iii. To establish the effect of supply chain integration anti-counterfeit strategies on the financial performance of pharmaceutical retail pharmacies in Nairobi.

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1.5 Research Questions

i. What is the effect of chemico-physical anti-counterfeit strategies on the performance of pharmaceutical retail pharmacies in Nairobi?
ii. What is the effect of tracking as anti-counterfeit strategies on the performance of pharmaceutical retail pharmacies in Nairobi?
iii. What is the effect of supply-chain integration anti-counterfeit strategies on the performance of pharmaceutical retail pharmacies in Nairobi?

1.6 Scope of the Study

This study focused on counterfeit-limiting practices as exercised by retail pharmacies in Nairobi county. The population considered for this study consisted of pharmacies in Nairobi county, and thus, the unit of study was the retail pharmacy as represented by the respective manager or owner. The study's objectives centered on the strategies involved in addressing drug counterfeiting as pertinent to the retail pharmacy. WHO (2018) study identifies 12 issues as contributory to the prevalence of counterfeit drugs, five of which relate directly to drug manufacturing and distribution companies – pricing of medication, inability to meet the demand for medicine, corruption, ineffective collaboration among stakeholders, and multiplicity of intermediaries in the distribution of drugs; this study was limited to strategies pertaining to retail pharmacies looking to identify and prevent the distribution of counterfeit products.

The study thus did cover the full range of factors deemed contributory to the problem. In particular, the following aspects were considered - chemico-physical strategies, tracking approaches, and supply chain integration strategies in relation to the performance of retail pharmacies. A total of 91 pharmacies distributed evenly across the county's constituencies were considered. The study period was expected to be one month to collect data and a subsequent month for the preparation and analysis of data. This schedule was maintained. The researcher based the projection on the assumption that the considered pharmacies would be forthcoming in availing data – an expectation that was met.

1.7 Significance of the study

This section aims to highlight the various stakeholders to whom study findings would be insightful and in what manner the findings will be of use. To legislators, this study offers insights into the most efficient approaches to anti-counterfeiting as viewed from the vantage point of retail pharmacy financial performance. Findings thus serve to inform on possible legislation to ensure efficient distribution of authentic medication without crippling retailers' financial performance.

Manufacturing and distribution companies play a vital role in the pharmaceutical industry – this role involves creating and distributing medicines to retailers. Understanding the various strategies

implemented by retailers would allow for assessing the level of risk involved in manufacturing and distributing medication within the county. Furthermore, this study sheds light on the current strategies employed by the stakeholder in light of literature identified anticounterfeit strategy hence allowing for a benchmarking of efforts in the local context vis-à-vis current counterfeit prevention strategies. Furthermore, this study also provides insight into the efficacy of the various strategies currently in place vis-à-vis the financial performance of the involved retailers. Finally, from a consumer's perspective, this study shed light on the approaches that purchasers of medicines can employ to ensure the consumption of authentic medication.

CHAPTER TWO

LITERATURE REVIEW

This chapter discusses the underlying theories considered in assessing the relationship between counterfeiting and anti-counterfeiting approaches and their applicability to the retail pharmaceutical industry. Discussed herein are the theoretical framework, empirical reviews, gap in research, conceptual framework, and the operationalization of variables.

2.1 Theoretical Framework

Two related theories are subsequently discussed – Theory of Reasoned Action and Theory of Planned Behavior as developed by Fishbein and Ajzen, and Ajzen, respectively (Fishbein & Ajzen, 1975; Ajzen, 1991; Azjen, 2002). The theories have likewise been applied by Okpe (2016) and Omotoba and Ekiti (2017), both of whom conducted studies on falsified drugs. The two theories were chosen as they allow for the explanation of the strategy selection process of pharmaceutical owners/managers vis-à-vis their understanding of the efficacy of anti-counterfeiting techniques. The theory was chosen over the expectancy theory of motivation the retail pharmacy owners/managers had not conducted research to assess the benefits that would accrue from the utilization of the anti-counterfeiting approaches; this indicated that the respondents were not particularly motivated to utilize the approaches in question. Findings from the study can be assessed through the expectancy theory to assess the attractiveness or lack thereof of the techniques used in light of the end of financial sustainability of the retail pharmacies.

2.1.1 Theory of Reasoned Action

As first put forward by Martin Fishbein and Fishbein and Ajzen (1975), the theory of Reasoned Action suggests that the motivation/intention to carry out a given action is predicated by one's preconceived attitude towards the action the normative influences that shape the individual's motivation. Essentially, the theory draws links between an individual's willingness to engage in a task and shaping prior held notions of the task at hand. According to the authors, intention to

complete a particular task bore a high correlation with the completion of the actual task; influencers of intention are thus deemed useful predictors of actual engagement in the tasks.

Trafimow, Brown, Grace, Thompson, and Sheeran (2002) assess the validity of the concepts put forward in theory but argue the fallibility of the theory. According to Trafimow et al. (2002), the widespread application of the theory across multiple disciplines presents as the main challenge. The underlying concepts forming the foundation of the theory are not empirically confirmed. In a study assessing the influence of normative and attitudinal beliefs as predicates of behavior, the Trafimow et al. (2002) test the hypothesis the younger children, in a cohort of children aged 8 to 16, would be influenced more by normative than attitudinal beliefs in making decisions on whether or not to engage in activities. Findings forthcoming from the study did not confirm the theory of reasoned action. The inference, therefore, is that intervening factors, unaccounted for by the theory, mitigate the relationship between attitudes, normative beliefs, behavior intention, and actual behavior.

The theory of reasoned action is pertinent to the study's objectives as it is essential in throwing light onto the relationship between perceptions of anti-counterfeit interventions vis-à-vis their efficacy in curbing counterfeiting. As described in the model, the perception of the threat of counterfeiting and anti-counterfeiting approaches would imply the behavior of distributors and retailers of medication. For example, a retailer’s heightened awareness of the threat of counterfeiting would provide the impetus for selecting the most efficient approaches to anti-counterfeiting since they would be a guarantee for ensuring profit generation and competitive positioning. The theory relates to firm returns in that it seeks to explain how customers’ perception of product quality impacts their decision to purchase from a particular point of sale, in this case, pharmacies. This theory is sufficient to this study since it relays the reasoning behind players in the pharmaceutical industry deciding to explore anti-counterfeit strategies and the reasoning behind customers' intent to purchase from certain pharmacies over others, hence ensuring their profitability. Similarly, the perception of an anti-counterfeiting approach as being sure-fire, despite weaknesses, would curtail a retailer’s motivation to seek out more efficacious anti-counterfeiting approaches.

2.1.2 Theory of Planned Behavior

Ajzen (1991, 2002), in appreciation of potential shortfalls in the theory of reasoned action proposes modifications that resulted in constructing the Theory of Planned Behavior. The main contrasting difference between the two theories arises from introducing the notion of control over one's actions. As defined by the author, perceived behavior control refers to the ease by which an action is performed - an action deemed difficult to perform would serve to hinder the actual undertaking of the action, with the inverse being true.

In an empirical study by Madden, Ellen, and Ajzen (1992), the authors provide evidence of the added interpretive value of inclusion of behavior control as an explanatory variable alongside attitude, normative beliefs, and intention (as encapsulated in the Theory of Reasoned Action). The principal benefit of the theory over that of Reasoned Action is that more accurate predictions on the undertaking of certain behaviours can be achieved by factoring in the individual's perception of control of the actions involved and their resulting efficacy.

In a critique of the two theories – Theory of Reasoned Action and Theory of Planned behavior - Hausenblas, Carron, and Mack (1997) posit that the utility of intention as a predictor of behavior may be secondary to the utility of expectation as a predictor of behavior. The author also presents the theory of reasoned action as the inferior of the two theories, indicating that the aspect of control over one's actions plays a differentiating role in determining the action's conduct in question. In relating these criticisms to the study, it is apparent that the implementors of the various strategies must view them to be efficacious enough and that they must expect them to work as effectively as presupposed for the strategies to merit investment.

This theory of Planned Behaviour offers value to the assessment of the study's objectives as it provides a lens through which to further assess – over and above the provisions of the foregoing theory of reasoned action – the process of implementation of anti-counterfeit measures. In particular, the perceived difficulty of putting in place measures to address the threat of counterfeiting presents as a telling predictor of the likelihood of implementing the measure in question. For example, an intervention involving rigorous re-training of staff would be viewed as

more difficult to put in place than one involving minimal retraining efforts. The discrepancy resulting from the ease of implementation may thus present the less attractive option as more easily implementable despite possible differences in efficacy between approaches. The theory has also been efficient when seeking to explain the attitude intention-behavior of healthcare service providers. Pursuing anti-counterfeit strategies is a social responsibility measure, and pharmacists can only employ these strategies if they have an attitude against counterfeit goods which are cheaper than original medicines. This theory thus informs the pursuit of anti-counterfeit strategies.

2.2 Empirical literature review

This section highlights the various findings put forward in extant literature that pertain to the topic of study. Thus, the section is subdivided into three subsections, each addressing a specific grouping of approaches to anti-counterfeiting strategies. The three sections were arrived upon following literature review and subsequent normative grouping of actors by logical association. According to literature from Ozawa's (2018) meta-analysis, chemico-physical strategies, tracking strategies, and supply chain integration strategies are among the most commonly adopted strategies to counter the prevalence of counterfeit and substandard medicines in low- and middle-income countries. This section will explore literature linking them to the control of counterfeit medicines.

