

**THE EFFECTS OF COUNTERFEITS ON PHARMACEUTICAL
DISTRIBUTION AND RETAILING IN MOMBASA COUNTY,
KENYA**

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FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE
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DECLARATION

This research project is my original work and has not been presented for the award of degree in any other university or institution for any other purpose.

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

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DEDICATION

To my lovely husband Richard Wanjau, our dear daughter Nandia and my parents for the support, encouragement and understanding during my working on this proposal.

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LIST OF ABBREVIATIONS

CBD	Convention on Biological Diversity
IP	Intellectual Property
IPR	Intellectual Property Rights
OECD	Organisation for Economic Co-operation and Policy
PPB	Pharmacy and Poisons Board
SMEs	Small and Medium Enterprises
TRIPs	Trade Related Aspects of Intellectual Property Rights Agreement
WIPO	World Intellectual Property Organization

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ABSTRACT

Counterfeiting is unauthorised imitative production of products or a service without authority from the owner's which are protected by intellectual property rights in order to make profits. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabelled with respect to identity or source. The objectives of this study was to determine the effect of counterfeit on the pharmaceutical distribution and retailing in Mombasa County and the roles of pharmaceutical distributors and retailers in combating counterfeit. The findings from the study were that counterfeits had an effect in pharmaceutical distribution and retailing and it was noted that the least effect of counterfeit drugs was that they can lead to death of patients. The effects that counterfeit lead to loss of tax to the government and that they affected investors investments were rated above average. Counterfeits affect sales, causes loss of goodwill of the brand, innovation is affected and that the image of the pharmacy is affected were rated highly by most of the respondents. On average the pharmacist played the role of ensuring that the patients are aware of counterfeit drugs. They also made sure that the patients were aware of anti-counterfeiting strategies, the discussed the patient medication first before dispensing were highly rated. The respondents also indicated that they have continuous education, resources affect identification of counterfeit drugs and that technology is a challenge to branded products.

CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

Counterfeits are not limited to luxury products even toothpaste and shampoo as well as washing powders and dishwashing products are counterfeited on a commercial scale. The counterfeit market has become more and more professional. Small clandestine workshops have been replaced by a veritable industry equipped with high-tech material and their own distribution networks. Sometimes, counterfeit goods appear on the market before the authentic products themselves. Product counterfeiting and piracy of either luxury consumer or industrial goods is a major global problem and is more acute in developing countries than in developed nations. Of serious concern is the fact that consumers, in general, do not perceive that their behaviour is harmful to a particular industry or that it can lead to a social cost. Dubey J. & Dubey R. (2008) noted that the customers only perceive the social benefits of fake products.

According to WHO it has estimated that approximately 10 percent of the global pharmaceuticals market consists of counterfeit drugs, but this estimate increases to 25% for developing countries, and may exceed 50% in certain countries (World Health Organization (2005). The appearance of counterfeit medicines in international commerce was first mentioned as a problem at the WHO Conference of Experts on Rational Drug Use in Nairobi, Kenya; in 1985 this was sourced from conference of WHO (2005).

1.1.1 Concept of Counterfeit

Counterfeiting is unauthorised imitative production of products or a service without authority from the owner's which are protected by intellectual property rights in order to make profits. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabelled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

There have earlier cases of counterfeit medicines that were skin preparations GOK (2008). Recent case were those of Duocotexcin (dihydroartemisinin-piperaquine tablets that lacked piperaquine). Others included antibiotics and fast moving analgesics. Anti-malarial drugs, antiretroviral, anti-cancer and anti-viral, antibiotics are among the most counterfeited drugs found in developing countries Dahiya (2008). Muthiani (2012) observed that the medicines that are mostly counterfeited include, fast moving and well known drugs, those available over the counter (OTC) supplies to Government institutions and product for export.

The Kenya Anti-Counterfeit Act was established in 2008 but it has faced stiff competition from public health advocates and HIV treatment activists who claim it will infringe on the rights of Kenyans to access medicines. Public health advocates have argued on anti-counterfeit definition of counterfeit drugs to be vague and also

concern to importers and manufacturers of generic drugs. The act is so broad and can legally allow pharmaceuticals company to charge generic drugs in Kenyan market as counterfeit even though their patents rights are not registered here which could bring a lot of issues in territorial application of Intellectual property rights.

The Act defines counterfeit goods as those that are manufactured, produced, packed, re-packed and labelled as the original products that is already protected without the authority or permission of the owner .Counterfeit also mean manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights.Counterfeit goods can also be explained as the goods that are coloured using the same colours as protected goods in a way that the consumers will confuse the goods as they purchase.

The effect of this law applies to generic drugs which has an implication on HIV patients who rely on generic anti-retroviral generic drugs since they are cheap and affordable. Therefore if the law is enforced it limits the accesses of the dugs by HIV patients in Kenya. A case of people living with HIV and was filed in 2009 to challenge the aspects of the Anti-Counterfeit Act 2008 that confused counterfeiting with patent infringement, therefore threatening the importation of the generic medicines, including ARVs for people living with HIV. On April 20th 2012 the court ruled out that the intellectual property should not oversee the right to life, right to health and right to human dignity outlined in the Constitution of Kenya 2010. Patent holders will therefore not be able to use the act to legitimately block the import of generic medicines, as was feared by the petitioners. The anti-counterfeit bill should be amended to clearly distinguish between counterfeit and generic drugs.

WHO (2005) noted that there are various factors that account for why medicines are attractive for counterfeiting such as the high priced product due to their influx in demand, availability of cheap ingredients that act as substitute. Producing counterfeit also does not require a lot of overhead cost since they no presence of good infrastructure, no requirement of quality assurance, or license for good manufacturing practice standards hence there gross margins are very high.

The Anti-counterfeiting agency was established by an Act of parliament that prohibit trade in counterfeit goods and making sure that the anti-counterfeit law is followed to the fullest it come into operation in June 2010 after anti-counterfeit law act of No.13 of 2008. The roles of ACA includes: Protection against the infringement of Intellectual Property Rights- To manufacturers, innovators, artists and bookmakers, seeds and plant breeders among other IPR owners. They also have programmes that bring awareness to the public on issues of counterfeit, they train the target groups on intellectual property right and they also ensure that the Anti-Counterfeit act is effectively enforced.

1.1.2 The Impact of Counterfeit in Competing Business

OECD (2007) observed that they are two types of market that get affected by counterfeiting hence different strategies are applied ,there is primary market where buyers are not aware of the counterfeit and in secondary markets where buyers are aware that they buy the counterfeit product. The presences of counterfeit in the market affect the pharmaceutical business. It affects the brand value and reputation of pharmacy. It also affects the innovation used by such a firms since they have to invest more on their research and development for them to remain competitive in the market. Further, over the past decade, the massive public health problem of counterfeit and

Sub-standard drugs has become increasingly apparent, causing significant morbidity and mortality and reducing the effectiveness of health care in the developing world.

Lon et al. (2006) found that counterfeit and substandard anti-malarial drugs can cause death and contribute to the growing malaria drug resistance problem, particularly in Southeast -Asia. Newton et al. (2006) pointed out that the production of counterfeit or Substandard anti-infective drugs are a widespread and under-recognized problem that continuously contributes to morbidity, mortality, and drug resistance. Counterfeit drugs particularly affect the most disadvantaged people and business in developing countries.

