

**EFFECTS OF COUNTERFEITS ON SALES AND DISTRIBUTION OF
PHARMACEUTICAL PRODUCTS IN NAIROBI COUNTY, KENYA**

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DECLARATION

This research project is my original work and has not been presented for examination in any other University or institution of higher learning. No part of this research project should be reproduced without my consent or that of The University of Nairobi.

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D61/83885/2016

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

Signature Date

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DEDICATION

I dedicate to My Parents Mr. and Mrs. Ngethe for supporting me financially and encouraging me all through and most of all for praying for me. I wouldn't exchange you for anything. To my friends Mercy, Fridah, Jack and Ken who went out of there way, Ithank you so much and may GodBless for giving me hope and prayed for me every day.

ACKNOWLEDGEMENT

The Almighty God who saw me through my completion of this research project has shown that with Him all things are possible. All the Pharmaceuticals firms that gave me a chance to research in their company. My supervisor Dr. Catherine Ngahu and Dr. Albert Monayo who guided me through, may God bless you abundantly. The University of Nairobi for giving a chance defends my project and the profound support. I would also like to thank all participants of this research who made this project a reality.

ABBREVIATIONS AND ACRONYMS

ACA	Association of chartered accountants
CTI	Confederation of Tanzanian Industries
EAC	East African Community
IACC	International Anti-corruption Conference
KAM	Kenya Association of Manufacturers
KEBS	Kenya Bureau of Standards
KEMSA	Kenya Medical Supplies Agency
KIPI	Kenya Industrial property Institute
KRA	Kenya Revenue Authority
UMA	Uganda Manufacturers Association

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ABSTRACT

Sale of counterfeits has no indications of slowdown, despite numerous anti-counterfeits measures in the industry and economy as a whole. It has increasingly become challenging to eliminate the practice; there is need and urgency to investigate, consumption drivers. The ownership of a well-executed counterfeits could easily challenge the vision of the whole industry. The objective of the study was to establish the impact of counterfeits on sales and distribution of pharmaceutical products in Nairobi County. The study undertook a cross sectional survey approach of the major pharmaceutical distributors in Nairobi County. The study findings indicated that preference for counterfeits products arose due to the existence of the rampant practice in every sector of the economy, notwithstanding the pharmaceutical industry; the price of counterfeits; the regulatory framework and institutions not quite vigilant in their task of combating the practice; ease of distribution of counterfeits, supply chain well stocked with counterfeits. The study further noted that the counterfeits impact was quite heavy in various aspects of the economy. Effects include the loss of investment, effects on innovation, effects on image of the pharmaceutical network, loss of tax to the government, loss of goodwill of the brand process; the study investigated the remedial measures in the industry to curb the practice. There are various administrative and judicial approaches towards managing the counterfeits practice. There's the counterfeit agency "the criminal enforcement of anti-counterfeit laws" established under anti counterfeit act 2008 whose mandate is to enforce the provision of the act, to educate the public on counterfeits in Kenya. The intellectual property rights of Kenya are also part of the preventive measures. The criminal enforcement of anti-counterfeit laws do not result into compensation of the affected party, no gains are derived from its execution, making the remedy unpopular. The civil remedy to counterfeit practice involves the compensation of the rights holder. The study concluded that there's need to strengthen the various laws relating to counterfeits in Kenya.

CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

Business today is encompassed with challenges from all frontiers of the environment, political, social, economic, and technological. Modern businesses cannot operate and compete as solely autonomous entities but within the supply chains, in the emerging and future competitive forces success of any business will depend on the firm's capabilities to integrate the firm's delicate network of business inter-relationships. The globalization of business has accelerated need for firms to seek better and more, Inter linked systems and supply chain management (SCM) competencies. According to Norman & Lindroth (2004) the firm's competitiveness of its distribution networks is determined by different factors and firms resources with reference to networks, knowledge management and business environment. Channel flexibility and responsiveness becomes key parameters to success.

“Counterfeiting” is the deceitful collection, modification and or dispensation of a product of lesser value than the original product (IACC, 2016). A counterfeit medicine is one which is mislabeled, including character and source, with the intent to dupe consumers into believing that it is the original product. Duplication in pharmaceuticals applies both to marked and non-specified products. All the products categorized as counterfeit encompass things with the right fixings, those with wrong fixings, those which lack element fixings or the ones that mix up the element fixings or packaged wrongly (Sabin 2009). Forging in its moderate state is less harmful to the buyer as it. Counterfeiting has deadly effects to patients who may consume them due to lack of active ingredients contained in the original products or due to the toxic ingredients that may be in these

products. Pharmaceutical counterfeiting cases continue to penetrate local market with the most counterfeited being the expensive lifestyle medicines like antibodies, steroids, analgesics, hormones and antihistamines (Kibwage, 2008). Some of the pharmaceutical counterfeits entail fast moving and commonly known brands, those that are easily manufactured and those available for supply to government institutions and export (Mehta, 2006). The problem of counterfeiting has had huge impact on the distribution of pharmaceutical product.

The theories which support this study are the contingency theory which is a category of behavioral theory that indicates that there's no best or better way of organizing a firm, it all depends on the internal and external situations; the theory indicates that the best way to organize depends on the nature of the environment where the firm operates. Another notable contribution theory is the supply chain management. Another relevant theory is the stakeholder theory. According to Friedman & Miles (2006) individuals groups affect and get affected by organizations in their achievement, of objectives, these are referred as firms stakeholders. Stakeholders are entities with conceivable interest or stake in policy concerns. They can be individuals, organizations or the organized groups.

Nairobi County is the most populous county in Kenya and the largest consumer of pharmaceutical products. The county has four districts with these distribution networks Nairobi West, Westlands, Nairobi East and Nairobi North and constituencies namely: Makadara, Kamukunji, Starehe, Lang'ata, Dagoretti, Westlands, Kasarani and Embakasi, Lucky Summer, Dandora, Huruma and Kariobangi.

1.1.1 Counterfeiting

Counterfeiting refers to an unwarranted imitation of a product or a brand without the consent of the original proprietor who is entitled to enjoy all the profit benefits by the innovation rights. Counterfeit pharmaceuticals are those which are deliberately and falsely produced and wrongly labeled to beguile consumers that it is certified (PimTuytset al, 2007). Furthermore, counterfeiting alludes to fabricating or creating surrogate products in Kenya or else and hence infringing on the rights of the legitimate creators (Caroline, 2016). The legitimacy of the original pharmaceutical products raises eyebrow and consumers might fear buying the original products with a perception that it is fake. The net effect of counterfeiting is the loss of revenue to the original manufacturers of the original product and the government due to lower tax collection. The trend of the counterfeiting is on the increasing trend and requires various interventions from the government through the clear policies that reduces the export/imports of the counterfeit pharmaceuticals(kibwage, 2008). Moreover, administrating bottle necks to curb the sale of the pharmaceutical products in the market and hence plays a role in the distribution of the counterfeits.