2.2.1 Chemico-physical strategies

Habyalimana *et al.* (2015), in a study conducted in Rwanda, put forward a systematized approach to detecting counterfeit medicines. The study centers on quinine sulfate tablets, artemisinin-based combination tablets, and artesunate and powders for injection. In particular, the researchers perform tests based on the uniformity of mass, friability of tablets, disintegration, fluorescence, and assays particular to the medicines. Assays present as the most rigorous of the tests, with focus being placed on the physical characteristics of the substrates. The authors point out that the resource restriction among most retail and distribution companies prevents the employment of such tests as roman spectroscopy and spectral imaging. The equipment required for such tests is often limiting in cost. The resulting situation is thus reliance on more physical-based tests in assessing the authenticity of medications.

Dégardin, Roggo, and Margot (2014), in their exposition on techniques applied in anti-counterfeiting, posit that relying on such characteristics as weight, shape, color and subsequent chemico-physical tests – such as simple density or viscosity measurements – through cheap and readily available, often offer comparatively low accuracy and reliability. These studies, therefore, point to possible physical-quality-based approaches to anti-counterfeiting measures that can be used by low-revenue retail and distribution outlets.

The most apparent consequences of counterfeit medication are treatment failure, antimicrobial resistance, adverse drug reactions, and increased healthcare costs (Kovacs *et al.*, 2014). These challenges are most apparent in LMICs as weak institutions often characterize these regions, among which are atrophied pharmacovigilance systems. Kovacs et al. (2014) conduct a robust study of 42 innovations intended to curb counterfeiting to underline the most efficacious in the LMIC context of minimal resources channeled towards anti-counterfeiting. Findings from the study indicate four technologies that are of both low cost and high feasibility of implementation in the context; these were – the WHO checklist, paper chromatography, PharmaCheck, Counterfeit Device. The main approaches predominantly included chemico-physical tests.

Bajema, Barstis, and Lieberman (2013) discuss a screening tool that can aid in the fight against counterfeit drugs in the market. The authors point out the negative effects that can occur when pharmaceutical products are counterfeited. When active ingredients are under-dosed, lives can be lost. Some of the screening tools include high-performance liquid chromatography, mass spectrometry, and infrared spectroscopy. The authors propose a screening method that is reliable, cost-effective, and fast. The method involves the use of a paper analytical device. Using the technology in this device, it is easy to create screening devices for just about any medication. For the study leading up to the effectiveness, test subjects are asked to analyze pill samples made from known ingredients, take pictures of the test results and send the test results to the researcher's database. The researchers analyzed results from the tests. The final results showed that there were only 5% false positives, thereby indicating the approach's effectiveness.

Deisingh (2005) discusses the extent to which pharmaceutical counterfeiting is spread, the effects of counterfeit products on stakeholders, the different types of methods used to identify counterfeit

drugs, and anti-counterfeiting measures. The author state that some of the most counterfeited drugs include antibiotics and steroids. Some of the identified effects of counterfeiting include death, exposure to huge damage claims for healthcare providers, and lawsuits against manufacturers. The ways that have been employed to aid in anti-counterfeiting include bulk property testing, where methods employed include physically describing the tablet and measuring the solubility, viscosity, and weight of the medication. Other methods include colorimetry and thin-layer chromatography. The author identified the use of anti-counterfeiting measures such as implanting holograms and security print features, using tracers, taggants, and inks on the drugs, and electronic tracking methods. The data collection method used for this research was a literature review. The author recommends adopting and enforcing stringent anti-counterfeiting laws, developing new tracking technology, and adopting secure business practices for everyone involved in the drug supply chain.

2.2.2 Tracking strategies

In a study featuring tracking technology similar to that conducted by Arppe and Sørensen (2017), Hamid and Asher (2014) highlight the efficacy of radio frequency identification tags (RFID) technology from a consumer's perspective. The authors posit that among the main benefits of the approach are enhancing coordination in the distribution of medication, accuracy in the supply chain, enhanced trust between transacting parties, improved efficiency, and most importantly, delivery of authentic medication to patients. Hamid and Asher (2014) point out that the need for tracking of medication is underlined by the fact that in the United States, up to 40% of expenditure on medication is wasted on efficiency losses involved in the supply chain; the figure, as suggested by the authors, is as high as 50% in LMICs. The main benefits of RFID as a tracking approach are the durability of the tags, the unique code assigned to each drug, immediate reading without the need for a line of sight, and the ability to store more data than such approaches as bar code tracking.

The use of physical unclonable functions (PUF) presents an alternative approach in tracking medication (Arppe and Sørensen, 2017). PUFs, as defined by the authors, constitute tags of virtually unclonable qualities. The tags involve the scattering of polymers input in medication through the use of specific laser technology. The tags are subsequently illuminated to provide

specific 3D representations deriving from the stochastically determined input polymer configurations. These 3D representations are subsequently assessed through appropriate spectroscopic means linked to the initial creation of the patterns. The visual readers thus assess and either confirm or refute the authenticity of the mediation. According to Arppe and Sørensen (2017), the novel approach, though costly, provides a near sure-fire means by which to ensure the legitimacy of medication. This need is amplified by the fact that current tracking mechanisms such as labeling through active ingredients have been successfully replicated by counterfeiting parties.

The main challenge with overtly visible markers is the ease with which they are replicated. As Hall (2012) points out, markings on packages and the use of holograms and other distinguishing features often result in quick replication by unscrupulous manufacturers. Thus, it is necessary to employ less easily copied mechanisms in ensuring the authenticity of supplied pharmaceutical materials. Hall (2012) sheds light on five technologies that aim to bridge the identified gap – GPHF-Minilab, TruScan, TruTag, Nanoguardian, and AuthentiTrack. The technologies are based on cutting-edge innovations – such as nano-encryption for Nanoguardian – and, more notably, increased efficacy complexity and reliability in assessing the authenticity of medications. The author posits that although some of the technologies required considerably higher investment (compared to traditional physical approaches), the returns and benefits deriving from their utility are well worth the investment.

Berman (2008) conducted a study to identify the strategies that can be employed to detect and reduce counterfeiting activity. The author proposes four stages that can be used to detect and reduce counterfeiting. The four steps are: coming up with warning signs to identify counterfeits, allocating a budget to help monitor, deter and curb counterfeiting, employing demand-side strategies to curb counterfeiting, and using supply-side strategies to deter counterfeiting. Some of the identified effects of counterfeiting include losses in tax revenue, unemployment, and incurred financial losses due to incurred trade deficits. The author goes into an in-depth analysis of the types of counterfeits as well as the ways through which counterfeiting affects the economy. The author recommends public education on the presence of counterfeits and how to identify them, monitor internet searches, and employ track and trace authentication technology.

Coustasse, Arvidson & Rutsohn (2010) conducted a study to analyze the scope and severity of pharmaceutical counterfeiting and establish the effectiveness of the Radio Frequency Identification Device (RFID) model in dealing with counterfeit products in the pharmaceutical industry. The methodology used by the researchers was a comprehensive literature review. The study found that using the RFID model at the pharmaceutical organization level to help track drugs can help reduce counterfeit drugs presence in the market. The authors state that despite RFID requiring costly infrastructure, it is the most effective way for the authenticity of drugs to be tracked. The authors recommend using systematic efforts such as appropriate and timely exchange of information at the international level to help reduce the spread of counterfeit drugs. Some of the identified effects of counterfeit drugs are losses for manufacture, losses in taxes for host nations, and increased treatment costs for patients due to under-dosing. The authors also recommend joint effects among regional and international governments to curb the problem.

Fei and Liu (2016) propose that biodegradable drug-laden code labels be used to fight against counterfeiting. The drug-laden code is fabricated by laser cutting to attain a roughness in different surfaces hence differences in grade levels. The authors screened biomaterials that presented the relevant conditions as well as further requirements needed for packages. To assemble the device, the researchers purchased different materials from original suppliers. The device was then used to demonstrate the solubility of various materials used in labeling films. After using various materials, the researchers decided on a biodegradable film of 0.05mm in thickness. The film could easily be attached to pills without using a lot of adhesives.

Information on the QR codes could easily be obtained when scanned with a QR reader application. In addition, the researchers note that using the biodegradable polymer micro-label on drugs would not affect their bioactivity. Funding for this research was obtained from the National Natural Science Foundation of China, Tsinghua University Initiative Scientific Research Program, National Scientific Equipment Development Special Foundation of China, the Tsinghua-Salubris Joint Center for Cancer and Infection Diseases Drug Discovery and Development, and the Foundation of Beijing Laboratory in Biomedical Technology and Instruments.

Bansal *et al.* (2012) reviewed the strategies that various governments have employed to help fight falsified medicines' prevalence. The authors note that developed nations such as the United States use RFID technology to keep track of medication. Nations in Europe continue to use 2D barcodes to trace drugs. The authors suggest the need for anti-counterfeiting technology to help ensure that pirates cannot copy genuine products. The article states that for technology to be deemed effective, it should be hard to clone, hard to remove, and replace easily. Some of the anti-counterfeiting technology being used currently include the use of tamper-resistant packing, product authentication, and track and trace technology. The study recommends regular alteration of counterfeit resistant technology to avoid duplication. The most popular technology being used are serialization and track and trace systems.