Counterfeiting affects the pharmaceutical business on sales volume and prices, brand value, pharmacy reputation, royalties, firm-level of investment and cost of operations. OECD (2007) noted that criminal networks and organised crime thrive via Counterfeiting and piracy activities. The drugs that is counterfeited and produced are often substandard, sometimes endangering the patients lives. These illicit activities steal market share from legitimate businesses and undermine innovation as concluded by Zakiuddin (2012) with negative implications for economic growth. The high rate of corruption in Kenya has also encouraged counterfeiters who bribe the officials which eventually affect the effectiveness of public institutions at the expense of society at large. Governments are directly affected since the tax revenue is reduced. It becomes costly to the government since they spend a lot of money in combating the counterfeit drugs. There is lack of integrity in the public institutions due to the corruption between counterfeiters and government.

In Kenya access to treatment of such infectious diseases such as tuberculosis, malaria and cholera is a big issue. Nsimba (2008) noted that so many people are affected by untreated health conditions worldwide and the drugs that can provide

benefit have become an extremely sought-after commodity. The market for drugs is extremely competitive since the sale of such products has become so profitable both in the U.S. and globally. Some of these pharmaceutical industries are always looking of ways to maximize profits and one of the simplest ways is to decrease costs. Hence they end up in the illegal trade of counterfeit drugs that make higher profit and are affordable to most of the patients due to low prices. The manufactures in such market may also manufacture and distribute drugs that contain substandard bioequivalence quantities. He also found out that the dimension of detecting counterfeiting is possible because methods of detecting such drugs are difficult for the end user, whereby if the pharmaceutical product is defective its impossible for distributors and patient to identify it unless the patient does not respond.

1.1.3 The Mombasa County Pharmaceutical Industry

The Pharmaceutical Industry is a very highly regulated, capital as well as labour intensive industry. The Kenyan Pharmaceutical Industry operates in a liberalized environment that is characterized by stiff competition of the price nature, political factors, and fight against counterfeit medicines, prohibitive and wanting regulation. Muthiani (2012) noted that there is a rise on the drugs that are being imported into the Kenyan market since the drugs are not taxed hence a need to clearly identifying whether the pharmaceuticals industry have ways of combating counterfeit drugs. Zakiuddin (2012) noted that the fundamental role of the wholesalers is to distribute the pharmaceutical products in the most effective and efficient way. The role of the pharmaceutical retailers is to ensure the patient health and safety. All the Kenyan pharmaceutical businesses from the manufacturing stage to the supply stage is regulated by the Pharmacy and Poisons Board (PPB) of Kenya as per the Cap 244

Act, inspection of premises and registration of qualified personnel and businesses, quality control and pharmaco-vigilance among other duties.

Mombasa County is the smallest county in coast province and its Administration is segregated into seven divisions, Mvita, Chagamwe, Jomvu Kuu, Likoni, Kisauni and Nyali. These are the areas where the data is to be collected at distributor and retail pharmacies. The pharmaceutical distributors in Mombasa get most of their supplies from Nairobi and they distribute the products to the retailers. The pharmaceutical industry is a sector that is highly regulated by the Ministry of Health/ Pharmacy and Poisons Board, Pharmaceutical Society of Kenya, Kenya Medical Association, Kenya Medical Supplies Agency (KEMSA) and the Kenya Bureau of Standards (KEBS). The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons. They are also in charge of issuing Licences to qualified, Professionals, retailers and pharmaceutical distributors. Opiyo (2006) noted that the retail pharmacy is in direct contact with the patient and doctors therefore act as a link between both. Hence serve as a link between both. Retail pharmacy is both a product and service oriented Industry they sell product to the patients and also give information to the clients they also provide information on general health. According to Stumpf & Chaushry (2011) the product focus is the actual selling of the on-shelf products at any given time. Services can be divided of two types: Information service such as drug information programme, a pharmacy newsletter and more general health and disease information services.

1.2 Research Problem

Counterfeit goods can be available anywhere in the world and in all sectors of global economy. The products are produced in and sold in underground economies or in unregulated economies where they escape normal tax tariff. Counterfeiting affect legitimate business due to lost sales, lower profits and loss of brand trust and value. The changing technology has greatly contributed to the rise in counterfeits and pirated drugs; this has resulted to influx of such medicines into the market. The counterfeiters are so fast in updating their products to be confused with the original brands. Mombasa County might be highly be affected by counterfeits drugs due to presence of the port which can easily clear the drugs and find their way into the market. Hence a need to clearly understand the effects that counterfeit medicines may impact the existing pharmaceutical distributors and retailers in Mombasa County. If their business is greatly affected what roles are played by the pharmacist in the pharmacies.

Lybecker (2007) noted that the economy and research in these developing countries is greatly affected since the resources to be used in buying genuine drugs are used in controlling the counterfeit drugs. Counterfeiting not only reduces supply and endangers the genuine products if not controlled. The Manufactures tend to increase the price of the genuine drugs as they employ the anti-counterfeiting technologies into their products and packing. Counterfeit products are threat to the genuine products hence the pharmacies have to adopt ways of dealing with the counterfeit to remain successful in the market.

Zakkiudin (2010) noted that the Pharmaceutical business is a prone to malpractices by professionals and quacks through unofficial channels of distribution that also

encourage the circulation of the counterfeits. Kenyan pharmacies and distributors continue to face several challenges from illegal trade in pharmaceuticals products. Counterfeit drugs are a global public health problem causing death, disability and injury affecting adults and children Kibwage (2008). Additionally, patients may lose confidence in health care professionals including their physician. The importation of illegal products is also increasing competition in the pharmaceutical industry hence a need to study its effect on pharmaceutical distribution and retailing.

Several studies have been done on counterfeit medicines. Yomans and Law (2011) found out that the Californians pharmacist lacked knowledge of counterfeit medication; they faced great challenge from the new developing technologies. Hwang & Wang (2010) suggested the various options that should be applied to adversely prevent the presence of counterfeit drugs in the market. Nsimba (2008) reviewed the global implication on counterfeit and substandard drugs in developing countries and focused on antiretroviral (ARVS) and ant malarial drugs. Muthiani (2012) studied the factors influencing influx of counterfeit medicines in Kenya and their roles in combating counterfeit drug. There still exist a gap on the effect of counterfeits on pharmaceutical distribution and retailing.

Nsimba (2008) reviewed the global implication on counterfeit and substandard drugs in developing countries and focused on antiretroviral (ARVS) and malarial drugs . There are also few studies that have been done in Kenya but focused totally on different organizations other than the pharmaceutical distributors and retailers Muthiani (2012) studied the factors influencing influx of counterfeit medicines in Kenya, so far am not aware of studies done on effect of counterfeit drugs in pharmaceutical industry in Mombasa County. There still exists a research gap on roles

of these pharmaceutical distributors and retailers in combating counterfeit drugs in Mombasa County. The study undertakes to answer the following questions: What are the effects of counterfeit drugs on pharmaceutical distribution and retailing in Mombasa County? What is the role of these pharmaceuticals distributors in combating counterfeit for them to remain competitive?

1.3 Research Objectives.

The objectives of this study are:

- i) To determine the effect of counterfeit on the pharmaceutical distribution and retailing in Mombasa County
- ii) To determine the roles of pharmaceutical distributors and retailers in combating counterfeit.

1.4 Value of the Study

The study is of value to both pharmaceutical distributors and retailers who wish to sustain their business and remain competitive since they will adopt ways of combating counterfeit drugs and also train the patients on ways of detecting the counterfeits drugs.