1.1.2Distribution Networks

Distribution is the process of transferring goods from the manufacturer to the consumer through stipulated distribution channels (Agbonifohe al, 2007). These channels are properly organized processes which help enhance business transmeasures. Basically, a distribution channel offers a link between production and consumption while creating time, place and possession utilities all of which increase a business value (Kotler,

2006).Manufacturers cannot solely conduct direct marketing to consumers hence they need intermediaries (wholesalers, distributors, suppliers, agents, brokers). The distributor plays a critical role in the sale of the counterfeit products. Therefore, they are intermediaries between the producers of the pharmaceuticals and the final users or retailers. Most wholesalers and producers collude with other personnel in the chain of distribution to sell the counterfeit products to the retailers an Most wholesalers and producers collude with other personnel in the chain of distribution to sell the counterfeit products to the retailers, hospitals. Factors influencing distribution networks include market characteristics, company characteristics, product characteristics, and middlemen characteristics, intensity of competition and environmental trends and factors.

According to the health informatics (2011) the concept of distribution is facilitated by the importers and wholesalers which creates a link between manufacturers and retailers to ascertain the continuity of pharmaceutical product distribution regardless of the geographical locations of the required medications. Distribution has been viewed as the portal of entry for counterfeit products. The explanation on distribution lies on the organizational distribution channel for local manufactures and for imports. Global supply chains are complex and risky and encompass problematic distribution risks (Opiyo, 2006). The distribution of the pharmaceutical product has many divisions which may result in the compromise of the distribution chain. Most of the countries have adopted the method of fee for service model where the margin for wholesaler is negotiated between the distributor and the manufacturers. The methods continue to impose exploitation on originality (Chambliss et al., 2012).

1.1.3 Pharmaceutical Industry in Kenya

The pharmaceutical industry is under strict regulation and with an intensive capital and labor. The pharmaceutical industry in Kenya is hinged on a liberalized and competitive space. The Kenya Pharmacy and Poisons Board regulate all the pharmaceuticals in Kenya (Cap 244 Act). The board exercises its mandate by inspecting pharmaceutical premises, regulating and registration and issuance of licenses. The board also issue licenses to the qualified pharmacists, retailers and distributors.

The retail pharmacy acts as a link between doctors and patients because of its direct contact with doctors and patients (Opiyo, 2006). The key players in the regulation of pharmaceutical industry in Kenya by The Ministry of Health are; Pharmacy and Poisons Board, Pharmaceutical Society of Kenya, Kenya Medical Association, Kenya Medical Supplies Agency(KEMSA) and the Kenya Bureau of Statistics. The industry is dominated by foreign firms (%) and the balance is locally owned establishments. The industry consists of three segments, the manufacturers, the distributors & the retailers, Kenya leads in pharmaceutical products in central and East Africa (COMESA) region. The pharmaceutical health market is estimated to be 180 million dollars a year (KAM 2013). The pharmaceutical sector supports the regions health sector which has approximated 4557 health facilities in Kenya. (Muiya and Kamau 2013) the Kenya pharmaceutical industry has 38 out of 50 recognized units within the COMESA region (Ongu 2012).

1.1.4 Nairobi City County

Nairobi County is the most populous county in Kenya and the largest consumer of pharmaceutical products. The county has four districts; Nairobi West, Westlands, Nairobi

East and Nairobi North and constituencies namely: Makadara, Kamukunji, Starehe, Lang'ata, Dagoretti, Westlands, Kasarani and Embakasi, Lucky Summer, Dandora, Huruma and Kariobangi.

Majority of the pharmaceutical distributors are headquartered in the county. Nairobi county enjoys the status of the capital city of the republic of Kenya. To the North the county is boarded with Machakos County; to the East there's the Kajiado County, to the West there is the Kiambu. All these counties contribute to the greater demand of pharmaceutical products. (NCC Bulletin 2017).

1.2 Research Problem

Counterfeit products can be obtained anywhere, across all economic sectors globally (FDA, 2014). These products are manufactured in and distributed in illegally to evade normal traffic tax. Counterfeit pharmaceuticals directly affect the mainstream pharmaceutical industry due to lost sales, reduced profit and reduced profit and loss of general public confidence. Youmans & Law (2011) reveals that 59.3% of respondents believe that counterfeit pharmaceuticals posit a problem to the profession, but most had been minimally or completely not experienced these counterfeit pharmaceuticals. Counterfeiting business operators are leveraging on technology to make their firms better. This however, is not a symbiotic relationship because the legitimate companies are choked by the ones producing counterfeit medicines. The counterfeiters are tech savvy, and they are able to update their products to match the legitimate ones, hence creating confusion among the consumers. Counterfeit pharmaceuticals are a global health threat posing causing death, disability or injury to both adults and children (Kibwage, 2008).

Nevertheless, patients who consume counterfeit pharmaceuticals might lose confidence in their healthcare providers upon realization. The importation of counterfeit pharmaceuticals also creates unfair competition in the pharmaceutical industry, making it necessary to delve into its impact on pharmaceutical distribution and retailing.

Supply chain management is all about managing flows of resources; logistics is an important part of supply chain management; the supply chain management encompasses of the planning, management of all activities involved in the sourcing and procurement, conversion and other logistics management activities. It also includes coordination and collaboration with channel partners which may be supplier's intermediaries, third party, service providers and customers. Xardel (2006) argues that with recent global development and rapid changes in the business environment especially in technology and communications, the shape of supply chain has not only become non-linear but in some cases even intermediate, materials flow in all directions hence channel comprehension & coordination becomes difficult.

Nairobi City County is one the largest counties in terms of population, with the largest network of pharmaceutical distributors. The population sector requires the much needed healthcare medication and other medical facilitation. Nairobi City County encompasses of the following district or county districts, Nairobi west; Westlands, Eastlands and Nairobi North. Constituencies include Kamukunji, Makadara, Lang'ata, Starehe, Embakas, Dandora, Huruma, Kariobangi. (County govt Bulletin 2017).

International studies undertaken include a research by Blumberg (2001) on marketing and sales capabilities of pharmaceutical firms in Europe; the findings indicated that effective

marketing channels were essential to any business venture(s). Leat&Revoredo (2013) conducted a research on risk and resilience in Agri Food Supply chains a case of ASDA Portlink. Supply in Scotland the study revealed that challenges affected the pig sector in Scotland and indicated major risks which impinged on its normal operations; some other risks were equally applicable to other sectors of the business.