2.2.3 Supply chain integration strategies

Through conducting an inductive qualitative study of secondary data on strategies employed in drug counterfeiting, Stevenson and Busby (2015) propose a four-item categorization of counterfeiting approaches – extraction strategies, production strategies, distribution strategies, and infiltration strategies. Extraction strategies, as defined by the authors, predominantly involve theft and repackaging of components, whereas production strategies, among other approaches, involve mimicking medication. As depicted by the authors, distribution and infiltration strategies involve the bundling of legitimate and illegitimate medication and selling of products through informal avenues, respectively. This paper is of particular importance to the ongoing study. The current author seeks to focus on the distribution and infiltration efforts involved in counterfeiting; these are incidental to distribution and retailing entities. Stevenson and Busy (2015) thus provide approaches for which anti-counterfeiting approaches employed by retailers (the population of the study) are crafted to address. In particular, there is the obscurity of trademarks, multiple distribution paths, bundling of counterfeit drugs with authentic drugs, infiltration of markets, informal avenues, impersonal media, recruiting of fronting legitimate distributors, and masquerading suppliers (Stevenson and Busby, 2015).

Liberman (2012), in addressing the challenge of drug counterfeiting at a global scale points to the intricacies of association between the World Trade Organization's agreement on Trade-Related

Aspects of Intellectual Property Rights and the World Health Organization's mandate of addressing counterfeit medicines. A notable point of discussion was the intricate association between the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and WHO in that whereas WHO's mandate emphasizes collaboration between national entities to ensure effective distribution of authentic medication, the purpose of the TRIPS was essentially to ensure that the financial interests of investors are preserved. In addressing the use of generic mediation across nations, it became apparent, as was the case in India, that TRIPS requirements may not necessarily be aligned with the mandate of ensuring the effective provision of affordable medication through generic options. The WHOs mandate of addressing counterfeit medication, as carried out by the International Medical Products Anti-Counterfeiting Task (IMPACT), is rendered convoluted when viewed in light of TRIPS and generic medication. This finding thus offers insights into potential challenges that stand in the way of an integrated supply chain. The interests of various stakeholders, when conflicted, may result in the disunity of the supply apparatus, a disunity that offers leeway to opportunistic counterfeiting entities.

Kumar, Dieveney, and Dieveney (2009) underline that the reverse logistics involved in returning expired, damaged packaging, and incorrectly delivered medication amount to USD 2.5 billion annually. Given that expired and damaged medication forms a notable avenue for counterfeit drug generation, it is imperative that returning medication to manufacturers be conducted efficiently. Kumar, Dieveney, and Dieveney (2009) apply a define, measure, analyze, improve and control (DMAIC) approach in addressing the challenge of reverse logistics positing that such technologies as RFID would be effective in ensuring efficient channeling of the returned medication to the appropriate parties. However, the finding most pertinent to the ongoing study was that suggesting the use of a single carrier for transportation of pharmaceuticals throughout the supply chain. The authors note that Pfizer utilized UniChem as the single distributor of prescription drugs. Thus, the approach allows for a more straightforward process in tracing the distribution of drugs from manufacture to final delivery to consumers. In applying this approach to the distributor space, it is apparent that sourcing medication from a single distribution point would likewise minimize the risk associated with the entrance of counterfeits in the distributor-retailor dyad and particularly so if the manufacturing entity confirms the authenticity of the distributor.

According to Dégardin, Roggo and Margot (2014), medical counterfeits take different forms and operate in varied manners – a factor that leads to convoluted anti-counterfeit mechanisms. Among the most common counterfeits generally involve the mimicry of active pharmaceutical ingredients (APIs) or structure of active medicines. For instance, counterfeit medication may involve APIs of decreased concentration in the medication or substitution of APIs with constituents of similar composition. The authors further posit that counterfeit medication can differ in type based on the destination of use, with Low- and Middle-Income-Countries LMICs having life-saving medication targeted and developed countries experiencing a targeting of lifestyle medicines.

Dégardin, Roggo, and Margot (2014) propose the consolidation of the supply chain as among the first frontiers in curbing the threat of counterfeit medication. The authors draw parallels with the banknote industry, where regulatory bodies institute multilevel checks involving passive and active measures addressing counterfeits. Among the passive approaches is identifying features in bills, whereas active measures involve tracking the distribution of medicines dispatched the different locales. Therefore, findings from this paper serve to shed light on system-based approaches that can be implemented at the retail level in addressing the threat of counterfeits. In particular, putting in place tracking mechanisms to trace medication distribution from manufacturer to producers would allow for the shutting out of potential illegitimate entrants at the lower level of the supply chain.

Chaudhrya, Cordellb & Zimmermanc (2005) state that approximately 200 billion US dollars are lost due to counterfeiting. Chaudhrya *et al.* (2005) identify the increase in registered trademarks as one of the causes of increased counterfeiting. The study developed a model that is currently being tested using surveys. The model is aimed at protecting intellectual property rights. The questions addressed in this study are the anti-counterfeiting strategies that are commonly employed, the effectiveness of these strategies in each country, and the effect of intellectual property rights decisions on the market entry decision.

The study obtained data using phone surveys and literature review. The authors noted that increased consumer complicity, increased pirate activity, and relaxed legislation on the host country's part regarding anti-piracy rules are key contributors to counterfeiting in host nations.

Companies' measures to deal with piracy include burning the pirated goods, identifying and suing the offending outlets, and lobbying for strict penalties against pirates. The approaches thus involve identifying dispersions from normal practice and seeking out ways to consolidate the distribution process.

Haman (2010) discusses some of the measures that business people in Africa have adopted to help curb counterfeiting. In the article, the author analyses some of the developments that have recently been adapted and propose possible solutions that can be used to solve the issue. The author posits that the growing economy in Africa creates a market for some products hence counterfeiting to address these market needs. Lack of adequate resources at the borders results in counterfeit products being smuggled into Africa. Some of the progress made includes a willingness by intellectual property owners to come together to work against counterfeiting. The implementation of trademark legislation has also aided in anti-counterfeiting. Some of the challenges facing progress include boards being taken to court by public health activists who claim that enacting the legislation could bar the importation of generic medication. Some of the proposed solutions from the author include governments focusing on creating reforms in intellectual property laws and the creation of cooperation to enforce said legislature.

Hoetch and Trott (2014) conducted a study to review the anti-counterfeiting strategies employed to curb the rise of counterfeit goods. The study reviewed available literature on anti-counterfeiting. The study identified 11 anti-counterfeiting strategies and the conditions that contributed to the success of the strategies. The researchers propose that firms should invest in protecting their technology-based competitive advantage. The author notes that some Japanese companies are already using this data protection method. These companies have opted to protect their sensitive information by moving said information back to Japan and stopping the manufacture of high-tech products in risky areas. The authors also propose that governments use anti-counterfeiting strategies in a complementary manner instead of relying heavily on one approach. Some of the conditions that foster anti-counterfeiting strategies include taking legal action against pirates and aggressive advertising.

Siva (2010) discusses some of the progress that has been made in combating counterfeit drugs. The article discusses the effect of the Pangaea III campaign on the war against anti-counterfeits. The author states that the campaign resulted in the arrest of 76 people and the confiscation of 2.6 million US dollars. The article states that the main challenge in addressing the problem is understanding how widespread it is. The article points out the need for international cooperation when it comes to implementing anti-counterfeiting policies. Increasing the circulation of genuine drugs is also a positive step towards fighting counterfeits in the pharmaceutical industry.

Said (2010) conducted a study to establish the effect of consumer demand on distribution of counterfeit drugs in Mombasa County and establish the roles played by pharmaceutical regulatory bodies in the county. The target population for this study was pharmaceutical retailers and wholesalers in Mombasa. The study found that the demand for drugs played a role in the distribution of counterfeit drugs. The researcher recommends that manufacturers, distributors and anti-counterfeit bodies should conduct education. The author also posits that the retailers should be urged to buy products directly from the manufactures to avoid buying counterfeit goods. The design used for this study was a cross-sectional descriptive survey. Data was sampled using the systemic random technique, and data analyzed through descriptive statistical analysis. Some of the challenges faced during the importation of drugs include damaged products, corrupt officials, and inter fluctuations in currencies.

Stevenson & Busby (2015) conducted a study to identify the strategies that product counterfeiters have employed in their exploitation of legitimate supply chains. The study was also aimed at developing a theoretical understanding of counterfeiting and its effects on competitive resources. The authors also propose countermeasures that should be used to increase the fight against counterfeits. The research used an inductive design to obtain data. The data was then analyzed using qualitative analysis. The study identified four strategies that have been implemented, namely production strategies, extraction strategies, infiltration strategies, and distribution strategies. Managers can use the results obtained from the study to come up with ways to curb counterfeit products from entering the market. The researchers state that carrying out consumer education may result in the consumers choosing not to purchase counterfeit products as opposed to genuine yet expensive products.