The Kenya anti-counterfeiting agencies can also use the studies to explain to the Pharmacies, the public and all medical personnel on the effects of counterfeit medicines to their future business. The intellectual property protections will also put strict measures to combat the counterfeiting and piracy of all products that are in the market hence making sure the business of the genuine products is not greatly affected.

The study is also of value to the Ministry of health Pharmacy and Poison Board (PPB), when making policies on counterfeit since they can also include the roles of the pharmaceutical industry when amending the anti-counterfeit act.

The study will increase awareness of issues of counterfeiting therefore encouraging the pharmacists to play their roles in combating counterfeit drugs. The recommendations of this study will form part of the action plans that the pharmaceutical industries should adopt to remain competitive. For academicians, this study will form the foundation upon which other related and replicated studies can be based on.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

The chapter looks at the literature review on intellectual property rights. Counterfeiting is an issue that infringes the intellectual property rights of the company. There have been cases of violations of intellectual property rights that are discussed. The roles of pharmacist and pharmacy technologists are also discussed. Lastly a summary is also given on literature review.

2.2 Intellectual Property Rights

Counterfeiting is seen as infringement of the IPR of the brands that was originally registered. Hence it lowers the profits of the company that has patent rights, downsizing of workers may also take place and the government loses a lot of potential tax due to the presence of illegal imports. Counterfeiting also affect innovation strategies of the inventor company.

Mossinghuff and Bombelles (1996) noted that market protection plays a major role in growth of pharmaceutical industry. The pharmaceutical industry invests in years in research and development, clinical trials and lengthy legal requirements before the approval of products in the market. The IP gives the investors an opportunity to recover their investment costs that were incurred. The trademarks of their products are registered and patents given to those companies. The patent is usually given for 20 years and an addition of three years to prevent competition from generics according to WIPO (2010)

According to WIPO (1967) the meaning of Intellectual property rights is the creations of the mind: inventions literary and artistic works; and symbols, names and images used in commerce. Intellectual property is divided into two categories: Industrial Property includes patents for inventions, its trademarks, industrial designs and geographical indications. Copyright covers literary works (such as novels, poems and plays), films, music, artistic works (e.g., drawings, paintings. Silva (2011) suggested that the IP rights need to be enforced to reduce the increased rate of counterfeiting and piracy.

Intellectual property rights play an important role in our economy: they encourage creativity and research and allow companies to reinforce their competitive position in the global economy. Counterfeit goods and piracy, however, pose a serious threat to this reality. More and more organisations (often criminal) make huge profits via counterfeit designs and signs which are protected by intellectual property rights and/or by trading these counterfeit goods.

Other works are sceptical or completely against IPRs. Studies done by Lerner (2009) explore the role of the state and finds that there is little positive impact of protecting patents on innovation. He focuses on the number of patents demanded and negates specific processes limiting these activities—violations and institutional quality, which can discourage or encourage production. Boldrin and Levine (2009) argue that protecting innovative activities is important for the first units of “discovery,” but in the long-run, protecting intellectual property is damaging because of diminishing returns and the extent to which less developed economies can imitate and copy.

Violations of IPR studies have done by McLennan and Quan (2011) in 71 countries the effect of violations in IPR in economic growth is increasing at robust rate. He noted that countries that had increasing rates of property rights violations tend to have lower growth rates, since means of production are disrupted, ignored or taken away people tend to be less productive hence lowering the economy.

Counterfeiting and piracy are concepts which are generally used to indicate a violation of intellectual property rights. This means that certain acts are carried out without the consent of the intellectual property right holder. Some examples of intellectual property right violations are the fabrication or selling of illegally manufactured counterfeit versions of products protected by a trademark (sunglasses, clothing, sports goods, etc.), pharmaceutical products, designer furniture, seeds, software, DVD players, music players and films and other protected works. In principle, any product sold today is a potential victim of counterfeiting as noted by Lybecker (2009).

2.3 Intellectual Property Rights as a Strategy

According to Muthiani (2012) managing the IP assets of a company in the pharmaceutical industry are more than just acquiring the formal IP rights through the national or regional IP office. Patent or trademark rights are not worth much unless they are adequately exploited. Hasbani and Bretan (2012) noted that in South Africa, some types of valuable IP (such as trade secrets) do not require formal registration but called for other practical measures for their protection (e.g. confidentiality agreement and that the enforcement of IP rights might be crucial to ensure that the IP rights are respected in the marketplace. Enterprises in the pharmaceutical industry willing to

extract full value from their know-how, innovation and creativity should, therefore, take adequate steps to develop an IP strategy for their business and seek to integrate it within their overall business strategy as discussed by Wilkie, Johnson & Whire (2010). This implies, for example, including IP considerations when drafting business plans and marketing strategies. Understanding the relationship between the IP system and the system for obtaining marketing approval for new drugs by the relevant public health regulatory body is also important.

According to Hasbani and Breton (2012) a basic IP strategy include: Firstly a strategy on protection of IP rights whereby in the pharmaceutical industry, various aspects of a new drug may be patented (e.g. the chemical compound, processes, new uses for the same compound, improved variations, dosage regimes and packages. Making an IP audit of the company may be an important first step for identifying protectable assets that may not have been adequately exploited by a company in the past. Secondly there is a strategy of exploitation where the company commercialize the IP of protected products without infringing the IP rights of others. Thirdly is strategy on IP monitoring whereby the consulting patent databases regularly is important in order to find out about recent technical developments and new technologies, identify new licensing partners, suppliers or new market opportunities, ensure your freedom to operate, monitor the activities of competitors, find out about the legal status of a patent and identify possible infringers. In addition, companies will need to monitor the market to identify possible infringement by other companies (e.g. the use of your trademark by others that may be eroding or diluting a company's own trademark or the release of an infringing generic). Fourthly is Strategy on IP enforcement whereby clear strategy on IP enforcement is crucial to avoid the losses that may be incurred by

the existence of infringing goods in the market and the high costs involved in some IP disputes. The main responsibility for identifying and taking action against imitators or infringers of IP rights lies with their owner (unless such responsibility has been transferred to a licensee). A patent owner, therefore, is responsible for monitoring the use of its patented invention(s) or registered trademark(s) in the marketplace, identifying any infringers and deciding whether, how and when to take action against them.

Boldrin & Levine (2009) suggested that it is advisable to contact an IP lawyer to assist in taking any steps for enforcing IP rights, both domestically and/or in any export markets, which may include the sending of a "cease and desist letter" informing the alleged infringer of a possible conflict between your rights and the company's business activity, approaching a court to obtain an "interim injunction" in order to surprise the infringer at his business premises and/or initiating civil proceedings against the infringing company.

In many cases, IP disputes are settled out of court and often result in a licensing agreement thus providing the authorization to the alleged infringer to continue selling the product in question in exchange for a lump-sum payment or royalties. Arbitration and mediation are often used to avoid long and expensive litigation. It is generally advisable to include a special provision in licensing contracts for any dispute that may arise to be referred first to arbitration or mediation. More information on arbitration and mediation can be found at WIPO (2010).

2.4 Importance of Intellectual protection

The consequences of the counterfeit market are not only detrimental to holders of intellectual property rights but to companies as well. According to Zakiuddin (2010) Counterfeit goods deprive companies of the fruit of their notoriety, positive image and their investments in research and development, innovation and marketing. This affects not only companies themselves but all of society.