Locally, several studies have been undertaken. Gitau et al (2014) researched on marketing strategies adopted by pharmaceutical firms in Kenya. The findings indicated that most pharmaceutical firms adopted multiple types of marketing strategies to gain competitiveness and maintain sustainability. Moenga (2011) conducted a study on supply chain management practices and challenges facing the small tea sector in Kenya. The findings indicated that the challenges were Limited to the small tea sector alone and could not be applied to other companies in other industries. Muthiani and Wanjau (2012) did a study on factors influencing the influx of counterfeit medicines in Kenya. Their findings indicated that lack of proper policy guidelines unscrupulous traders, corruption practices contributed to the influx. Nsimba (2008) researched on the problems associated with standard drug in developing countries. Opiyo (2006) researched on responses of pharmaceutical firms to challenges of illegal imports. From the above studies none of these studies has focused on my topic of research. The research question is what is the impact of counterfeits on sales and distribution of pharmaceutical products in Nairobi County Kenya?

1.3 Research Objectives

The objective of this study was to establish the impact of counterfeit sales and distribution of pharmaceutical products in Nairobi County, Kenya

1.4 Significance of the Study

This study can be used by the Kenya counterfeit agencies to create awareness to the pharmacies, public and medical professionals on the adverse impact of counterfeit medicines to the future business. The Ministry of Health and Pharmacy and Poisons board can also use this research to help formulate policies to combat counterfeiting and piracy of all products to ensure success of business of the legitimate medicines in the market. The intellectual property protections will also put strict measures to combat the counterfeiting and piracy of all products that are available in the market. This will ensure the business of the legitimate pharmaceutical products is not greatly affected by the presence of counterfeit drugs.

The Pharmacy and Poisons board can refer to this study when making policies against counterfeit medicines by including the role of pharmaceutical industry when amending the anti-counterfeit act. The study will create awareness on counterfeit drugs and rally the pharmacist to act against counterfeit medicines. The recommendations of this study will include action plans that pharmaceutical industry should adopt to survive competition. This study will also expand knowledge of Pharmacy and Medicine practitioners.

This study will also be beneficial to academicians through publishing and formulation of bills and relevant literature which can boost and improve research findings. The academia's can also utilize the study to publish books, hold seminars to sensitize the community of the pros and dangers of counterfeits.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This section introduces the relevant theory's supporting the study, and relevant literature review on distribution function.

2.2 Theoretical Framework of the study

This study will be hinged on these theories, stakeholder theory, theory of supply chain management & the contingency theory.

2.2.1 Stakeholder's theory

Stakeholders are those parties considered pivotal for the success of a corporation. It includes suppliers, employees, customers, communities and shareholders and managers (Keitany&Moronge, 2013). Donaldson and Preston (1995) ascribe to the notion that stakeholder's interest is so essential, not only to the benefit of the company. The theory is founded on the tenet that the company's decisions affect the stakeholders. Each company is therefore obliged to define fundamental moral principles to use in making decisions about their products. This theory is applicable to this study due to its ability to outline the importance of stakeholders; their roles and significance contributing towards the pharmaceutical industry success. The theory postulates that agents and stakeholders should operate on ethical terms and while addressing the interests of stakeholders. The illegitimate trade on counterfeit medicines however is not founded on ethics, and these impacts negatively on stakeholders. The theory is relevant to the intended study since it satisfies and ensures that the diverse needs of all stakeholders are well articulated and

represented. This is made possible through establishment of networks of relationships, with stakeholders of the firm which may include the suppliers, employees and customers.

2.2.2 Contingency Theory

The contingency theory was advocated by House (1996). The theory implies that the contingency approach method is based on the premise that there's no specific way of planning, managing, organizing leading and controlling organizations operations. The specific circumstance where the firm is determines its operations. Morgan (2007) asserts that leaders need be flexible and accommodate the ever changing business environment and needs of clients. The contingency theory holds that the best decisions made should be flexible and dynamic.

2.2.3 Theory of Supply Chain Management

Spulber(1996) defines an intermediary as intrinsic ingredient of economic activity. He proposes this theory as an exchange between a group of suppliers and customers. When the gains in intermediate exchange usurp the gains in direct exchange from a supplier to the consumer, a new firm is created. The theory explicitly explains the existence of intermediaries, their advantage over direct sales and their roles in setting prices, cost and creating competition (Spulber, 1996). The existence of intermediaries creates a loophole for counterfeit activities. The longer intermediary chains spur longer chain of counter drug retailing in the industry. The principal focus on market competition is not only between goods but also between supply chains delivering the goods, coordination, quality logistics, between suppliers and distributors becomes critical and marks the success of the supply chain links. Jacklick (2005)

Market trends and uncertainties compels supply chains to be flexible to changes in the immediate business environment; This flexibility encourages effective supply chain & logistics management; Grant, Lambert, Eilarm, Stock (2006) indicates that supply chain refers to corporate business processes integration firm end users through suppliers that provide goods, services, information and add value for customers. Supply chain is viewed as a series of interconnected activities which are involved with the planning, coordinating and controlling of materials, parts and finished products from suppliers to customers. (Laureenco 2001). The effectiveness of SCM heavily relies on incorporation of the activities of supply chain, corporation, information sharing and organization throughout the entire supply chain. The supply chain of the pharmaceutical industry is complex involving linkages between big suppliers, downstream distributors, information and capital.

2.3 Counterfeiting and distribution efficiency

The prolonged use of counterfeit drugs can lead to therapeutic failure and drug resistance. Counterfeit pharmaceuticals have varying detrimental effects and bizarre characteristics, some containing lethal ingredient that if ingested or injected into patient's system, can cause health complications (WHO, 2016). Recent findings revealed glaring counterfeited Procrit drug which is essential for cancer AIDS patients was found to contain no sterile tap water capable of causing infection in the bloodstream (FDA, 2009). The availability of counterfeit medicines in the market impacts negatively on the pharmaceutical business. The brand value and reputation of pharmacy are compromised. The manufacturers of genuine pharmaceuticals have to boost their research kitty in order to facility in-depth research and create advanced pharmaceuticals to counter competition. The past decade

has witnessed wanton production of counterfeit pharmaceuticals, causing high level maladies and mortality in developing countries (Newton, 2006).

The productions of counterfeit drugs affect the underprivileged people and developing countries. The implication on the government is the reduction in revenue collection. Effacing out the counterfeit drugs can be so costly to the government. This vice sprouts when there is lack of integrity and corruption between the government and the manufacturers and sellers of counterfeit pharmaceuticals. The factors prompting the importation of counterfeit medications in pharmaceutical Small and Medium Enterprises (SMES) was studied by Muthiani (2012). The study's objective was to investigate the influence of legislation on influx counterfeit medicine, influence of brand equity on influx of counterfeit drugs in the pharmaceutical SMEs, to investigate whether pricing strategy of medicines influences the availability of counterfeit medicines and finally to investigate the extent of perceived health hazards. The study finding on a response rate of 80.3% were that legislation, brand popularity, and various perceived risks have impacts on the availability of counterfeit pharmaceuticals. The study further revealed that brand popularity increases the willingness to purchase counterfeit products. Price exchange influenced consumers to buy counterfeit products when the legitimate products are highly priced.