Effective integration of the supply chain involved in medication distribution allows for ensuring that authentically manufactured medicines reach rightfully targeted patients (Fadlallah *et al.*, 2016). Fadlallah et al. (2016) focus on the efficiency, feasibility, reliability, and economic outcomes of interventions aimed at curbing the distribution of counterfeit medication. The researchers employ a content analysis approach featuring 10,220 studies with 19 that merit inclusion based on the aforementioned criteria of efficiency and feasibility, among other aspects. Findings from the study indicate that minimization of drug diversion, enhanced lines of communication in the supply apparatus, ensuring feedback on drug use, and promoting strict licensing present as efficacious approaches. Further proposed interventions include on-site quality inspections and public awareness campaigns as measures that also present as yielding. Furthermore, Fadlallah et al. (2016) propose enforcement of tracking mechanisms allowing for purchasers of medication to confirm the authenticity of the purchased drugs. As emphasized by the authors, the key to all highlighted interventions is the use of robust information systems throughout the supply chain.

According to Hamilton *et al.* (2016), anti-counterfeit measures to address the distribution of authentic medication require multi-layered prevention systems. The authors define pharmacovigilance as efforts involving detection, assessment, understanding, and prevention of adverse effects drug-related complications. Given the wide scope of the concept, pharmacovigilance would require concerted efforts at the governmental through to the individual patient level of interaction with medication. At the governmental level, the authors propose the institution of effectively coordinated agencies particularly centered on the monitoring, licensing, and legislation of issues related to medication distribution. Thus, this publication underlines the importance of the consolidation of the supply chain apparatus as a measure towards curbing the distribution of counterfeit medication.

Anghel, Siminica, Cristea, Sichigea, and Noja (2018) carried out a study to identify the relationship between biotechnology firms' intellectual capital and financial performance. The study measured financial performance in terms of return on equity (ROE) return on assets (ROA), and debt-to-equity (DE) ratio. The study found a positive relationship between efficiency of research and

development expenditure and firms' ROA and ROE and a negative relationship with DE. This demonstrates that it is important to invest in new methods of improving medicine quality among biotechnology firms since this results in increased profit generation.

In examining the impact of the informal health sector on the financial performance of Zimbabwean pharmacies, Mutambara (2017) adopted a survey research design whose nature was both descriptive and explanatory. The study sampled 130 managerial heads of pharmacies in Harare City center. The study adopted a simple random sampling technique. It was noted that tightening immigration laws and cross-border trading would impact the volume of counterfeit products. The study identified the informal drug sector as major competitors to formal pharmacies. Strategies adopted to mitigate the growth of the informal drug sector include price controls, use of import duty on drugs, and taxation but noted that effective implementation of these strategies is necessary to promote profitability in the formal drug sector. Stricter implementation of importation controls will ensure sustained competitiveness.

Chemiati (2020) investigated the effect of counterfeit drugs on the performance of independent community pharmacies operating in Nairobi, Kenya. A descriptive research design guided the study. The study established that the prevalence of counterfeit drugs in the country negatively impacted the performance of independent community pharmacies by increasing their exposure to risks associated with counterfeit drugs, with potential legal suits undermining and damaging the reputation of community pharmacies. Miller and Winegarden (2020) note that illegal medicines pose a health risk and contribute to annual losses ranging between $200 billion and $450 billion. The study concluded that drug quality control is key to ascertaining the quality of drugs. The study recommended increased awareness through seminars and workshops to sensitize community pharmacy operators on the risks of counterfeit drugs and the strategies that can be used to identify counterfeit drugs and medicines.

2.3 Research Gap

The theory of reasoned action and the theory of planned behavior collectively predicate an individual's behavior on attitudes, normative beliefs, subjective factors, and perceived control over actions (Fishbein & Ajzen, 1975; Ajzen, 1991; Azjen, 2002). Assessing the efficacy of various strategies to address the challenge of counterfeit medication would thus serve to shape retailers' attitudes, normative beliefs, subjective beliefs, and perceived control of anti-counterfeiting approaches currently applied in the local market. This study thus bridges the gap of a scarcity of literature in linking anti-counterfeiting strategies and the financial performance of retail pharmacies in Nairobi.

From an empirical perspective, the study assesses the relative effectiveness of the various strategies discussed in the foregoing section vis-à-vis the financial performance of pharmacies in Nairobi County. Findings forthcoming from the study would thus bolster or refute prior postulations on the implications of the various strategies from a cost-efficiency point of view; factors offering high correlation with performance would thus be viewed as generally most impactful to the financial performance of retailing pharmacies in Nairobi County.

2.4 Conceptual framework

The various constructs considered in this study were introduced in the first chapter and elaborated upon in the foregoing section on empirical literature review. Therefore, the main relationships assessed in the current study are highlighted in the conceptual framework presented in figure 2.1.

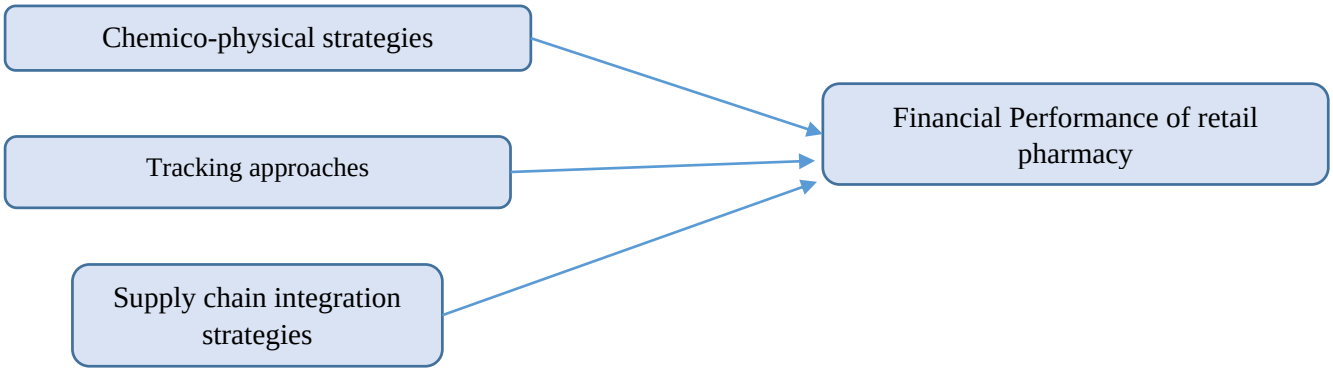

Figure 2.1 Conceptual Framework

2.5 Operationalization of Variables

The sub-variables under consideration for each construct – constituting the operationalization of the variables – are depicted in the subsequent table 2.1. The understanding behind interrelating the independent variables and the dependent variable, as depicted in the conceptual framework, derives from the theory of Planned Behaviour, which stipulates that the attitudes, beliefs, and control of actions influence their engaging in the behavior. For the current study, an understood relationship between the various strategies and their impact on financial performance would influence their attitude, beliefs, perception of controlled action as it pertains to using strategies to combat anti-counterfeiting.

Table 2.1 Operationalization of variables

VARIABLE	CONSTRUCTS	MEASUREMENT	SOURCE
Dependent	**Financial performance of** (Average monthly revenue difference, average frequency of sale)	Continuous Scale	(Davison, 2011).
Independent	**Chemic-physical approaches** • Visual packaging cues • solubility tests • uniformity tests • Friability tests • Florescence tests	Five Point Likert Scale	(Habyalimana et al., 2015; Bajema, Barstis & Lieberman, 2013; Deisingh, 2005).
Independent	**Tracking approaches** • (Bar code technology • QR codes • RFID codes • Biodegradable labels • Unclonable tags	Five Point Likert Scale	(Hamid and Asher, 2014; Fei & Liu, 2016; Bansal et al., 2012).
Independent	**Supply chain integration strategies** • Integration of information systems • adequate staff training on protocols • customer sensitization and empowerment • Anticounterfeiting initiative involvement • Sourcing from similar suppliers	Five Point Likert Scale	(Said, 2010; Stevenson & Busby, 2015; Fadlallah et al. 2016; Kumar, Dieveney & Dieveney, 2009).

CHAPTER THREE
RESEARCH METHODOLOGY

3.1 Introduction

The chapter elucidates the research design utilized in carrying out the research. Also discussed are the study population, methods adopted to gather data, and the approach employed to analyze the collected data in light of study objectives. Measures to ensure reliability, validity, and adherence to ethical standards are also put forward.

3.2 Research Design

The study assumes a correlational research design as the author sought to establish the relationship between the various factors put in place to address the distribution of counterfeit medication and their impact on the performance of retail pharmacies (Saunders, Lewis & Thornhill, 2007). The correlational design thus provided information on the relative impact of the approaches, thus further allowing for identifying the most efficacious; information that can then be used for the practical benefit of informing practitioners on which anti-counterfeiting practice to focus on. As incorporated in the current study, the correlational research design enabled the drawing of inferences between the nature of relationship between the independent and the dependent variables, thus answering the research objectives.

3.3 Target Population

There are 1266 registered retail pharmacies in Nairobi County (Pharmacy and Poisons Board, 2019). These institutions formed the population from which the targeted sample was sourced. The main managers charged with monitoring counterfeiting activities in the pharmacies were required to participate in the study.

3.4 Sampling approach

A random sampling approach was employed in reaching pharmacies in the region. This was done to ensure unbiased representation by the county population (Saunders, Lewis & Thornhill, 2007). Each of the nine constituencies of the county was allocated an equal number of targeted pharmacies from which to source information. The constituencies of the county are, Kamukunji, Kasarani,

Westlands, Starehe, Dagoretti, Embakasi, Makadara, Njiru, and Langata. Random sampling, based on computed sample size, allowed for an even cover in the representation of the target population and further ensured that each unit in the population was likely as any other to be included in the sample size; this enhanced the validity and reliability of findings (Saunders, Lewis, Thornhill, 2007). A random number generator was used to assign numbers to each of the pharmacies. The pharmacies were then sorted by number, and the first 89, chosen by the representation of constituency, were picked for the study.