According to WIPO (2010) the loss of revenues from counterfeiting is estimated at hundreds of billions of Euros worldwide. The counterfeit market represents 5 to 10% of global trade. This results in a significant loss in taxes and customs duties. More than 100,000 jobs in European industry are estimated to be lost from counterfeits. Moreover, counterfeit goods encourage the development of unregulated working environments, sometimes clandestine ones, which employ workers who are exploited due to their vulnerability. Similar studies done by Silvia (2011) indicate that there is a risk to the health and safety of consumers. Products are manufactured without being controlled by relevant authorities and do not always meet quality standards. Counterfeit medicines are an eloquent example of this lack of oversight.

According to WHO (2005) counterfeiting and piracy have an especially negative impact on innovation and investment. Companies are less inclined to invest in research and development if the results are not efficiently protected. An effective way to fight counterfeiting and piracy is therefore extremely important. In the wake of international and European treaties, Belgian legislators have thus come up with a variety of ways to prevent copyright violation.

2.5 Roles of Pharmaceutical Distributors and Retailers

In Kenya all of the pharmaceutical distributors and retailers have a Pharmaceutical technologists or a pharmacist who can also be the owner and is the key person in the business .He act as a link between the customers and the Doctors and is also in charge of procurement department. According to Youmans and Elaine (2011) most patients in developing countries are aware that counterfeit medications exist. The Pharmacist can educate the patients or discuss counterfeit medications. He noted that most pharmacist due to their nature of their jobs they really discussed the counterfeit or even offer the patients the anti-counterfeiting strategies that are available in the market. WHO (2005) has clearly set guidelines on procurement of drugs and hence its the role of the pharmacist to ensure that they only source drugs from legitimate suppliers since they act as the first line defender in identifying the counterfeit medicines. Pharmacist has the opportunity to quickly to quickly alert patients on any FDA open cases and provide all the necessary information.

The pharmacist can also teach patients on how to protect themselves when using online pharmacies and educating them to identify legitimate Internet Web sites. The study done in USA by Youmans & Elaine (2011) suggested that pharmacist can also be more vigilant to enquire from patients whether they receive prescriptions from other source. It's also the role of the pharmacist to provide information to manufacturing companies and suppliers on the counterfeit medicines available in the market. The pharmacists should also be consulted by the manufacturing companies on the anti-counterfeiting measures to be used to protect the brand from counterfeiting which will affect the economy and profits of the pharmaceutical industry.

Evidence and experience shows that the patients trust their pharmacists are compelled to ask questions when their medications appear differently. But in a study done in California by Youmans & Elaine patients queried their knowledge of counterfeit medications since they would suspect the purchased drugs to be counterfeit. In Kenya some of these Pharmacist are so corrupt in a way that they encourage the business of counterfeit since they extraordinary profits for them compared to genuine products as noted by Opiyo (2006). Hence unless they decide to be responsible enough to discourage the counterfeiting trade hence this becomes a challenge to the government when trying to combat counterfeit trade.

According to study done by Youmans & Elaine (2011) no one knows whether the pharmacists can physically differentiate the counterfeit medications brought in by patients. Lack of resources is a challenge to the pharmacist hence they are unable to recognised the counterfeit medications. Even though drug information can readily be accessed via the internet not all pharmacists have access to online resources in their pharmacy due to Internet restrictions by their company or lack of funding to purchase these types of programs. Continuing medical educations programs can help introduce and expose them to available resources, strategies in identifying counterfeit medications and tools to educate their patients. Since internet is one of the highest source of counterfeit medications the pharmacists should be in a position to train the patients on alternatives to Internet and suggest generics available, discussing with their doctors to help effectively consolidate therapy, or outreaching to both private and public patients prescriptions programmes.

2.6 Empirical Studies

Muthiani (2012) did a study on factors influencing the influx of counterfeit medicines in pharmaceutical SMEs Kenya. The objectives of the study was to investigate how legislation influences influx of counterfeit medicines, to determine the extent to which brand equity influences influx of counterfeits into pharmaceutical SMEs, medicines, to investigate whether the pricing strategy of medicines influences the influx of counterfeit medicines and also to establish the extent of perceived risks of counterfeit medicines. The study found out from a response rate of 80.3%, legislation, popularity of a brand, pricing strategy and various perceived risks had influence on the influx of counterfeit medicines. The components identified as important in regard to legislation were weak enforcement of the anti-counterfeit law and ambiguity of the definition of counterfeit. Further, the degree of popularity of a brand was found to influence the willingness to purchase counterfeit products. Consumers were found to buy counterfeit medicine over genuine ones if there is a price advantage. It was also found out that consumers take into consideration the influence of various perceived risks in the decision making process to purchase counterfeits.

Deisingh (2004) studied pharmaceutical counterfeiting in developing and developed countries .His objectives were to determine the effect of counterfeit medicines. He found out that in 1999 to December 2002 Antibiotics, Hormones and steroids drugs were mostly counterfeited due to the high prices. He also found that counterfeit drugs had effect on consumers, health care providers, drug manufactures and government. He described the methods used to detect the counterfeit medicines such as near-infrared spectroscopy, Raman spectroscopy, isotopic characterization, tensionography,

chromatographic and mass spectrometric approaches. He also looked at the anti-counterfeiting measures that are used such as holograms, tracers and taggants and electronic tracking.

Youmans & Law (2011) studied ways of combating counterfeit medications a case of California pharmacist. The objective of the study was to examine Californians pharmacist knowledge of counterfeit medicines, impact of technology and barriers to pharmacist involvement, and also to determine the roles of undertaken by the pharmacists. He found out that 59.3% of respondents believe counterfeit drugs pose a problem to the profession, but most had little to no experience with counterfeit medications. For potential sources, 44.5% believe patient use of Internet pharmacies, 39.4% indicated professional counterfeiters, and 16.1% indicated importation. Pharmacist agreed lack of knowledge (46.8%) and resources (82.5%) were barriers to detecting the presence of counterfeits. He concluded that use of Radio Frequency Identification technology as the most effective method that should be used to detect counterfeit medicines.

Nsimba (2008) did a study on problems associated with substandard and counterfeit drugs in developing countries: Review article on global implications of counterfeit drugs in the era of anti-retroviral (ARVs) drugs in a free market economy. The objective was to review the global implications associated with the use of substandard and or counterfeit drugs in developing and may be developed countries. He focused particularly on antiretroviral (ARVs), antimalarials and other drugs. He found out that counterfeit drugs can adversely affect the patient's life, patients lose confidence in health care professionals, and the society is greatly affected not only in terms of health but also to public in terms of trade relations, economic implications and effect

of global pandemics. He concluded that developing countries should try their best at all costs establish good laboratories for monitoring or checking for quality control for all pharmaceuticals locally manufactured and those imported(entering) or donated to countries to make sure that they meet the set or established international or national standards. Short of that countries will be wasting a lot of money using forex which has been borrowed in a form a loans procuring and distributing to its people sub-standard medications which will do more harm than good to its indigenous people and this is unethical to give people drugs not meeting required set international standards.

Lybecter (2007) studied issues on combating counterfeit medicines in developed countries .The objective of the study was to determine the magnitude of counterfeit medicines on the public and various strategies used by companies to combat the issue of counterfeit medicines. He found out that the pharmaceutical counterfeiting is a pervasive problem, impacting nations of every size and income level and drugs of every description. He concluded that anti-counterfeiting strategies used may not necessary reduce the presence of counterfeit medicines in the market. Since providing the consumers with the knowledge needed to distinguish genuine products from counterfeit versions may increase the suspicion of such customers and the counterfeiters may alter the packing or improve the appearance of fake version. He concluded that the anti-counterfeiting strategies that were used to increase the counterfeiters cost were most effective in developing countries than educating the consumers on dangers of counterfeit drugs.