The study on pharmaceutical counterfeiting in developing countries as conducted by Desisign, (2004) determined effects of counterfeit medicines. The findings of the study reveal that between 1999 to December 2002, Antibiotics, hormones and steroids were the mostly counterfeited due to their high prices. The study also found out those counterfeit pharmaceuticals have various impacts on consumers, manufacturers, healthcare

professionals and the government. According to the research, some of the methods used to determine counterfeit medicines include chromatography, spectrometry, isotopic characterization, Raman spectroscopy, tensiongraph and near-infrared.

Effects of ownership of counterfeit products were studied by Bian&Motinho, (2011) the objectives of this study was to determine whether the consumers are favorable to genuine branded products or counterfeit branded ones, to determine whether consumer perceptions about counterfeit products are altered by the producers of the counterfeit products. However, no relation was established between counterfeit branded products with consumer's perception of the counterfeit branded products.

2.4 Management of distribution system(s)

Distribution decisions are critical in any business firm, they affect firm viability and product; there decisions also affect market share of the firm, market diversity changing customer expectations have failed expectations hence making it difficult for the firm to attain maximum competitive advantage position in the industry (Saxena 2006). The roles of middlemen in the distribution system is quite critical, key roles identified include the informative role, facilitation of price stability, promotional effect, financing and the element of title, the title component entails risk reduction between the manufacturer and the consumer; classification of channel participants include the merchant middlemen, agents and facilitators.(Rajan 2006)

The firmslength and structure of distribution channel is determined by the size of the market, order size, service requirements, product variety distribution decisions are also influenced by the market characteristics company characteristics, product characteristics and environmental characteristics.

2.5 Ethical Stakes& Corporate Social Responsibility

According to Martin et al (2010) ethics relate to the moral obligation to undertake decisions rightly and avoidance of wrong applications the concept addresses personality traits and qualities of those who make decisions. A critical analysis of causes of ethical problems in business reveals the following key issues, the narrow self-interest attitude; stunted moral growth and development, rationalization; distancing from responsibility, emotional pressures, authority, tunnel vision and communication breakdown. Ethical lapses in business decisions can be corrected through a series of measures and managerial interventions including undertaking of a policy and procedures audit, sticking to fundamentals, cultivation of moral imagination, use of guides and rationalization practices leading by examples, making ethics part of dialogue, emphasizing responsibility and accountability throughout the firm; fostering communication and feedback, introduce ethics education.

According to Keith Davis & Fredrick (1994) business and society relationships create new challenges and opportunities for firms; business primary involvement with the society includes all the direct relationships vital for it to undertake major mission of producing goods and services for the society; business primary intermeasures with the society includes suppliers, creditors, stockholders, employees, competitors, customers, retailers and wholesalers; business secondary intermeasures involves the government, social interests groups, media, business support groups, public opinion, local communities; Epsein (1979) asserts that responsible corporate social behavior contributes to the legitimacy of a corporation and its rational interaction with other sectors of the society; today and increasingly in the future, business is an arena for conflicts of

economic, social and political influences and demands. Bowen (1978) outlines various reasons for business social involvement, this involves the changing public needs and expectations, moral obligations, societies limited resources, firm better position to get involved; business contribution to social problems, business has resources and the element of system interdependence requires social involvement. Major consumer issues in business today include truth in advertising, product liability, energy and ecological impacts on consumer behavior.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the methods that was be employedso as to achieve the set objectives. It addressed the study design that will be adopted, the population of the study,and the variables for the study, data collection and analysis.

3.2 Research Design

This study was carried out within the framework of a descriptive cross-sectional research design employing mainly quantitative data collection methods. A research design is an outline of study which indicates what the researcher will do from the hypothesis stage to final analysis of data (Kothari 2014) explains that research design constitutes decisions regarding what/ where/ when and how concerning an inquiry of study. (Sekeran 2011)

3.3Study Population

Burns and Groove (2003) indicates that a population is that elements that meet the criteria for inclusion in a study. Population is an entire group having common characteristics.The population of the study constituted of the pharmaceutical firms in Nairobi County. Which number (24), a census approach was undertaken for this study.

3.4 Data Collection

The study adopted the use of primary data which was collected using a structured questionnaire (appendix I).The questionnaire comprised offour sections. Section A had data on demographic characteristics of the respondent &business; while section B focused on the factors contributing to preference of counterfeits; section C examined on

distribution networks; section D focused on control measures on counterfeits. Respondents were managers/ in charge of distributive functions of these firms.

3.5 Data Analysis

Burns and Grove (2003) explain that data analysis is a mechanism for reducing and organizing data to produce findings that require interpretation by the researcher. Hyndman (2008) indicates that data processing involves translating the answers on the questionnaire to a format easily manipulated to produce statistics; descriptive statistics and inferential statistics were utilized to derive conclusions and generalizations regarding the population. This enabled the researcher to establish the central tendency of the variables. The findings were presented in form of tables, graphs, pie charts and diagrams.

CHAPTER FOUR: DATA ANALYSIS FINDINGS AND INTERPRETATION

4.1 Introduction

This chapter presents the analytical details of the research, in line with the objectives of the study. The main objective of the study was to establish the impact of counterfeits on sales and distribution of pharmaceutical products in Nairobi County Kenya.

4.2 Response rate

The study targeted twenty four firms engaged in the distribution of pharmaceutical products in Nairobi County. (appendix II attached) a total of seventy two (72) questionnaires were distributed successfully administered and returned were sixty two (62) questionnaires were collected and as per the table 4.1 below

Table 4.1 Response filled questionnaires rate

Statement	Frequency	Percentage
Responded	62	86%
Did not respond	10	14%
Total	72	100%

Source: primary data

From the research outcome its indicated that the response rate was 86% eighty percent, which was quite impressive. Success of this response can be attributed to the preparedness of the researcher and good will as Cordial Corporation accorded by the respondents from different employers.

4.3 Demographic Data

This section outlines the demographic information of respondents, covering the education qualifications, position in the firm and years of experience.

4.3.1 Education Qualifications

The study sought to investigate the educational level of respondents to ascertain the level of understanding of the counterfeit issues relative to their existence, format and even the regulatory framework in place to safeguard their business(s). The study findings indicated that 82% comprising of 50 respondents had university education in either pharmaceutical fields or management discipline, while 18% comprising of 11 respondents had diploma and tertiary/ college qualifications from recognized institutions. This outcome clearly indicates that the respondents were learned academically and understand the business laws especially issues pertaining to counterfeits and how they affects their operations.