3.5 Study Sample Size

The study employed Yameane's (1967) formula to compute the study's sample size. This formula is indicated below, and the subsequent calculations are highlighted. A 90% level of precision was employed to account for the limitation in time and resources for the study.

$$n = N/(1 + N(e)2$$

Where: -

Sample size = n

Total population = N

The level of precision = e

Hence

$$n = \frac{1266}{1 + 1266(0.1)\text{^}2} = 89.27$$

The sample size was, therefore, 89 respondents.

3.6 Data Collection Methods

Primary data was collected using a questionnaire addressing the various objectives of the study. Wright (2005) observes that questionnaires allow for quick and convenient data collection but present a challenge of high non-response rates, particularly when the respondents are not known to the researcher and no incentives are involved in completing the questionnaires. The questionnaires were distributed at retail outlets to increase response rates. The questionnaire included four main sections. The first three sections centered on the independent variables with the contribution of each anti-counterfeiting approach assessed on a five-point Likert scale. The fourth section assessed the relative financial performance of the pharmacies under assessment.

This section, as was the case with the foregoing, was assessed through a five-point Likert scale. A drop and pick method was applied in delivering the questionnaires.

3.7 Analysis Approach

All study variables derive from extant literature and the relationships between the variables also follow that indicated in the aggregated literature. The study thus applied a regression model to test these relationships in the Nairobi context. All the data collected for the study were assessed for correctness and completeness by comparing the data in the study questionnaire following transcoding to spreadsheets. SPSS version 22 was used as the primary analysis software for the study and was particularly used to assess the relationships between the constructs outlined in the study. The main analysis approach applied for the study was ordinary least square regression (OLS). As a prerequisite, tests of multicollinearity and normality were conducted to ensure the reliability of the findings deriving from the regression analysis. The formula to be applied is highlighted below:

$$Y = \beta 0 + \beta 1X1 + \beta 2X2 + \beta 3X3 + \varepsilon$$

Whereby Y = Financial Performance of retail pharmacy

X1 = Chemico-physical strategies

X2 = Tracking approaches

X3 = Supply chain integration strategies

Beta Zero (β 0) represents the regression constant and the error term is represented by e. All other beta values represent the regression coefficients of the respective variables.

3.8 Research Reliability and Validity

The Cronbach alpha based on data collected from a pilot study formed the basis for evaluating the scale's reliability. A cut-off value of 0.6 was used as the base reliability score (Saunders, Lewis, and Thornhill, 2007). Chemico-physical approaches presented a Cronbach score of 0.562, with tracking and supply chain integration approaches presenting a score of 0.651 and 0.669. As all

rounded up to 0.6, the scores were conserved satisfactorily reliable for assessing the relationship between constructs. Validity assessed the agreeability between a construct and the constructs used to measure it (Saunders, Lewis, and Thornhill, 2007). However, the study was based on perceptions put forward by the respondents; hence,e the researcher observes that an inherent risk of bias would be observed in the data. To address this concern, the author structured the research questions in such a manner as to minimize confirmation bias in the presentation of answers.

3.9 Ethical Considerations

Ethical considerations allow for the consideration of proper conduct in conducting a study (Bryman & Cramer, 2012). Among the considerations put in place was the ensuring of consent by all participants of the study. The confidentiality and anonymity of responses were further communicated to all individuals that opted to participate in the study. By way of Strathmore's ethical committee and the National Commission for Science Technology and Innovation (NACOSTI), relevant authority bodies were also required to provide approval for the study. All cited authors were further be highlighted.

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CHAPTER FOUR

DATA ANALYSIS AND INTERPRETATION

4.1 Introduction

This chapter presents findings on the analysis conducted on the collected data in accordance with the research objectives. The chapter is divided into five major subsequent sections – response rate, respondents' profile, objective one, objective two, and objective three. Each objective assesses the impact of an anti-counterfeiting strategy on the performance of pharmacies. The three considered strategies are chemico-physical, tracking, and supply chain integration, respectively.

4.2Response rate

As detailed in the forgoing chapter, the pilot study indicated a high level of non-response among pharmacy owners and representatives. To address the issue, a 20% addition was made to the initial sample size bringing the final total to 107, of the 107, 96 provided responses. The response rate for the study was therefore 89.7%. Given the higher than 70% figure, the response rate was thus deemed satisfactory for the study (Morton et al., 2012). Given that, as presented in section 3.8, the scales were generally reliable, the data collected for the study was deemed sufficiently representative of the population and adequately reliable as indicated by the Cronbach Alpha scores for each construct.

4.3 Respondents profile

Data was collected from nine locations. Three areas had less than the anticipated number of responses – Embakasi, Kasarani, and Njiru with eight respondents for the first two and seven for the final. The overall number was, however sufficient for the making of inferences at the county scale. Additional responses from other regions were included making up for the shortfall in the three regions. Table 4.1 provides a summary of the responses for the various regions.

Table 4.1 Number of entries by region

Region	Frequency per category	Rel. frequency per category (%)
Dagoretti	12.00	12.50
Embakasi	8.00	8.33
Kamukunji	13.00	13.54
Kasarani	8.00	8.33
Langata	10.00	10.42
Makadara	11.00	11.46
Njiru	7.00	7.29
Starehe	9.00	9.38
Westlands	18.00	18.75

Respondents from Westlands were most receptive to the study, with 18 respondents accepting to participate in the study. Respondents from Njiru were least responsive, with seven respondents providing feedback with multiple requests for participation. Respondents from Westlands appeared to be more receptive as the value of the study was apparent to them; the same was not clear among respondents from Njiru.

4.4 Objective I: The effect of chemico-physical anti-counterfeit strategies on the financial performance of pharmaceutical retail pharmacies in Nairobi

This section addresses the first objective of the study. Two subsections are included – descriptive and inferential statistics.

4.4.1 Descriptive statistics

This section presents descriptive statistics on the two variables considered in the first objective – chemico-physical anti-counterfeiting strategies and financial performance of pharmaceutical retail pharmacies. The purpose of the section is to provide a general depiction of the data gathered for each variable.

4.4.1.1 Chemico-physical anti-counterfeiting strategies

To assess the usage of chemico-physical anti-counterfeiting strategies in the county, five questions, as detailed in table 4.2, were put forward. Responses indicated that the most commonly used tracking approach was the use of packaging cues such as seal appearance. The general trend as inferred from the relative percentage frequencies was neutrality of disagreement with the statements, albeit with noteworthy agreement by some respondents. A noteworthy example would be responses to the statement assessing the use of solubility tests and assessing packaging ques. Whereas majority respondents, 68.75% (51.042 plus 17.708), indicated that they used packaging ques, 80% (7.292 plus 36.458 plus 36.458) indicated a rating of neutral, disagreed, or strongly disagreed with the statement assessing the use of solubility tests the inversion of trend resulted in negation, therefore, overall neutral response was likely. However, it was noteworthy that most of the mean responses for the various questions indicated a rating tending to 3 (neutral). As indicated by the responses, the general observation was a low tendency to rely on chemico-physical approaches to address challenges in anticounterfeiting. The highest variation in responses was observed in questions assessing the use of packaging cues and the use of uniformity tests with standard deviations of 1.01 for both. The finding pointed to a lack of uniformity in applying chemico-physical anti-counterfeiting strategies, particularly as indicated by answers from the two questions. The frequent 'neutral' response may also point to a lack of active engagement by the respondents to take note of any if at all, approaches applied to address the issue of counterfeiting; this would suggest a general apathy regarding the seriousness of the matter concerning the efficacy of medication in treating patients. The impact of the factor – chemico-physical anti-counterfeiting strategies is assessed in the subsequent section on inferential statistics.

Table 4.2 Descriptive Statistics Chemico-physical practices

		1 (Strongly Disagree)	2 (Disagree)	3 (Neutral)	4 (Agree)	5 (Strongly Agree)	Mean	Standard deviation (n-1)
[Use of packaging cues (such as seal appearance) to identify counterfeit drugs.]	Frequency	5	6	19	49	17		
	Relative Frequency %	5.208	6.25	19.792	51.042	17.708	3.7	1.01
[Use of solubility tests to assess the authenticity of drugs.]	Frequency	7	35	35	16	3		
	Relative Frequency %	7.292	36.458	36.458	16.667	3.125	2.72	0.94
[Use of uniformity tests (e.g. the average mass of tablets) to check for counterfeit drugs.]	Frequency	5	23	27	36	5		
	Relative Frequency %	5.208	23.958	28.125	37.5	5.208	3.14	1.01
[Use of friability/ease of crumbling of tablets to test for authenticity of tablets]	Frequency	3	34	30	23	6		
	Relative Frequency %	3.125	35.417	31.25	23.958	6.25	2.95	0.99
[Use of florescence of a tablet to screen for counterfeit drugs]	Frequency	5	34	30	25	2		
	Relative Frequency %	5.208	35.417	31.25	26.042	2.083		
Chemico-physical Approaches							**3.07**	**0.59**

4.4.1.2 Financial performance

There was a wide variance in the revenue reported across pharmacies in the various regions. This is indicated by the standard deviations observed in the before and after statistics (table 4.3). This observation was expected given the difference in demographics among frequenters of the various pharmacies; pharmacies operating in the Westlands region were generally expected to report higher sales because of the frequency of visits and pricing differences. There was an increase in revenue, as indicated by mean ratings, in the after period, thus pointing to the potential impact on sales due to anti-counterfeiting strategies. This increase, therefore, suggests that when applied, anti-counterfeiting measures were useful in securing business from clients who were successfully recovered after treatment. This observation was subjected to subsequent testing through inferential statistics; findings are subsequently discussed.