Bian and Motinho (2011) studied counterfeit and branded products: effects of counterfeit ownership. The objective of the study was to determine whether the

consumers are more favourable to branded products over counterfeit branded products, also to determine whether the owners of counterfeit branded products alters consumers perceptions of counterfeit products and branded products and finally to determine whether counterfeit branded products ownership interact with perceptions of counterfeit branded products in determining counterfeit branded products intention..He found out that consumers are aware of superiorities of branded products over counterfeit branded products in many aspects of the product and brand, but they are aspects in which counterfeit branded products are more favourably evaluated than branded products. They concluded that the counterfeit owners and non-owners perceptions of branded products do not differ significantly. This implies that from a perception perspective counterfeit branded products do not seem to have an impact on branded products brand image. In contrast counterfeit branded products owners tend to evaluate counterfeit branded products more favourable than counterfeit branded products non-owners.

2.7 Summary

The intellectual property rights are one of way of protecting the original brand from other generics and counterfeit products. The company would make so many losses if the product it's not protected. There are cases of violations of IPR that have been noted and they adversely affect the economy, government losses potential tax and innovations of many companies are frustrated.

The pharmaceutical industry can only combat the issues of counterfeit by themselves being responsible and discourage the trade of counterfeit medicines. They can also educate the patients on counterfeit drugs by informing them of the anti -counterfeit

strategies that are used by the companies. These might not work at all times due to nature of patients who are informed and may more become more suspicious on such brands and may tend to shift the purchase to other products. Counterfeiting brings new challenges to brand management and it implies intra-brand completion. Brand owners are not only competing with other products in the market but also confronting new challenges introduced by counterfeiters.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1. Introduction

This chapter details the research design that was used to achieve the objective of the study which is to determine the effect of counterfeits in pharmaceutical distribution and the roles played by the pharmaceuticals distribution in combating counterfeit.

3.2. Research Design

The study employed a cross sectional descriptive survey. According to Cooper and Schindler (2006) a study concerned with finding out who, what, which and how of a Phenomenon is a descriptive study. According to Sekaran (2006) descriptive study is undertaken in order to ascertain and to be able to describe the characteristics of the variable of interest in the situation. It is designed to describe the characteristics or behaviours of a particular population in a systematic and accurate fashion population.

3.3 Population

In Kenya, there are 3057 registered pharmacies according to the PPB website visited as at 22nd July 2013 out of which 252 are in Mombasa County. The population of this study was therefore all the pharmaceutical wholesalers and retailers in Mombasa who had renewed licence for 2013 and have been in the business for more than one and half years. The list was availed by PPB in their website.

3.4 Sample Design

In Mombasa county only 90 pharmacies and distributors had renewed their 2013 licence and have been in business for more than one and a half years. The Pharmacist in such pharmacies had enough information on counterfeit drugs due to their experience in handling and dispensing medicines to the clients.

3.4. Data Collection

The data was collected using a semi structured questionnaire. The questionnaires was distributed on a drop and pick basis. The questioner was targeting the senior managers who are either pharmacist or pharmaceutical technologist.

The questionnaire was done in two parts. Part A was to gather the Company Profile of the business. Part B was to gather information on effects of counterfeiting in the pharmaceutical industry and to gather information on roles of the pharmacist and Pharmaceutical technologist in combating counterfeit drugs. The respondent in all the pharmaceutical wholesalers and retailers given the questioner included the registered Superintendents Pharmacists / Pharma-technologists who also played the role of managers in their respective chemists.

3.5. Data Analysis

Since the research was carried out is descriptive in nature, the data analysis method that was most appropriate is descriptive statistical analysis such as measures of central tendency and measures of dispersion. Measures of central tendency include the Mean,

Median and Mode. While the measures of dispersion used will be the Standard Deviation.

The first part which is the organizational bio data was analysed using the frequency tables and percentages. The second part was analysed using the frequency tables, mean and standard deviation. The data will further be analysed by cross tabulation with some first part of the questions.

Prior to data analysis the questioners was checked for completeness, entries checked for consistency and coding done. The data was both qualitative and quantitative and to the objective, systematic and free from any selective perceptions that could dilute the reliability and validity.

CHAPTER FOUR: DATA ANALYSIS, RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents analysis and findings of the research. From the study the target was 90 registered pharmaceutical distributors and retailers and but at the time of data collection 8 were closed,4 would not be physically be located and 78 questionnaires were distributed and only 67 responded this constituting to 86% response rate.

4.2 Demographic and Firm Characteristics

This contains the general organization profile such as the number of years the pharmacy has been operational, form of business, number of permanent employees and the type of business

4.2.1 Number of Years the Pharmacy has been in Operation

The respondents were required to indicate the number of years they were in operation in Mombasa County. This was important since the longer the pharmacy has been in operation the more experienced they were in business and hence aware of counterfeits drugs. The data captured is shown in the table 1.

Table 1: Number of years of the pharmacy

Period	Frequency	Percent
2-3 years	27	40%
4-11 years	18	27%
12-16 years	9	13%
Over 16 years	13	20%
Total	67	100%

Source: Research data

The study sought to establish the numbers of years that the pharmacy had been in operation. From the response as per table 1 above, most of the pharmacies had been in operation for over 2 years as shown by 40% of the respondents, 27% of the pharmacies were in operation for more than 11 years, 13% have operated between 12-16 years and 20% of the pharmacies had operated for more than 16 years. According to the information it was clear that the pharmacies existed for more than 2 years and therefore they were aware of the counterfeit drugs and were in a position of explaining their effects in the business.

4.2.2 Form of Business

This refers to whether the pharmacy was a sole proprietorship, partnership, limited liability or others which could be an institution pharmacy or a hospital-based pharmacy. This was important since the pharmaceutical business is wide and hence

shows variation on the response they gave. The respondents were required to select the option that fits them. The results are shown in table 2 below

Table 2: Form of business

Form of business	Frequency	Percent
Sole proprietorship	23	34%
Partnership	27	40%
Limited liability	4	6%
Others	13	20%
Total	67	100%

Source: Research data

The study also required the respondents to indicate the form of business they were in. According to the study 40% of the pharmacies were in partnership, 34% were in sole proprietorship, 4% were limited liability and 13% were others pharmacies that are institutions or hospital pharmacies. The pharmacies that were sole proprietorship and in partnership may be affected more by counterfeit drugs.

4.2.3 Number of Permanent Employees

Determining the number of permanent employees was very crucial to ensure the data was collected from the respondents who were permanent employees since they had more experience in pharmaceutical retailing and distribution. The respondents were required to tick appropriately on the number of permanent employees. The results were captured as shown in table 3

Table 3: Number of permanent employees

Permanent employees	Frequency	Percent
2-5	10	15%
6-10	29	43%
10-14	18	27%
More than 14	10	15%
Total	67	100%

Source: Research data

The study also sought to establish the number of permanent employees that were employed. From table 3, 43% of the pharmacies had 6-10 employees, 27% had 10-14 employees and the lowest number of employees was 15% of. The pharmacies are required to have many employees to facilitate effective dispensing of the drugs in the pharmacy.