Table 4.2 Academic Qualifications

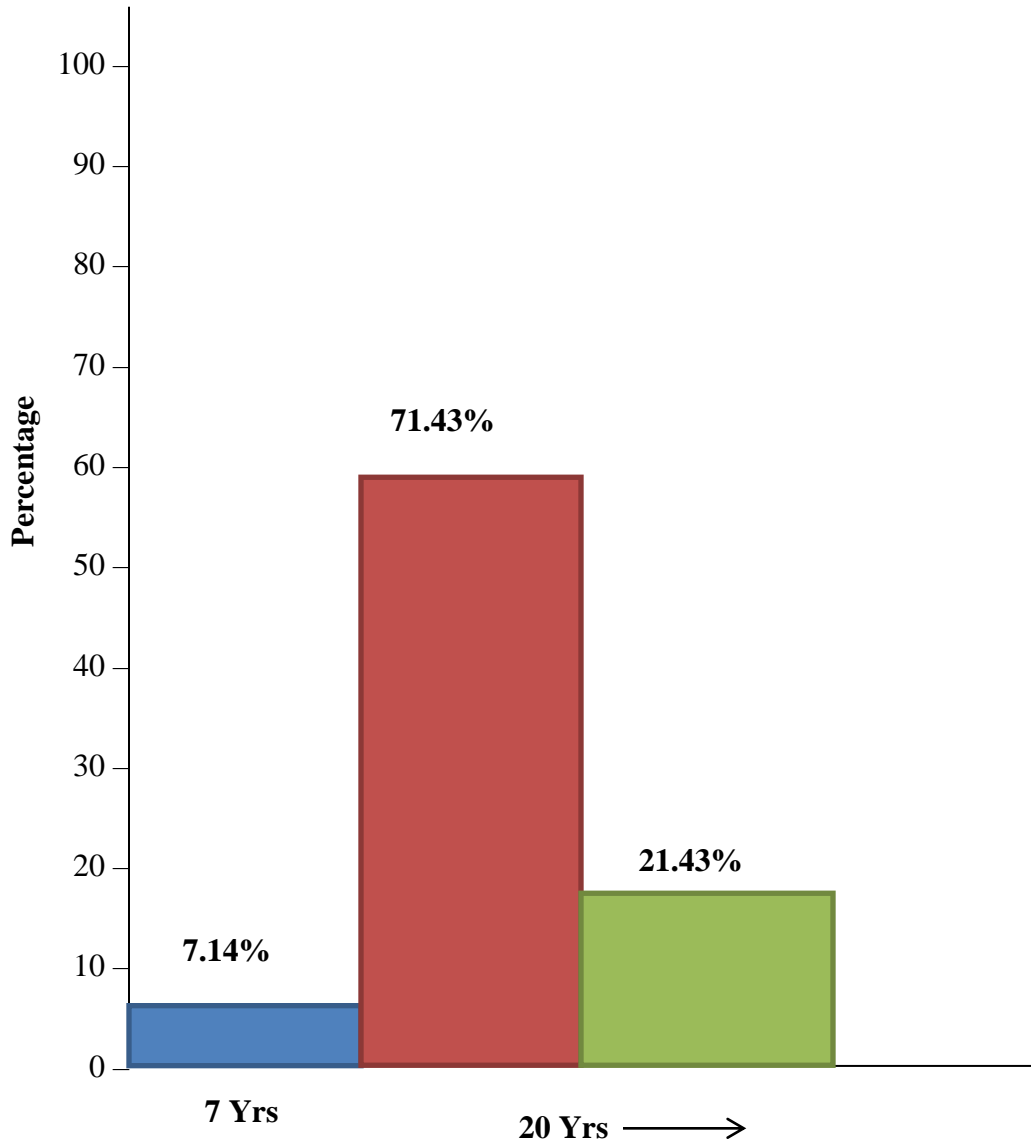
Statement	Frequency	Percentage
University level education	50	82%
Diploma & tertiary level education	12	18%
Total	62	100%

Source: primary data

4.3.2 Respondents Length of Service

The study sought to investigate the length of period respondents had served in their respective positions. This information was deemed important in order to determine the in-depth awareness and knowledge possessed by these respondents especially in their verification and analytical skills of counterfeits. The study findings indicated that 7.14% respondents had worked for up to 7 years; 71.43% had worked for up to 20 years and 21.43% had worked for more than twenty years (20 years).

Figure 4.1 years of service



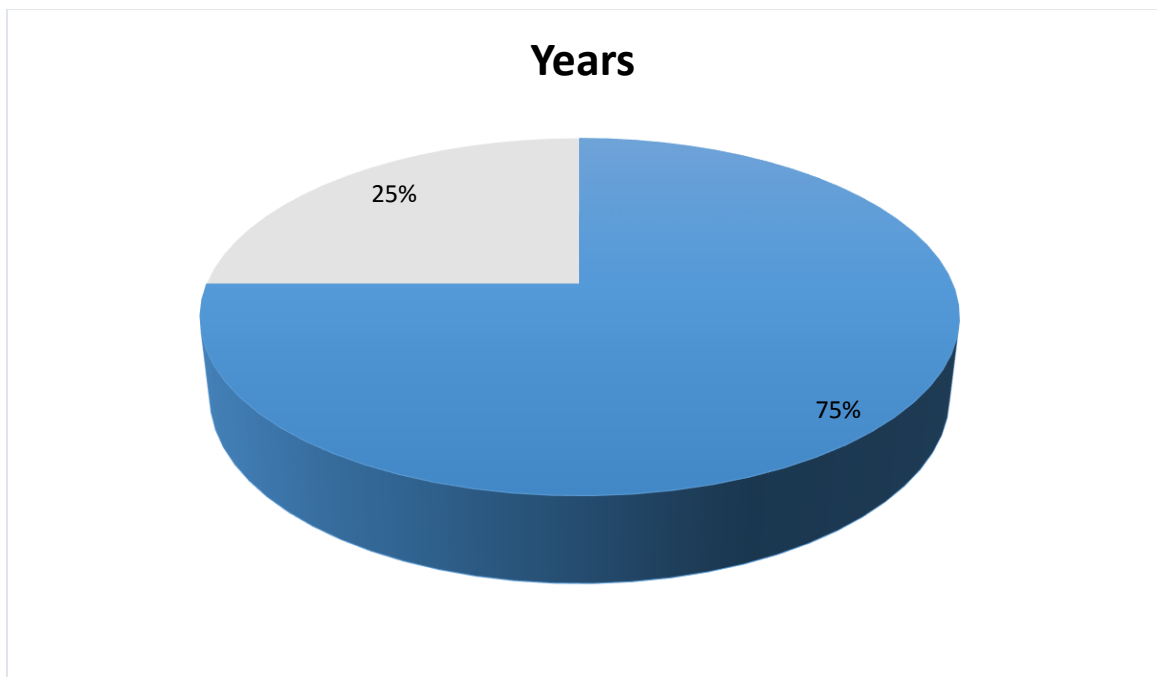
Source: primary data

4.3.3 Length of Firms Years of Operation

The researcher wanted to know the years of service the firms have been in operation. The purpose of this investigation was to understand the effects of counterfeits on the operations of the firm; this could also imply that the surviving firms in operation have

