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Abstract

Performance of pharmaceutical firms is critical to their sustainability and growth. Worldwide, independent community pharmacies are growing at a rapid pace contributing immensely towards global economy. However, majority of independent community pharmacies in Nairobi City County are victims of counterfeit drugs that threaten their performance. The declining performance of independent community pharmacies has largely been attributed to influx of counterfeit drugs in the industry, which is yet to be empirically determined. This paper sought determine the effect of counterfeit drugs on performance of independent community pharmacies by specifically focusing on the effect of risks associated with counterfeit drugs, effect of potential legal suits and the role of drug quality control surveillance on performance of independent community pharmacies in Nairobi County. This paper also established the effect of regulatory policies on counterfeit drugs and performance of independent community pharmacies in Nairobi County. The study applied the descriptive research design and a population of 423 licensed independent community pharmacies in Nairobi City County was targeted. Data analysis was conducted with the help of SPSS software program v 25.0. The results also revealed that risks associated with counterfeit drugs and performance of independent community pharmacies have a negative and significant relationship (β=-.465, p=0.000<0.05), potential legal suits and performance of independent community pharmacies are negatively and significantly related (β=-.317, p=0.000<0.05) while drug quality control surveillance and performance of independent community pharmacies have a positive and significant relationship (β=-.282, p=0.000<0.05). Test for moderation results also showed that the explanatory power of regulatory policies in the relationship between counterfeit drugs and performance of independent community pharmacies improved to 60.9% from 59.9 after introducing it implying that regulatory policies moderates the relationship counterfeit drugs and performance of independent community pharmacies. The study concludes that risks associated with counterfeit drugs,

potential legal suits badly undermine the performance of independent community pharmacies by damaging their reputation and scaring customers aware. The study further concludes that drug quality control surveillance is essential in ascertaining quality of drugs and medicines supplied to retailers and consumers. It was also concluded that regulatory moderates the relationship counterfeit drugs and performance of independent community pharmacies. The study recommends for the need of awareness training on counterfeit drugs trough workshops, seminars organized by community pharmacy operators in conjunction with relevant product quality monitoring authorities like Kenya Bureau of Standards, Kenya Poisons Board. Community pharmacy operators may then be sensitized about the various risks associated with counterfeit drugs and how it may impact the performance of their business. The study recommends that there is need for the independent community pharmacies to ascertain the credibility of suppliers of drugs and medicines by checking their registration details and license from Kenya Bureau of Standards and Kenya Poisons Board. The study recommends that the independent community pharmacies may need to have their own laboratories fully equipped with reagents to check the quality and credibility of drugs and medicines supplied. The study recommends for enhanced enforcement and implementation of laws and policies relating to drug production, distribution and consumption. Government, producers, distributers and consumers may need to work in collaboration to ensure effective implementation of relevant drug policies.

Keywords: *Counterfeit drugs, independent community pharmacies, Nairobi County*

1.1 Introduction

Performance of pharmaceutical firms is critical to their sustainability and growth (Yorke, Oyebola, Otene & Klein, 2019). Worldwide, independent community pharmacies are growing at a rapid pace contributing immensely towards global economy. However, majority of independent community pharmacies are experiencing some challenges that threatened their performance (Sholy, Gard, Williams & MacAdam, 2018). The declining performance of independent community pharmacies has largely been attributed to influx of counterfeit drugs in the industry, which is yet to be empirically determined (Kho, Hassali, Lim & Saleem, 2017).

Community pharmacies have both an important responsibility of distributing drugs and medicines to consumers and monitoring the ongoing safety of medicines (Doucette, McDonough, Mormann, Vaschevici, Urmie & Patterson, 2012). Community pharmacies are recognized by members of the public as a vital, integral part of the health services in their country, are known to be conveniently accessible places where sound, objective advice on health issues can be obtained and early identification of adverse events done (Baratta, Germano & Brusa, 2012). However, more often, independent community pharmacies have the tendency of not adhering to some set pharmaceutical regulations and guidelines paving way to the emergence of counterfeit drugs.