4.2.4 Type of Business

This refers to whether the organization is a pharmaceutical wholesaler, retailer or both. The level and the type of drugs handle differ in terms of quantities and brand names that they distribute hence the response will also vary. The respondents were indicate whether their organization is operating as a pharmaceutical wholesaler, retailer or operating both. The data was captured as shown in table 4.

Table 4: Type of business

Type of business	Frequency	Percent
Wholesale	6	9%
Retail	55	82%
Wholesale and Retail	6	9%
Total	67	100%

Source : Resource data

From the analysis shown in Table 49% of the pharmacies were operating as wholesalers as well as wholesales and retailers.82% of the pharmacies were in retail business.

4.3 Effects of Counterfeit in Competing Business

The respondents were also required to explain whether they were aware of the Kenya Anti-counterfeit Act and what it portends for the pharmaceutical industry and all of the respondents indicated that they were aware of the Anti-counterfeits bill and the various explanations used to explain the meaning of the counterfeit drugs.

They were also required to indicate whether counterfeiting affect their business and all of the respondents indicated that their business is affected this was mostly with wholesales their profits are affected due to presence of counterfeit drugs in circulation.

To determine the effects of counterfeit drugs in pharmaceutical distribution and retailing was the first research objective hence its relevance. The respondents were required to indicate the effects of counterfeit drugs in their business on a scale of 1 to 5, where 1 was strongly disagree, 2 was slightly disagree,3 was not sure,4 slightly

agree,5 strongly agree. Frequency (f) = number of respondents. The respondents gave different choices as shown in table 5 below

Table 5: The effects of counterfeiting in pharmaceutical distribution and retailing

Attributes	1		2		3		4		5	
	f	%	f	%	f	%	f	%	f	%
Selling counterfeits affect sales	7	(11)	7	(11)	5	(8)	38	(55)	10	(15)
Buying counterfeit causes loss of goodwill of the brand	4	(6)	10	(15)	3	(5)	20	(30)	30	(44)
Counterfeits affect investors investment	9	(13)	12	(18)	14	(21)	15	(22)	17	(26)
Counterfeits affect innovations	5	(8)	7	(11)	7	(11)	20	(30)	28	(40)
Counterfeits can lead to death of the patients	28	(41)	20	(30)	10	(15)	5	(8)	4	(5)
Counterfeits lead to loss of tax to goverment	20	(30)	10	(15)	13	(19)	9	(14)	15	(22)
Selling counterfeits Affect image of the pharmacy	3	(5)	2	(3)	27	(40)	23	(34)	12	(18)

Mean ranking and standard deviation of the above Table 5 of effects of counterfeits in pharmaceutical distribution and retailing are summarised in Table 6 below. The following formula was used to compute the standard deviation.

$\sigma = \sqrt{1/N \sum (x_i - \mu)^2}$ where σ = standard deviation, N = total number of respondents, x_i = rank number and μ = mean.

Table 6: Mean ranking and standard deviation of the effects of counterfeits on pharmaceutical retailing and distribution

Attributes	Mean	Standard deviation
Selling counterfeits affect sales	3.55	1.16
Buying counterfeit causes loss of goodwill of the brand	3.92	1.27
Counterfeits affect investors investments	3.28	1.37
Counterfeits affect innovations	3.88	1.26
Counterfeits can lead to death of patients	2.06	1.18
Counterfeits lead to loss of tax to the government	2.83	1.53
Selling counterfeits affect image of the pharmacy	3.58	0.96

Source: Resource data

Buying counterfeits causes loss of goodwill of the brand had the highest mean of 3.92 and standard deviation of 1.27 which means that the individual scores were further

away from the mean. Counterfeits affect innovations had a mean score of 3.88 and a standard deviation of 1.26 which was almost equal to the mean score of counterfeits affecting goodwill of the brand.

Buying counterfeits causes loss of goodwill of the brand and counterfeits affect innovation had the highest mean that is further explained in the frequency table 7 and table 8 respectively.

Table 7. Counterfeits affect good will of the brand

Counterfeits affect goodwill of the brand	frequency	%	Cumulative
Strongly disagree	4	6	6
Slightly disagree	10	15	21
Not sure	3	5	26
Slightly agree	20	30	57
Strongly agree	30	44	100
Total	67	100	

Source: Research data

As in table 7 above most of the respondents strongly agree that selling of counterfeits drugs affect the goodwill of the brand followed by those respondents who slightly agree.

Table 8: counterfeits affect innovation

Counterfeits affect innovations	Frequency	%	Cumulative
Strongly disagree	5	8	8
Slightly disagree	7	11	19
Not sure	7	11	30
Slightly agree	20	30	60
Strongly agree	28	40	100
Total	67	100	

It's evident from table 8 that most of the respondents strongly agree that counterfeits affect innovations followed by respondents who slightly agree that innovations are affected by selling counterfeits due to loss experienced by the patented companies.

4.4 Roles of the Pharmacist

The first were required to explain where they mostly procure their drugs and most of the respondents indicated that they buy from local distributors and also directly from the main suppliers.

4.4.1 Frequencies of Purchase made in a month

It was also important to determine how frequently the pharmacies do make their purchases on monthly basis since only those pharmacies that made frequent purchases were at a risk of buying counterfeits goods and also their sales would be affected more due to the high sales that were made.

Table 9: Frequencies of purchases

Less than 5	Frequency	Percent
5-9	0	
10-15	31	57.14%
Over 15	16	44.4%
Total	36	100%

Source: Research data

From table 9 above it can be noted that 57.14% of the pharmacies purchased drugs between 10-15 times and 44.4% made purchases over 15 times. The respondent did not indicate that they make purchases less than 5 times since most of these pharmacies were in to contact with the suppliers who constantly supplied on request.

4.4.2 Products that are mostly Counterfeited

The drugs that are easily counterfeited are the drugs that are frequently used by patients highly priced and their margins turnover is high in such drugs. This was important since pharmaceutical industries are wide and hence it was important to study their variation in counterfeited drugs.

Table 10: Products that are counterfeited

Products	Frequencies	Percent
Anti-diabetic medicines	0	
Antibiotic medicines	50	79.4%
Vitamins	17	20.6%
Antiretroviral medicines	0	
Total	63	100%

From table10 above it can be noted that 79.4% indicated that antibiotics were the drugs that were easily counterfeited since most of the patients buys without prescriptions.20.6% indicated that vitamins are also counterfeited this is because Vitamins supplements can also be purchased by the patients without prescription. The pharmacist also indicated that they were aware of the anti-counterfeiting act in Kenya.

4.4.3 Roles of the Pharmacist

The second objective was to determine the roles of pharmaceutical distributors and retailers in combating counterfeit drugs. The pharmaceutical distributors and retailers are directly managed by a pharmacist who is licensed with the pharmacy and poison board to dispense the drugs in the pharmacies hence their one who plays a major role in combating the counterfeit drugs. The respondents were required to tick where appropriate the roles they play and the results were tabulated as shown in table 11.