particular characteristics or competencies which they have utilized to mitigate against the effects of counterfeits. The findings indicated that out of the twenty four distribution firms 25% of the firm (six firms) had been operational for less than two years; 75% of other firms (18 firms) had been in operation for over twenty years and above. Figure 4.1 below indicates

Figure4.1 Duration of Years of Operation



Source: primary data

4.3.4 Nature of Business

The study investigated the nature of business operated by these chain links of distributors. The findings indicated that majority of these outlets were undertaking wholesale transactions in distributive functions.

These findings indicate that many establishments are wholesale outlets and are easily prone to the effects of counterfeits trade and practices.

4.4 Preference for Counterfeit Products

The study sought to establish reasons for preference of counterfeits, table 4.4 below indicates.

Table 4.4 Preference for Counterfeits Products

Statement	Mean	Std deviation	Interpretation
Counterfeiting exist in pharmaceutical industry	4.20	0.88	Strongly agree
The price of a product is a good indicator of its quality	4.11	0.93	Strongly agree
Counterfeiting practices are rampant	3.99	0.85	Agree
Counterfeiting agencies not vigilant on their operations.	4.07	0.75	Strongly agree
The distribution chain is well stocked with counterfeits	4.0	0.95	Strongly agree
Counterfeit products are distributed easily	4.07	0.73	Strongly agree
The policy safeguarding the pharmacists is not standardized	3.98	0.85	Agree
Having distributors increases the chance of counterfeit prevalence	3.99	0.88	Agree

Source: primary data

The study findings indicate that various factors contributing towards prevalence of counterfeit products among the customers and channel networks. The element of counterfeiting exists in pharmaceuticals mean score 4.20 was strongly rated as a contributing factor. This acknowledges the fact that the Kenyan industry is rampant with counterfeit trade practices; secondly the price of counterfeits seems good to attract consumers and middlemen mean score 4.11, the interpretation being strongly contributes to the availability of these counterfeits hence promoting the trade.

Respondents acknowledged good stock levels of counterfeits contributory factor mean 4.0 and the availability of counterfeits being distributed easily mean 4.07. Availability of easily counterfeits has a great compact on promotion of the trade. Other contributory factors which respondents agreed contribute were the practice being rampant mean 3.99, policy safeguarding the pharmacists not standardized mean 3.98, and many distributors stocking the products encouraging the trade mean 3.99.

4.5 Impact of Counterfeiting on Pharmaceutical Distribution

The study analysed the impact of counterfeiting on pharmaceutical distribution; the findings indicated a number of notable trend & effects arising from the analysis.

Table 4.5 Impact of Counterfeits on Pharmaceutical Distribution

Statement	Mean	Std deviation	Interpretation
Selling counterfeits affects sales	4.02	0.95	Strongly agree
Buying counterfeit causes loss of goodwill of the brand process, which further reduces the cost associated with distribution.	4.0	0.96	Strongly agree
Counterfeits affect investors Investment	4.62	0.99	Strongly agree
Counterfeits affects innovation	4.66	0.97	Strongly agree
Selling counterfeits affects the image of the pharmacy.	3.95	0.68	Agree
Counterfeits lead to loss of tax to government.	4.05	0.97	Strongly agree
Government is doing enough to curb counterfeiting within the health sector.	4.22	0.87	Strongly agree
Counterfeiting disrupts the distribution network	3.75	0.85	Agree

Source: primary data

From the analysis, the study indicates the following. The counterfeits affect the selling of genuine brands mean 4.02 , loss of goodwill mean 4.0, affect the investment patterns and levels in the economy The study also revealed that counterfeiting has a negative effect, innovation it also indicated that, counterfeits contribute to loss of income through tax evasion mean 4.05 and the government control measures mean 4.22. All these factors had a great bearing on the impact these counterfeits had on the pharmaceutical industry. Other factors which affectingthe industry include image and disruption of distribution networks.

4.6 Factors Influencing Supply Chain Management (Logistics)

The study sought to understand the various factors which influenced the supply chain management and logistics. This informs how counterfeits find their way to their distribution networks. The table 4.7 below indicates the various factors and their respective impact on the industry research findings indicating to a very large extent were issues of long term relationship with suppliers mean 4.02; meaning that the relationship with channel members propagates and cultivates strong relationship with its partners; middlemen features mean 3.93; product features mean 3.66; marketing infrastructure mean 3.99; all these factors have a large extent in their impact as far as the factors influencing supply chain management of pharmaceutical firms understudy.

Statement	Mean	Std Deviation	Interpretation
Management information systems competency of the firm	3.15	.502	Moderate extent
Long-term relationships with other suppliers & its effect on activities of the firm (transportation & storage)	4.02	.720	Very large extent
Marketing infrastructure of pharmaceutical products being adequate and reliable	3.99	.749	Large extent

The channel structure being reliable	3.93	.627	Large extent
Storage & transportation facilities	3.65	.622	Moderate extent
Product/ market characteristics	3.66	.621	Great extent
Middleman characteristics	3.93	.622	Large extent

Source: primary data

4.7 Control Measures on Counterfeit Trade

The study sought to understand the various measures the industry has put in place to manage the vice of counterfeit practice, table 4.4 below indicates

Statement	Mean	Std Deviation	Interpretation
Improve identity detection of drug products	3.744	.2261	Agree
lead in anti-counterfeit measures	4.155	.4286	Strongly agree
Prevent entry of counterfeit prescriptions	3.864	.6530	Agree
Ensure the chain of distribution is monitored through evaluation	4.167	.4288	Strongly agree

From the study findings it is noted that lead in counterfeit action by relevant authorities mean score 4.155 and ensuring channel monitoring & evaluation exercises mean score 4.167 these findings indicate that there are strong ties to curb the counterfeit trade in the pharmaceutical industry. The other measures like prevention entry of counterfeits prescriptions mean 3.864; and improved identity in defection of drug products mean 3.744; indicate that these measures are relatively undertaken to connect the position of counterfeits in the industry.