Table 4.3 Descriptive statistics – Average Sales

Statistic	Average monthly revenue - BEFORE	Average monthly revenue - AFTER
Mean	154213.26	189957.98
Standard deviation (n-1)	264953.83	308993.52

Sales frequency was assessed on the average number of return customers (out of 5 or 10 customers) reported in the before and after periods. The ratio between the after and before the period was computed as the indicator of sale frequency. A ratio higher than one would indicate increased frequency, while a ratio lower than one indicates the lower frequency using anti-counterfeiting approaches. As indicated in table 4.4, there were higher return customers in the 'After' period with a mean rating of 1.328. This indicates a near 33% increase in frequency – a finding in keeping with the increase in revenue observed in the various regions. In viewing this finding in light of that on increased revenue, it is apparent that the after period may have shown increased revenue on account of increased frequency of visits. An inferential assessment of the findings sheds light on the extent to which the increase in frequency is associated with utilizing the anti-counterfeiting approach.

Table 4.4 Descriptive statistics – Sales frequency

Statistic	Sales frequency
Mean	1.328
Standard deviation (n-1)	0.646

4.4.2 Inferential statistics chemico-physical approaches

The dependent variables under consideration were standardized through computation of the quartiles within which the various responses fell. This was done for each of the dependent variables – average monthly revenue and frequency of sale. The result was an ordinal rating of 1 to 4 based on the allocated quartile of the various responses. This was done to ensure congruency between the measurement employed in the Likert scales assessing the independent variables and the continuous scale applied for the dependent variable. Results for the regression analysis are presented below.

Table 4.5 Model Summary

Model Summary				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.226[a]	.051	.020	.9915
a. Predictors: (Constant), Supply Chain Integration Strategies, Chemico-physical Approaches, Tracking Approaches				

The model summary indicated an R-square value of 0.051, indicating that the model explained 5.1% of the variability in the dependent variable. The model was thus marginally predictive on account of its low predictive value. This pointed to a possible low explanatory power of the independent variables in the study.

Table 4.6 ANOVA

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	4.883	3	1.628	1.655	.182[b]
	Residual	90.451	92	.983		
	Total	95.333	95			
a. Dependent Variable: Combined Performance						
b. Predictors: (Constant), Supply Chain Integration Strategies, Chemico-physical Approaches, Tracking Approaches						

An analysis of the variance model was run to assess the difference between the generated and null models. Findings from the analysis revealed that the generated model with an F value of 1.655 and a p-value of 0.182 was not statistically different from a null model (with no predictors) at the 95% confidence level. In keeping with the observations from the R-square value, the model was found not to show significant predictive value in assessing pharmacies' performance as a function of anti-counterfeiting strategies.

Tale 4.7 Coefficients

Coefficients[a]						
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.865	.697		2.675	.009
	Chemico-physical Approaches	.118	.183	.070	.642	.522
	Tracking Approaches	.309	.172	.206	1.790	.077
	Supply Chain Integration Strategies	-.207	.158	-.144	-1.306	.195
a. Dependent Variable: Combined Performance						

Assessing on account of magnitude, chemical-physical strategies were the least impactful on pharmacies' performance. The factor presented a beta value of 0.118, thus indicating that a unit increase in rating of the factor was associated with a 0.118 increase in the overall performance of the pharmacies. However, the relationship was not confirmed at the 95% confidence level as the p-value of 0.522 was higher than $\alpha = 0.05$.

4.5 Objective II: The effect of tracking anti-counterfeit strategies on performance of financial, pharmaceutical retail pharmacies in Nairobi.

This section addresses the second objective of the study. Two subsections are included – descriptive and inferential statistics.

4.5.1 Descriptive statistics tracking approaches

To assess the usage of tracking anti-counterfeiting strategies across the various pharmacies, five questions were put forward. Findings indicated low usage with the general trend indicating high proportions of neutrality or agreement with the statements. For example, the highest reported proportion for the five questions was observed on the question of assessing the use of RFID codes where 44.8% of the respondents disagreed with the observation whereas 29.2% were neutral to the observation and a further 12% agreed with the observation the statement. The highest mean reported for the various questions was 3.3 (between neutral and agree). This was reported for the use of unclonable tags. The overall mean on tracking approaches was 2.96, indicating that most of the respondents indicated that they disagreed or were neutral on statements assessing usage of tracking approaches. This finding thus points to low usage of the tracking approach. A possible reason for this would be the extra expenses involved in securing equipment such as RFID scanners and barcode readers. The low usage of the approach contrasts with the increase in revenue and frequency among the clients. Thus, it is anticipated that the subsequent inferential analysis will reveal a negative relationship between the two factors if any relationship between the constructs is established.

Table 4.8 Descriptive statistics – Tracking approaches

		1 (Strongly Disagree)	2 (Disagree)	3 (Neutral)	4 (Agree)	5 (Strongly Agree)	Mean	Standard deviation (n-1)
[Use of barcode technology to assess the authenticity of drugs.]	Frequency	11	34	21	26	4		
	Relative Frequency%	11.458	35.417	21.875	27.083	4.167	2.77	1.1
[Quick response codes to assess the authenticity of drugs]	Frequency	5	37	22	28	4		
	Relative Frequency%	5.208	38.542	22.917	29.167	4.167	2.89	1.02
[Radio Frequency Identification tags (RFID) use to assess the authenticity of purchased drugs.]	Frequency	6	43	28	12	7		
	Relative Frequency%	6.25	44.792	29.167	12.5	7.292	2.7	1.02
[Biodegradable bio labels used to screen for counterfeit drugs]	Frequency	8	17	29	35	7		
	Relative Frequency%	8.333	17.708	30.208	36.458	7.292	3.17	1.07
[Unclonable tags on medications used to screen for counterfeit drugs]	Frequency	3	18	29	39	7		
	Relative Frequency%	3.125	18.75	30.208	40.625	7.292	3.3	0.96
Tracking Approaches							**2.96**	**0.67**

4.5.2 Inferential statistics tracking approaches

As indicated in table 4.6, tracking approaches presented a beta value of 0.309, thus indicating that a one-unit increase in the metric rating was associated with a 0.309 increase in the average performance of the pharmacies in question. The was the highest value reported for the three variables. Therefore, the inference from the study was that tracking approaches bore the most significance in determining the performance of pharmacies. However, the findings could not be confirmed at the 95% confidence level as it was associated with a p-value of 0.077, which was higher than $\alpha = 0.05$.

4.6 Objective III: The effect of supply chain integration anti-counterfeit strategies on the financial performance of pharmaceutical retail pharmacies in Nairobi.

This section addresses the third objective of the study. Two subsections are included – descriptive and inferential statistics.

4.6.1 Descriptive statistics supply chain integration strategies

The highest incidence of use was reported on the use of supply chain integration strategies. Apart from responses to the statement on the issuance of information on how to check on counterfeit drugs, most of the respondents, as indicated by the relative percentage frequencies, agreed (rating 4) or strongly agreed (rating 5) with statements on the variable; this is indicated by highest mean rating for the construct as compared to the foregoing two at 3.50. This indicated that most respondents agreed with the view that the pharmacy used the proposed integration strategies. The highest rating was reported for assessing that staff was adequately trained on protocols involved in handling drugs. The highest variance in responses was observed in the questions assessing efforts towards informing customers on how to validate the authenticity of drugs and the sourcing of medicine from the same suppliers; these presented standard deviation ratings of 0.18. Therefore, the observation was that informing customers on approaches to avoid counterfeit medication and using the same providers of service were not common practices across the pharmacies. This, given the increase in revenue and frequency of visit would suggest, as was the case with tracking approaches, a negative relationship, a valid relationship between supply chain integration strategies and performance. The impact of the various integration approaches on performance is tested in the subsequent section on inferential statistics.

Table 4.9 – Descriptive statistics – Supply chain integration strategies

		1 (Strongly Disagree)	2 (Disagree)	3 (Neutral)	4 (Agree)	5 (Strongly Agree)	Mean	Standard deviation (n-1)
[Integrated-information-system use for tracking drugs from purchase to sale]	Frequency	3	19	18	43	13		
	Relative Frequency%	3.125	19.792	18.75	44.792	13.542	3.49	1.06
[Adequate training of stuff on the protocols involved in handling drugs]	Frequency	1	9	13	46	27		
	Relative Frequency%	1.042	9.375	13.542	47.917	28.125	3.93	0.94
[Provision of information to customers on how to check for counterfeit drugs]	Frequency	10	27	21	28	9		
	Relative Frequency%	10.526	28.421	22.105	29.474	9.474	2.99	1.18
[Updated on supply chain strategies by affiliation with anticounterfeiting organizations and initiatives]	Frequency	2	9	17	51	17		
	Relative Frequency%	2.083	9.375	17.708	53.125	17.708	3.75	0.93
[Sourcing of medication from the same suppliers to minimize counterfeiting]	Frequency	9	14	20	39	14		
	Relative Frequency%	9.375	14.583	20.833	40.625	14.583	3.37	1.18
Supply Chain Integration Strategies							**3.5**	**0.7**

4.6.2 Inferential statistics supply chain integration strategies

Supply chain integration strategies were surprisingly depicted as inversely associated with pharmacy performance with a unit increase in ratings on the construct associated with a -.207 decline in ratings on overall performance. The independent variable was the second most influential on performance by magnitude after tracking approaches. However, the impact of the variable could not be confirmed at the 95% confidence level as it presented a p-value of 0.195, which was higher than the requisite lower than 0.05 at the confidence level.