Table 11: Role of the Pharmacist

Attributes	1	2	3	4	5	Mean
	f %	f %	f %	f %	f %	
Patient are aware of counterfeits	3 (4.5)	30(44)	5 (8)	5(7.4)	14(20)	3.10
Clients are aware of anti-counterfeiting strategies	1 (1.49)	0	15(22.39)	28(418)	23(34.3)	4.07
Customer medications is discussed first before Selling	0	0	0	29(43.3)	38(56.7)	4.57
Selling counterfeits Infringes intellectual	3(4.5)	13(19.4)	0	31(46.2)	20(29.85)	3.78

Property protection						
Resources affect Identification of counterfeit	6(8.96)	4(5.97)	20(29.9)	18(26.87)	19(28)	3.60
Technology is Challenge to branded products	3(4.45)	11(16.42)	7(10.45)	14(20.9)	32(47.46)	3.91
Patients are cautioned on Online prescriptions	17(25.37)	42(62.69)	0	3(4.47)	5(7.46)	2.06

Source: Resource data

From Table 11 it can be noted that the least role played by the pharmacist was to caution patients on online prescriptions as shown by mean of 2.06. The moderate mean of 3.10 which is above 3 (neutral) indicated that the patients were aware of the counterfeit drugs. Also noted is that the patients were aware of anti-counterfeiting strategies with a mean of 4.07, Pharmacist discussed the customer's medication first before dispensing with a mean of 4.57, Pharmacists agreed that selling counterfeits infringes intellectual property rights counterfeit as shown by mean of 3.78, The pharmacists also agreed that the resources affected identification of counterfeit drugs as shown with a mean score of 3.66 and technology applied by counterfeiters is a challenge to branded products.

The mean score of the above table 11 and standard deviation was shown in table 12. A standard deviation of >1.05 implies a significant difference on the impact of the variable among respondents.

Table 12: Mean ranking and standard deviation of the role of pharmacist

Attributes	Mean	Standard deviation
Patients are aware of counterfeits	3.10	1.29
Clients are aware of anti-counterfeiting strategies	4.07	0.83
Customer medication is discussed first before selling	4.57	0.5
Selling counterfeit Infringes the intellectual rights	3.78	1.19
Resources affect identification of counterfeit	3.60	1.21
Technology is Challenge to branded products	3.91	1.28
Patients are Cautioned on online prescriptions	2.06	1.05

Customer medication is discussed first before selling had the highest mean of 4.57 had least mean of 0.5 which means that individual score varied little from the mean. Clients are aware of anti-counterfeiting strategies had a mean 4.07 and standard deviation 0.83 which means that individual score varied little from mean. The mean of customer medication is discussed first and clients being aware of counterfeits drugs are further explained in frequency table 13 and 14 respectively.

Table 13: customer medication is discussed first before selling

Clients medication is discussed	Frequencies	%	Cumulative %
First before selling			
Strongly disagree	0		0
Slightly disagree	0		0
Not sure	0	0	0
Slightly agree	29	43.3	43.3
Strongly agree	38	56.7	100
Total	67	100	

From table 13 it can be noted that since the pharmacist were in charge of discussing the patients medications the respondents did not tick Strongly disagree, slightly disagree and not sure. The respondents strongly agreed that they discussed the patients medication followed by those who slightly agree.

Table 14: Clients are aware of ant-counterfeiting strategies

Clients are aware of ant-counterfeiting strategies	Frequencies	%	Cumulative %
Strongly disagree	1	1.5	1.5
Slightly disagree	0		
Not sure	15	22.4	23.9
Slightly agree	28	41.8	65.7
Strongly agree	23	34.3	100
Total	67	100	

Source: Research data

The respondents slightly agreed that customers are aware of anti-counterfeiting strategies followed by those who strongly agreed this because the pharmacist were in charge of answering to any queries from the clients about the counterfeits drugs.

CHAPTER FIVE: SUMMARY, CONCLUSION AND RECOMMEDATIONS

5.1 Introduction

This is the final chapter of the research project. This chapter attempts to cover the summary of the finding and also looks at conclusion drawn from research. Based on the finding, it will then give recommendations to the pharmaceutical organizations and the policy makers and also for further researchers. Results are also compared with the objective of the study.

5.2 Summary of the Findings

The data was analysed using descriptive techniques and was presented in form of tables. The first part was on the demographic and firm characteristics which the second part was aimed at collecting data on the effects of the counterfeits on pharmaceutical distribution and retailing and also the roles played by the pharmacist in combating counterfeit drugs in Mombasa County as a sample.

From the analysis made 40% of the pharmacies that responded have been in operation for over two years hence they had more experience on the counterfeits drugs available in the market and anti-counterfeiting techniques employed by these pharmacies to control the presence of counterfeit drugs in the market .The type of business preferred was partnership (40%) most of the pharmacies had 6-10 employees and 82% of the pharmacies operated as retailers.

The second was looked at the effects of counterfeit drugs in pharmaceutical distribution and retailing and it was noted that the least effect of counterfeit drugs was that they can lead to death of patients. The effects that counterfeit lead to loss of tax to the government and that they affected investors investments were rated above average. Counterfeits affect sales, causes loss of goodwill of the brand, innovation is affected and that the image of the pharmacy is affected were rated highly by most of the respondents.

On average the pharmacist played the role of ensuring that the patients are aware of counterfeit drugs. They also made sure that the patients were aware of anti-counterfeiting strategies, the discussed the patient medication first before dispensing were highly rated. The respondents also indicated that they have continuous education, resources affect identification of counterfeit drugs and that technology is a challenge to branded products

5.3 Conclusions

From the data collection it is very clear that the older the organization is the bigger is the size of the organization and they mostly operate as wholesalers and retailers. The first objective of the study was to determine the effect of counterfeit on pharmaceutical distribution and retailing in Mombasa County that affect their business and brand that is counterfeited. The results were that the sales are affected, innovation strategies used by the original company are also challenged, image of the pharmacy is also affected and the image of the brand is also affected.

The second objective was to determine the roles of pharmaceutical distributors and retailers in combating counterfeit and the managers of the pharmacies who were either

the pharmacist or pharmaceutical technologist played the major role of informing the clients about the counterfeit drugs, anti-counterfeiting techniques available, discussing the patient prescription first to determine whether is an online prescription. From the study most pharmacists did not emphasis mostly on online prescription since it's a threat to their strategies applied by the pharmaceutical organization to remain competitive.

5.4 Recommendations

From the above conclusions I strongly recommend the pharmaceutical distributors and retailers in Mombasa to clearly understand the effect of counterfeit drugs and the consequences of such drugs to their business and to the patient who end up consuming the counterfeited drugs. The Pharmacist should train the patient anti-counterfeiting techniques applied by these original branded products and work closely with the Kenya Intellectual Property Institute to avoid IPR infringement by the counterfeiters. Further all cases of counterfeiting should be reported to regulatory authorities for action.

The pharmaceutical, distributors should further consider educating the public on the effects of counterfeit drugs and the ant-counterfeiting techniques that are applied to identify the original brand

5.5 Suggestions for Further Research

Further research may be carried out to determine the challenges faced by the pharmaceutical importing original brands in implementing the anti-counterfeiting techniques. The effect of counterfeit drugs on the innovation of the counterfeited drugs should also be researched

REFERENCES

- Ansari H.A.&Laxman L. (2012).The Interface Between TRIPS and CBD:Efforts towards harmonisation. *A Journal of International Trade Law and policy*, 11(2),108-132.
- Bian X.&Mourinho L. (2011). Counterfeiters and branded products: effects of counterfeit ownership. *Journal of products and brand management* 20(5)279-292
- Boldrin M. & Levine D. (2009). Intellectual property and Economic growth in long run .A model of discovery. *American economic Review paper and proceedings*, 99(2) 337-342
- Chastry. E.P.&Stumpf A.S. (2011). Consumer implacability with counterfeit products. *A Journal of Consumer Marketing*, 28(2)139-151
- Dubey J.& Dubet.R. (2010). *International Journal of Pharmaceutical and Healthcare Marketing*, 4(2)125-190
- Hansen F. & Smith M. Managing intellectual property a strategic point of view. *Emerald Group publishing limited*,(4)366-374.
- Hieke S., (2010). Effects of counterfeits on the image of luxury brands:*An empirical study from customer perspective. Journal of Brand Management*, 18(3), 159 – 173
- Le V.Q. &McLennan G.P (2011).The Effects of Intellectual Property Rights Violations on Economic Growth. *Scientific Research Journal*.1 (2)107-113