The study findings indicated different systems of administrative and judicial approaches towards counterfeit management; the government has established anti-counterfeit laws to protect local business, despite various challenges involved. From the respondents feedback the following laws were mentioned as part of the control measures the “intellectual property doctrines,” safeguard intellectual property rights are considered as counterfeit laws, especially when the framework encompasses of patent, trademark, and copy rights; copyright laws governed by copy right act section 22 of the copy right act; this covers literacy works, musical element, artistic works, audio visual and sound broadcast; patent law is governed by industrial property act, respondents indicated that a patent is a certificate granted to an inventor, it’s given for products or processes; there is also trade mark law including trade mark act and penal code act. The penal act provides for criminal procedure in trade mark infringement, the respondent argued that a trade mark is a sign which identifies certain goods or services or issued by a particular firm/ person; The counterfeit act 2008 is also a measure to counterfeit laws in Kenya. It was established under anti-counterfeit agency, a corporate body with perpetual succession and authority to administer a counterfeit policy and law in Kenya.

Study findings indicated that the counterfeit agency had three main functions and mandates, firstly to enforce the provision of the Anti-counterfeit Act 2008; secondly to educate the public on counterfeiting issues, and thirdly to combat counterfeiting in Kenya. The study findings also outlined that there were judicial enforcement of anti-counterfeit laws; this laws had two dimensions, civil and criminal. Article 22(1) of the constitution of Kenya 2010, grants any person a right to institute court proceedings claiming that a right or fundamental freedom has been denied, infringed and threatened,

the study concluded that in case of counterfeit trade the owner of the intellectual property right can institute court proceedings. The study further indicated that civil enforcement of counterfeit laws need to compensate the intellectual property owner for loss suffered as a result of counterfeit trade, this provision is under the TRIPs agreement (Agreement on Trade Related Aspects of Intellectual Property rights). Under article 42 of the TRIPs agreement. The study concluded that the principle under civil judicial procedure is that compensation is done only to the right holder; section 55 of the industrial property Act enables the owner to right of injunction compensation and damages upon infringement of own right).

The study also examined respondent's explanations on criminal enforcement of anti-counterfeit laws, the respondents indicated that the criminal enforcement is also provided under TRIPs agreement under article 67. The study findings indicated that criminal enforcement of anti-counterfeit laws in Kenya is under the penal code and anti-counterfeit act 2008. Section 380 and 381 of the penal code penalize counterfeiting or forging of trademark; other criminal measures are provided for under the Anti-counterfeit Act 2008 section 32 and section 35. The study finally noted that criminal remedies are intended to prevent rather than to compensate; this has discouraged most intellectual property owners from reporting the cases as they feel there's no gain from damages. Suffered as a result it has rendered criminal remedies unpopular in Kenya.

CHAPTER FIVE: SUMMARY CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter outlines the summary, conclusions, limitations and recommendations for further study.

5.2 Summary of findings

The objective of the study was to assess the impact of counterfeits on sales and distribution of pharmaceutical products in Nairobi County. Counterfeits constitute a problem for the pharmaceutical industry. Counterfeits purchases arise from a boomerang effect of healthcare brands on-going strategy to attract more customers/ consumers. The study findings indicate that Kenyan pharmaceutical industry is facing an alarming increase in trade of counterfeit products; the local industry has registered a number of counterfeit control agencies to monitor and regulate the operations. Intellectual property rights (IPRs) is one of the key legislative organ in combat of counterfeit trade, despite such regulatory framework counterfeit trade is still rampant. The study findings indicated that counterfeit trade involves the production and sale of goods technologies and related services that are similar or substantially same to legitimate goods without proper authorization of the license or owner of the intellectual property right.

Further revelations indicated that counterfeit trade poses social and economic problems as it has contributed to loss of income from those who genuinely brand their products, thus leading to the destruction, and hinder growth of local talent and entrepreneurship. The practice has also reduced the revenue of most manufacturers & distributors. The study indicated that even the customers suffer in the process of counterfeit trade

especially where drugs and healthcare equipment's are of inferior quality. The counterfeit trade costs the government of Kenya Ksh 19 billion in lost revenue annually (KAM 2016). There's need for effective laws and proper enforcement mechanisms in which counterfeit trade can be combated, this requires a strong legal framework and enforcement mechanisms. The study noted that Kenya had an elaborate legal structures that takes care of intellectual property rights, this include the trade disruption Act, the seeds and plant varieties Act, the trade mark Act, intellectual property Act and the Kenya Anti-counterfeit Act 2008.

Administrative enforcement of anti-counterfeit laws in Kenya incorporates various clauses meant to combat the counterfeit trade. The study noted that enforcement is a process of compelling compliance with the law, mandate, command or decree, it also highlights issues of compliance to trademarks intellectual property rights industrial designs, copyrights in totality enforcement is the process of compelling observance of anti-counterfeit laws. The Kenyan administrative measures to curb counterfeit trade involves various parties and mechanism, these include the Kenya industrial property institute, which has a mandate of granting property rights registration or refuse to consent technology transfer agreements & licenses.

There is also the role of registrar of trademarks; whose mandate falls under trademark search, licenses assignments and general advisory; there's also anti-counterfeit agency which has mandate of combating counterfeits in Kenya; Border measures as an enforcement counterfeit laws, meant to curb counterfeit trade; industrial property tribunal is also entrusted with counterfeit management established under section 113 of the industrial property Act to hear appeals arising thereof. Preference of counterfeit products

arise due to price influences, raptness of the practice, the distribution channels fully stocks counterfeits, the policy on counterfeits is not standardized, easy availability of counterfeits; The impact of counterfeits include loss of revenue for the firms, include loss of revenue for the firms, cause of damage to customers hurting the economic preparations leading to poverty, the practice also kills entrepreneurship. On the factors affecting influence of supply chain management the following were noted, reliability of the channel structure, middleman characteristics, market product characteristics, marketing infrastructure of pharmaceuticals, long-term relationships with other suppliers and its effect on activities of the firm and the management information systems.

5.3 Conclusion(s)

The research concludes that the government agencies in charge of counterfeits and necessary regulator(s) to ensure fairness to all businesses, so that these legitimate business firms operate sustainable competitive business. In this context it could be necessary for the government to enforce strict laws and policy formulation to overcome the challenges and constraints involved. Sales of counterfeit products indicate no sign of slowing down despite the combined efforts of brands and legal enforcement. There's need to investigate the contributory factors on consumption of counterfeits. To transform the image of the trade and brands, there's needed to adhere to strict values and ethical stakes, and confirm to exceptional quality and standards.