4.7 Summary

There was general low utilization of the three anti-counterfeiting approaches, with tracking approaches relatively being the least utilized and supply-chain integration strategies being the most utilized. None of the anti-counterfeiting approaches were inferred to impact the financial performance of pharmacies.

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CHAPTER FIVE

DISCUSSION CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter relates the study findings, in accordance with the study objectives, to extant literature. The chapter is restricted into the following sections – discussion, conclusion, recommendations, limitations, and areas for further study. The three anti-counterfeiting approaches were generally underutilized. Tracking approaches were generally least utilized with supply-chain integration strategies being the most utilized. None of the anti-counterfeiting approaches were inferred to impact on the financial performance of pharmacies.

5.2 Discussion

This section provides an elucidation of study findings in light of extant literature. The section details the fit of the as pertains to the theories employed in the study and the empirical findings on the various relationships assessed under the study's objectives. This section is thus divided into three in keeping with the three objectives of the study.

5.2.1 Objective I: The effect of chemico-physical anti-counterfeit strategies on the financial performance of pharmaceutical retail pharmacies in Nairobi

The general trend as inferred from the relative percentage frequencies was that of neutrality of disagreement with the statements assessing using the various anti-counterfeiting approaches used under the category. The pharmacy representatives were, therefore, generally unlikely to apply the anti-counterfeiting technique as a means by which to improve profits. This points to a lack of appreciation of the prevalence of anticounterfeit drugs or, where the threat is appreciated, the perceived ineffectiveness of combating the prevalence of counterfeiting of drugs. Inferential analysis indicated that the use of the various techniques under chemico-physical approaches was not impactful on the performance of pharmacies.

According to Habyalimana et al. (2015), the resource restriction among most retail and distribution companies prevents employment of such tests as roman spectroscopy and spectral imaging as the equipment required for such tests is often limiting in cost. The resulting situation is thus reliance on more physical-based tests in assessing the authenticity of medications. The indication that most pharmacies were generally neutral to questions assessing the use of the approach thus indicates

that the choice of chemico-physical approaches was not necessarily an issue of the cost of alternative approaches. This finding thus points to a general unappreciation of the prevalence of counterfeiting medication or were appreciated a lack of intention to combat the issue. The latter observation would suggest, in accordance with The Theory of Planned behavior, an attitudinal factor in determining uptake of the anti-counterfeiting approach. The observation may, however also result from a behavioral control influence in that the pharmacies owners/managers did not think themselves capable of implementing the proposed approaches to the anticipated effect of reduced anticounterfeiting practices. The finding, notwithstanding the lack of a direct link between the two variables, points to the possible futility of the approach. Pharmacies that secure appropriate funding to implement the approach may not necessarily reap the benefits of improved performance. This follows from the observation that despite substantial usage of the approach in the local market, there is no apparent contribution of the approach to the performance of pharmacies in the region. It is, however noteworthy that the lack of a link between the variables may be as a result of the aggregation or simple and more robust chemico-physical approaches in one construct.

Dégardin, Roggo, and Margot (2014), in their exposition on techniques applied in anti-counterfeiting, posit that relying on such characteristics as weight, shape, color, and subsequent chemico-physical tests – such as simple density or viscosity measurements – through cheap and readily available, often offer comparatively low accuracy and reliability. The low utilization of the proposed chemico-physical approaches may be a factor of anticipated low impact of the approach – the managers/owners may consider an anticipated benefit to be unmeriting of the required investment required to systematize the techniques within their facilities.

The most apparent consequences of counterfeit medication are treatment failure, antimicrobial resistance, adverse drug reactions, and increased healthcare costs (Kovacs *et al.*, 2014). These perils are primarily incidental to sub-Saharan Africa. Given that the chemico-physical approaches are generally considered less expensive (Dégardin, Roggo & Margot, 2014), the realization that they are of no consequence to the prevention of acquisition and distribution of counterfeit medications is a sobering realization. This is because the approach presents as the most accessible of the three as most pharmacies in the region operate under small budgets.

5.2.2 Objective II: The effect of tracking anti-counterfeit strategies on the performance of financial, pharmaceutical retail pharmacies in Nairobi.

The overall mean on tracking approaches was 2.96, indicating that most of the respondents indicated that they disagreed or were neutral on statements assessing usage of tracking approaches. A possible reason for this would be the extra expenses involved in securing equipment such as RFID scanners and barcode readers; this observation is in keeping with observations by Habyalimana et al. (2015), who opine that the low usage of tracking approaches may be due to the high cost associated with anti-counterfeiting approach. An alternative explanation for low usage of the approach may result from the ease of replicating tracking identifiers. Hall (2012) points out, markings on packages and the use of holograms and other distinguishing features often result in quick replication by unscrupulous manufacturers.

Assessing by magnitude, tracking approaches presented a beta value of 0.309, thus indicating that of the three, they bear the highest potential to impact on identification and hence minimized prevalence of counterfeit drugs; chemico-physical and supply chain integration strategies presented beta values of .118 and -.207, respectively. It is, however noteworthy that none of the three approaches presented as a significant predictors of performance. It is thus apparent that the case for improved performance due to the use of the approach cannot be confirmed, but if one was to consider utilization of any of the approaches, then tracking approaches would be best advised; this is on account of their possible impact at a lower confidence level at 90% confidence level.

Among the main benefits of the approach are enhancingd coordination in the distribution of medication, accuracy in the supply chain, enhanced trust between transacting parties, improved efficiency, and most importantly, delivery of authentic medication to patients (Hamid & Asher, 2014). The low usage of the approach among pharmacy managers/owners signifies a large gap that, if filled, would result in a significant reduction in anticounterfeiting. As an example, according to Arppe and Sørensen (2017), the novel physical unclonable functions (PUF) approach, though costly, provides a near sure-fire means by which to ensure the legitimacy of medication. This need is amplified by the fact that current tracking mechanisms, such as labeling through active ingredients have been successfully replicated by counterfeiting parties.

As Hall (2012) points out, markings on packages and the use of holograms and other distinguishing features often result in quick replication by unscrupulous manufacturers. The use of such techniques to prevent the distribution of counterfeit mediation is thus risky on the part of the

investor. Findings, however paint a grimmer picture for local pharmacy owners looking to utilize tracking approaches to address counterfeit mediations in that the investment may not necessarily yield results even without the threat of replication of the specific tracking approaches. However, as Bansal et al. (2012), the use of such sophisticated tracking approaches as RFID codes are not common in the region. The missing link between tacking approaches and performance, as evidenced in the current study, may therefore result from the use of less sophisticated approaches that are more easily copied by counterfeiting agencies.

5.2.3 Objective III: The effect of supply chain integration anti-counterfeit strategies on the financial performance of pharmaceutical retail pharmacies in Nairobi.

The highest incidence of use was reported on the use of supply chain integration strategies. The highest rating was reported for assessing that staff was adequately trained on protocols involved in handling drugs. Supply chain integration strategies were the least tasking to the pharmacies. They were considered a broad set of approaches aimed at addressing more than just the counterfeit aspect of drug distribution. Essentially, supply chain integration approaches could be considered the status quo approach relative to the alternative two approaches – chemico-physical and tracking.

Stevenson & Busby (2015) propose the use of consumer education programs as a means by which to reduce the prevalence of counterfeit medication in the market. Notably, the provision of counterfeit avoidance information to purchasers of medication presented as the least used of the assessed approaches. This would particularly surprising as it was among the most accessible options that can be leveraged by the pharmacy owners/managers. This, therefore, suggested a lack of appreciation of the possible impact that the approach would have in combating the spread of illegitimate products in the market.

Inferential analysis, though not resulting in a significant beta value for the construct, indicated a negative association between the two variables. The increase in rating of usage of the approach was associated with decreased financial performance. The finding was counterintuitive given that Dégardin, Roggo, and Margot (2014) propose the consolidation of the supply chain as among the first frontiers in curbing the threat of counterfeit medication. Said (2010) further proposes that the retailers should be urged to buy products directly from the manufactures to avoid buying counterfeit goods. The prevalence of the approach vis-à-vis the increase in counterfeiting practices

suggests a deep infiltration of the system whereby counterfeit distribution channels have been systematized into mainstream delivery paths. The use of such approaches as training and sourcing from the same manufacturers may not achieve much of an impact if the main distributors are already involved in disseminating compromised products.