- Kibwage I. O. (2008) “Counterfeiting of Drugs and the Necessity of Quality Control Systems in Developing Countries” *Interdisciplinary Courses on Development and Cultures, Katholieke University Leuven* 1-12.
- Lerner J. (2009).The empirical impact of IPR on innovation: puzzles and clues. *American Economic Review paper and proceedings*, 99 (2) 343-348
- Lon C.T.Tsuyuoka R. Phanouvong S. Nivanna D,Socheat C. Sokhan C. Blum N. Christophel M.E. and Smine A. (2006) .Counterfeit and substandard antimalarial drugs in Cambodia *Oxford Journals*. 100(11), 1019-1024
- .McLennari G.P and Quan V.R. (2011), Effects of intellectual property violations on economic growth. *Modern Economy*, 2 No.10 107-113
- Muli M. (2012) Factors influencing the influx of counterfeit medicines in Kenya. *International Journal of Business and Social Science* .3,No.11 87-97
- Mossinghoff G.J.&Bombelles T, (1996).Intellectual property rights and pharmaceutical industry. *Columbia Journal of World business* 31(1)38-48.
- Naznin S.M. (2011).Protecting Intellectual Property rights in Bangladesh.*Bangladesh Publication* 6(1)12-21.
- Newton, P. Proux S. Green, M. Smithuis, F. Rozendaal, J. Prakongpan, S. Chotivanich, K. Mayxay M. Looareesuwan S. Farrar, J. Nosten, F. & White N. J. (2001). “Fake artesunate in southeast Asia” *Lancet*. 357(9272), 1948-50.

- Nsimba S.E. (2008). Problems associated with substandard drugs in developing countries: A review article on global implications of counterfeit drugs in the era of antiretroviral drugs in free market economy. *East African Journal of public health* 5 (3)205-211
- O'cass J.E. & Frost K.L. (2002), ``Gaining retailers' assistance in fighting counterfeiting: conceptualization and empirical test of a helping model'', *Journal of Retailing*, 68 (1) 90-109.
- Opiyo J.K. (2006), Responses of pharmaceutical firms to the challenges of illegal imports. Nairobi: *Nairobi University. MBA Thesis, Unpublished.*
- Organisation for Economic Co-operation and Development [OECD], (2007) the economic impact of counterfeiting and piracy.
- Qian Y.(2008) Impacts of entry by counterfeiters, *Quarterly Journal of economic*.1577-1600.
- Sihaya.B.&Wekesa M. (2003)*Intellectual property in Kenya*, Published in Nairobi, Konrad Adenauer Stiftung &Sportslink Limited.
- Silva J.A. (2011) Enforcing Intellectual Property Rights by diminishing piracy. *American University International Law.Review*.26 (2)601-643
- Spinello A.R. (2006) Intellectual property rights. *Emerald group publishing limited*. 225(1)12-22
- World intellectual property organization (2010) Intellectual property rights for SMEs in pharmaceutical industry.

- Wilki C.H.,Johnson W.L & Whre.L. (2010).Strategies used to defend Pharmaceutical brands from generic. *Emerald Publishing Group Limited*.46 (9)12-24
- Wang S. & Hwang C.H. (2011) Applications of options to the pharmaceutical markets: The solutions of corruption and counterfeit drugs in emerging markets.*International journal of accounting and information management*198(2)169-181
- Youmans L.S. & Elaine L. (2011) Combating counterfeit medications: The California Pharmacist Perspective. *Journal of pharmacy practice*,.24 (1)114-121
- Zakiuddin H.G. (2012) Innovation as strategy used by the pharmaceutical wholesalers and retailers in Kenya, *Unpublished Journal University of Nairobi*

APPENDICES

APPENDIX 1: Letter of Introduction

Joyce Kabiru

School Of Business

Mombasa Campus

06/08/ 2013

Name of Respondent-----

Pharmacist Name and address-----

Dear Sir/ Madam,

RE: REQUEST FOR RESEARCH DATA

I am a postgraduate student in the School of Business Administration (Strategic Management) student at the University of Nairobi (UON) undertaking a Research Project on **The Effects Of Counterfeits On Pharmaceutical Distribution and Retailing in Mombasa County**

The research is being carried out as part of the requirements of obtaining the degree. You have been selected to form part of this study and are kindly requested to assist in data collection by responding to questions in the accompanying questionnaire. As a participant, you are free to request for a soft copy which can be sent to you via email.

Your cooperation and assistance will be highly appreciated.

Yours faithfully,

APPENDIX 2: Questionnaire

THE Effects of Counterfeits on Pharmaceutical Distribution and Retailing in Mombasa County

Tick Where Applicable ✓

PART A: Demographic and firm characteristics

1) Name of the pharmacy

2) Name of respondent

3) Display of Pharmacy and Poisons Board Licence.....

4) How many years has your Pharmacy been operational in Mombasa?

a) 2-3 years b) 3-10 years

c) 11-15 years d) Over 16 years

5) Form of Business

a) Sole Proprietorship

b) Partnership

c) Limited liability

d) Others

6) Number of Permanent employees

a) 2-5

b) 6-10

c) 10-14

c) over 16

7) Type of business

a) Wholesale

b) Retail

c) Wholesale and Retail

PART B: Effects of Counterfeit in Competing Business

1) Are you aware of the Kenya's Anti-counterfeit Act and what it portends for the pharmaceutical industry in Kenya? Please explain

.....
.....
.....

2) Does counterfeiting affect your business in any way? Please explain

.....
.....

3) Please indicate the degree of your agreement or disagreement with each statement by marking (x) in the box provided below:

Attributes	1.Strongly Disagree	2.Slightly Disagree	3.Not Sure	4.Slightly agree	5.Strongly Agree
Selling counterfeits affect sales					
Buying counterfeit cause loss of goodwill of the brand					
Counterfeits affects investors investment					
Counterfeits affects innovation					
Counterfeits can cause death to patients					
Counterfeits lead to loss of tax to government					
Selling counterfeits affect image of the pharmacy					

PART C: Roles of Pharmacist

1) Where do you procure your drugs? Please Explain

.....
.....

2) Frequency of purchases made in a month

- a) Less than 5 b) 5-9
c) 10-15 d) Over 15

3) What kind of products do you think are counterfeited? Explain

- a) Anti-diabetic medicines
b) Antibiotic medicines
c) Vitamins
d) Antiretroviral medicines
e) Other specify.....

4) Are your aware of the anti-counterfeit act in Kenya?

.....
.....
.....

5) Please indicate the degree of your agreement or disagreement with each statement by marking (x) in the box provided below:

Attributes	1.Strongly Disagree	2.Slightly Disagree	3.Not Sure	4.Slightly Agree	5.Strongly Agree
Patients are aware of counterfeit					
Clients are aware of ant-counterfeiting strategies					
Customer medications is discussed first before selling					
Selling counterfeit infringes intellectual protection					
Resources affect identification of counterfeits					
Technology is a challenge to branded products					
Patients are cautioned on online prescriptions					