5.4 Recommendations

The judicial enforcement of anti-counterfeit laws in Kenya and the administrative measures employed to enforce anti-counterfeits laws in Kenya should be published and sensitized to the business community for awareness and action. As research findings

indicated the administrative measures employed in Kenya to curb counterfeits trade are insufficient, and its strongly advised that the various bodies charged with responsibility of enforcing anti counterfeits laws in Kenya like the managing director KIPi; Registrar of trademarks, anti-counterfeit agency, border measures and industrial property tribunals.

The study further recommends that the two acts of parliament, the industrial property act and trade mark act need be strengthened to enable them undertake necessary measures and measures on counterfeits. The study recommends that more power to accord to particular agencies to monitor and regularize measures to save genuine brands. Further recommendation to that the industrial property tribunal have representation in counties other than in Nairobi to enable the practice take root, also the study recommends on improvement on reporting systems and allocate resource to enable the relevant organs navigate the cases which arise.

The study recommends that due to lack of expertise of the court judges/ magistrates and advocates, these parties always handle cases from civil and criminal viewpoints, negating the critical intellectual property which is core in counterfeit case of counterfeits to other parties.

5.5 Limitations

Due to lack of proper legal and enforcement parameters in Kenya today, this has continued to provide a thriving environment for counterfeit trade: the war on counterfeit need public awareness and participation; this awareness and public education will enable the customers and to be clients to be aware of counterfeits dangers in existence. Another notable limitation is the respondents' inability to give confidential information on critical

issues pertaining to counterfeit trade. Notable constraint(s) include lack of coordination and information sharing among the various institutions time and resources required to undertake the research was not adequate, taking in consideration of the vast channel of distribution system. The ownership of particular counterfeits could challenge the vision of the whole industry, the reverse causation would represent a typical case of the influence of behaviours on attitudes, and it would mean overlooking the effect of counterfeits. The study focused on pharmaceutical counterfeits for distributors in Nairobi County. The limitation is that the findings from this study may not be applicable to other firms in other industries in Kenya, because of the specificity of the approach of study in pharmaceutical products. The primary data collected and analysed through the likert scale may contain some biases of particular respondents as indicated in the results. This might lead to results being dependent upon the recorded attitudes of those who responded; there are chances that if these respondents were different the results could have been different also.

5.6 Suggestions for further research

The study should be replicated to other sectors of the economy and industries there counterfeits are also a challenge. Critical analysis need be taken on individual firm performance against the vice of counterfeits.

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APPENDICES

APPENDIX 1: QUESTIONNAIRE

TOPIC:IMPACT OF COUNTERFEITS ON SALES AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS IN NAIROBI COUNTY, KENYA

SECTION A: DEMOGRAPHIC DATA

1. Name of respondent/ firm
2. Education qualification
3. Position in the firm
4. Years of experience
5. Firms membership of pharmacy poisons board

Others (specify)

6. How long has the firm been operational

Below 2 years Between 2-5 years Between 6-10 years
Between 11-15 years Between 16-20 years Above 20 years

7. Nature/ type of business

Wholesale Retail combined

Other (Specify)

8. Type of product distribution

OTC POM BOTH

9. Name of institution

SECTION B: PREFERENCE FOR COUNTERFEIT(S) PRODUCTS

Please indicate by ticking the extent to which the following procedural contribute to pharmaceutical distribution as per the following scale of 1 – 5

1 – Strongly Agree, 2 – Agree, 3 – Neutral, 4 – Disagree, 5 – Strongly Disagree

No	Preference of Counterfeits (Products)	1	2	3	4	5
1	Counterfeiting exist in pharmaceutical					
	The price of a product is a good indicator of its quality					
	Counterfeiting practices rampart					
	Counterfeiting not vigilant on their operation					
	The distribution chain is well stocked with counterfeits					
	Counterfeit products are distributed easily					
	The policy safeguarding the pharmacists is not standardized					
	Many distributors increases the chance of counterfeit prevalence					
No	Impact of counterfeiting on pharmaceutical distribution	1	2	3	4	5
1	Selling counterfeits affects sales					
2	Buying counterfeit cause loss of Goodwill of the brand process, which further reduces the cost associated with distribution.					

3	Counterfeits affects investors Investment					
4	Counterfeits affects innovation					
5	Selling counterfeits affects image of the pharmacy.					
6	Counterfeits lead to loss of Tax to government.					
7	Government is doing enough to curb counterfeit cases within the health sector.					
8	Counterfeiting disrupts the distribution network					

SECTION C: FACTORS AFFECTING/ INFLUENCING SUPPLY CHAIN

MANAGEMENT (LOGISTICS)

Indicate in a scale of 01 to 05 the relevant weightage of different factors impact on supply chain management especially the distribution & logistics activities 05= to a very large extent, 04= to a large extent, 03= moderate extent, 02= minimal extent, 01= no extent.

	5	4	3	2	1
Management information systems competency of the firm					
Long-term relationships with other suppliers & its effect on activities of the firm (transportation & storage)					
Marketing infrastructure of pharmaceutical products					

being adequate and reliable					
The channel structure being reliable					
Storage & transportation facilities					
Product/ market characteristics					
Middleman characteristics					

SECTION D: CONTROL MEASURE ON COUNTERFEIT PRODUCT

Please indicate by ticking the extent to which the company controls the cases of counterfeiting within the company in the scale of 1 – 5: 1 – Strongly Agree, 2 – Agree, 3 – Neutral, 4 – Disagree, 5 – Strongly disagree

No	Please tick to what extent the below statement align with your control strategies.	1	2	3	4	5
1	Improve identity detection of drug products					
2	lead in anti-counterfeit measures					
3	Prevent entry of counterfeit prescriptions					
4	Ensure the chain of distribution is monitored through evaluation					

Thank you for your contribution

APPENDIX II: LIST OF PHARMACEUTICALS IN NAIROBI

1. Gesto pharmaceuticals Ltd
2. Globe pharmacy
3. Hightech Pharmaceuticals

4. Infusion medicare
5. Jaskam& Company Ltd
6. KAM Industries Ltd
7. Sphinx Pharmaceuticals Ltd
8. Regal Pharmaceuticals
9. Medivet products Ltd
10. Mac's pharmaceuticals
11. Harley 's Ltd
12. GlaxoSmithkline [GSK]
13. Concepts (Africa) Limited
14. Biodeal Laboratories Ltd.
15. Dawa Ltd.
16. Didy Pharmaceuticals
17. .Elys chemicals Industries Ltd
18. Abacus Pharma (Africa) Ltd
19. Accord Healthcare (Kenya) Ltd
20. Pan Pharmaceuticals Ltd
21. Monks Medicare Africa Ltd
23. Medical Express Kenya Ltd
24. Enzymerx (Pty) Ltd
26. Merck (Pty) Ltd - Kenya