Some of the measures employed by companies to deal with piracy include burning the pirated goods, identifying and suing the offending outlets, and lobbying for strict penalties against pirates. The approaches thus involve identifying dispersions from normal practice and the seeking out ways to consolidate the distribution process (Chaudhrya, Cordellb & Zimmermanc, 2005). The lack of a valid relationship between supply-chain integration strategies and pharmacies' performance suggests a lack of implementation of context-specific approaches or a disregard for the consolidation of the distribution function as a determinant of performance. Given the posited link between the variables posited by such authors as Chaudhrya, Cordellb and Zimmermanc (2005), a contextual peculiarity is likely present in the Kenyan market and further investigations should be conducted to identify possible intervening or conflating variables that present in the local pharmaceutical industry.

5.3 Conclusion

The study was predicated on the Theory of Reasoned Action and the Theory of Planned Behavior. The intention/motivation of the respective managers/owners of the pharmacies involved in the study is therefore understood to be affected by the normative beliefs, attitudes, and perceived behavioral control associated with the various anti-counterfeit strategies examined in the study. Findings indicate that all three of the approaches are inconsequential with regard to the impact on the performance of pharmacies. This finding, therefore, indicates that the belief and attitude of the respondents towards the efficacy and utility of the approaches is likely to be severely negatively impacted. This contrasts with the status quo, which indicates high usage of supply-chain management approaches, partly as a means to achieve higher performance through minimization of the implications of counterfeit drug selling. According to the two theories, the pharmacy owners/managers would be more likely to have an attitude change following the uncovering of the study findings in that they may view the approach to be unimpactful, thus resulting in the uptake

of less of the currently utilized anti-counterfeiting approaches especially if the approaches required investment.

The two theories explain individuals' intent to engage in a particular behavior. Legal registration requirements are usually paired with conditions that pharmacies have to adhere to before operating. These include assurance of the quality of medicines; thus, explaining the adoption of anti-counterfeit strategies. They also explain customer's intent to purchase medicines from certain brands due to their perceived confidence in the quality of pharmaceutical products. The theories would have implications in showing how the relationship between the adoption of effective anti-counterfeit strategies and their impact on the profitability of drug-retailing pharmacies. Similarly, the findings may help shape the belief that the approaches are futile and, therefore should be discarded in the fight against counterfeit drugs in the country. Finally, considering the behavioral control aspect of the theory of Planned Behavior, it may be surmised that due to the possible impact of tracking approaches at a lower confidence level, easier applied tracking approaches may be more likely adopted in the pharmacies than the more tasking approaches – approaches such as quick response codes that are generally more expensive to utilize.

5.4 Recommendations

The managers and owners of pharmacies, findings from the current study suggest that currently utilized anticounterfeiting approaches are generally non-impactful in combating the prevalence of counterfeiting practices; alternative approaches should therefore be considered in the fight against illegitimate product in the market. To regulators of the industry, findings suggest the need for enforcement of current policies to address the challenge of counterfeit medication and the consideration of additional evidence-based approaches to combating the phenomenon. With regard to enforcement, it was apparent that the drug checking mechanism instituted by the regulator is rarely enforced as pharmacy managers do not generally provide information on how to check for legitimate drugs in the market. To academicians, it is apparent that the Kenyan context presents as a peculiar market. The use of anti-counterfeiting approaches seems to bear little impact on the financial performance of pharmacies. It is thus recommended that additional studies be conducted to address the reasons for the difference of findings from those posited in extant literature.

5.5 Limitations

The main limitation presenting in the current study was the consideration of pharmacies within one region of Nairobi County. This was due to a limitation in resources. Given that the factor at play in rural Kenya (the bulk of the country) may be different from those in the city, the current study's findings cannot be generalized to the country. The scope was also restricted to registered pharmacies; hence the findings cannot be generalized to unregistered pharmacies. The small sample size of the study and the sensitivity around the provision of financial data further hindered the generalizability of findings; hence subsequent studies considering Likert scale responses on financial data should be considered. Subsequent studies should thus be conducted to understand the impact of anti-counterfeiting practices in other regions. A second limitation presents in the lack of inclusion of qualitative information that would help in unearthing possible reasons behind the relationships (more accurately, lack thereof) observed in the current study. A mixed-method approach would have been better fitting for the study.

5.6 Areas for further study

The main areas for further study presents in understanding the reasons for the difference in findings between the current study and extant literature. Further studies should be considered to understand, for instance, the reasons behind a possible negative relationship between increased use of supply-chain management approaches and lower performance among pharmacies. Further studies should also be conducted to unearth alternative anticounterfeiting approaches that may be more effective in the local context. Alternative studies focusing on the choice of variables and their structuring may also be considered to assess the impact of the various techniques on retail pharmacy performance. Further studies on the impact of anti-counterfeiting approaches may be considered through the lens of the Expectancy Theory of Motivation. The rationale is that the findings put forward in this study would serve to demotivate usage of the anti-counterfeiting methods.

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APPENDICES

Appendix I: Letter Of Introduction

Molly Cheruto

P.O Box,

Nairobi,

Date…….

Pharmacy Manager

…… ,

Nairobi, Kenya

Dear Sir/Madam,

RE: PERMISSION TO CONDUCT A RESEARCH STUDY ON YOUR PREMISES

I am a post-graduate student at **Strathmore Business School**. I wish to conduct my research in your firm. My research is a systematic analysis of counterfeit- drug-prevention strategies on the performance of retailing drug pharmacies in Nairobi county**.** I thus request that the main manager/owner of the retail pharmacy take part in the study.

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

The surveys 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. You can reach me on 0727453318 if you require any clarification or additional information about the research.

Yours faithfully

Molly Cheruto

Appendix II: Questionnaire

PART A: RESPONDENT'S PROFILE

1. **Within which area is your pharmacy located?**

Westlands	☐
Kasarani	☐
Dagoretti	☐
Starehe	☐
Langata	☐
Embakasi	☐
Kamukunji	☐
Njiru	☐
Makadara	☐

PART B: Chemico-physical approaches

This section assesses the chemico-physical approaches used to prevent the purchase and sale of counterfeit medication

2. **Kindly indicate your level of agreement with the following statements.**

	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
The pharmacy staff generally use packaging cues (such as seal appearance) to identify counterfeit drugs.					
The pharmacy generally uses solubility tests to assess the authenticity of drugs.					
Uniformity tests (e.g. the average mass of tablets) are generally used to check for counterfeit drugs.					
The friability/ease of crumbling of tablets is used					

as a test for authenticity of tablets					
The florescence of a tablet under is used to screen for counterfeit drugs					

PART C: TRACKING APPROACHES

This section assesses the pharmacy's use of tracking approaches to check for counterfeit drugs.

3. Kindly indicate your level of agreement with the following statements.

	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
Pharmacy staff generally use barcode technology to assess the authenticity of drugs.					
Quick response codes are usually used to assess the authenticity of drugs					
Radio Frequency Identification tags (RFID) codes are typically used to assess the authenticity of purchased drugs.					
Biodegradable bio labels are used to screen for counterfeit drugs					
Unclonable tags on medications are used to screen for counterfeit drugs					

PART D: SUPPLY CHAIN INTEGRATION STRATEGIES

This section presents questions on the use of supply chain integration strategies

Kindly indicate your level of agreement with the following statements.

	Strongly Disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly Agree (5)
The pharmacy has an integrated information system that tracks drugs from purchase to sale					
All staff are adequately trained on the protocols involved in handling drugs					
We generally inform customers on how to check for counterfeit drugs					
The pharmacy remains up to date with supply chain strategies by affiliation with anticounterfeiting organizations and initiatives					
The medication is generally sourced from the same suppliers to minimize counterfeiting					

PART E: FINANCIAL PERFORMANCE

This section assesses your general financial performance. Kindly note that this information is not will not be identifying of your organization.

What was your performance before and installation of your most effective anticounterfeiting technique, if any? Kindly indicate below

	Before	**After**
Average monthly revenue		
Average sales volume		
Average frequency of sale		

Thank you for taking time to fill in this questionnaire.

Appendix III: Ethical Approval

Strathmore UNIVERSITY

26th March 2020

Ms Cheruto, Molly
cheruto.molly@strathmore.edu

Dear Ms Cheruto,

RE: Analysis of Counterfeit- Drug-Prevention Strategies on Financial Performance of Nairobi's Drug Retailing Pharmacies

This is to inform you that SU-IERC has reviewed and **approved** your above research proposal. Your application approval number is **SU-IERC0726/20.** The approval period is **26th March 2020 to 25th March 2021.**

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-IERC.
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-IERC within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-IERC within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to SU-IERC.

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

Yours sincerely,

for: Dr Virginia Gichuru,
Secretary; SU-IERC

STRATHMORE UNIVERSITY INSTITUTIONAL ETHICS REVIEW COMMITTEE (SU IERC)
26 MAR 2020
TEL: +254 (0)703 034 000
P. O. Box 59857 - 00200
NAIROBI - KENYA

Cc: Prof Fred Were,
Chairperson; SU-IERC

Appendix IV: NACOSTI Research Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **130798**

Date of Issue: **28/March/2020**

RESEARCH LICENSE

This is to Certify that Miss.. Molly Chebuto Cheruto of Strathmore University, has been licensed to conduct research in Nairobi on the topic: ANALYSIS OF COUNTERFEIT- DRUG-PREVENTION STRATEGIES ON FINANCIAL PERFORMANCE OF NAIROBI'S DRUG RETAILING PHARMACIES for the period ending : 28/March/2021.

License No: **NACOSTI/P/20/4572**

130798

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

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