Counterfeits drugs are medication products manufactured, produced, packaged, re- packaged and labelled where they are imitated in such a manner and to a degree that they are identical or substantially similar copies of the protected goods (Fadlallah, El-Jardali, Annan, Azzam & Akl, 2016). The process is referred to as counterfeiting which involves infringement of protected intellectual property rights or imitation in that the other goods are calculated or confused with original or genuine ones (Von Braun & Munyi, 2010; Glass, 2014). Fake drugs

are items purposely and falsely created as well as mislabeled as for character and additionally source to make it give off an impression of being a certified item. According to Bate, Jin and Mathur (2015), counterfeit products are generally low priced and often of lower qualities than the originals products. Counterfeiting either in drugs or other products is prevalent problem globally.

Besançon, Humbert and Pedersen (2019) reported that counterfeit medicines potentially make up more than 50% of the global drug market, with a significant proportion of these fake products being encountered in developing countries. This occurrence is attributed to a lack of effective regulation and a weak enforcement capacity existing in these countries, with an increase in this trade resulting from the growing size and sophistication of drug counterfeiters (Glass, 2014). In addition, due to both cost and lack of availability of medicines, consumers in developing countries are more likely to seek out these inexpensive options (Baratta, Germano & Brusa, 2012). The impact of counterfeit drugs on consumer confidence in health care systems, health professionals, the supply chain, and genuine suppliers of medicines and medical devices is evident (Pisani, 2017). Antibiotics, antituberculosis drugs, and antimalarial and antiretroviral drugs are frequently targeted, with reports of 60% of the anti-infective drugs in Asia and Africa containing active pharmaceutical ingredients outside their pharmacopoeial limits (Urick, 2016).

Counterfeit drugs are both a problem to both consumers who risks their lives by consuming fake drugs and genuine drug manufacturers and distributors who lose revenue to counterfeit drug dealers (Sholy, *et al.*, 2018). In some countries for example Lebanon, to counter the problem of counterfeiting, medicines have to be registered and approved for importation by the Ministry of Public Health (MoPH). They are available only from pharmacies and dispensed by registered pharmacists, unlike other developing countries, where medicines may be dispensed by different retailers (Sholy, *et al.*, 2018). Since 2004, a 3D hologram with the slogan 'from the producer to the citizen/consumer' has been used to indicate that the medicine had been imported through an unbroken chain of responsibilities directly from the producer to the consumer, however, not all importers use the hologram.

Independent community pharmacies have the important responsibility in ascertaining the the drugs in their counters and store are safe and are widely accessible to do it (Doucette, McDonough, Mormann, Vaschevici, Urmie & Patterson, 2012). Community pharmacies are recognized by members of the public as a vital, integral part of the health services in their country, are known to be conveniently accessible places where sound, objective advice on health issues can be obtained and early identification of Adverse Events done (Baratta, Germano & Brusa, 2012). However, more often, independent community pharmacies have the tendency of not adhering to some set pharmaceutical regulations and guidelines giving room to the emergence of counterfeit drugs.

Kenya Association of Manufacturers, KAM (2018) estimated that the counterfeit penetration ranges up to 40 percent for some items. The aforementioned association claims that in 2018 counterfeits cost businesses 50 billion shillings ($650 million) and the government 38 billion shillings ($500 million) in taxes (Kalekye & Kariuki, 2020). Drugs that are easily counterfeited include, fast moving and well-known brands, easily manufactured drugs, those available over the counter (OTC), supplies to Government institutions and products for exports. Kenyan pharmaceutical enterprises continue to face several challenges from illegal trade in pharmaceuticals products (Muthiani & Wanjau, 2012). There are incalculable financial costs to the reputation of these pharmaceutical importing enterprises and the public

health systems as a result of counterfeits. Business enterprises lose revenues and profits, with consequences for their shareholders (as stock values are curtailed), their employees (as jobs are lost), and their customers (on to whom the financial losses will be passed in the form of increased prices). Furthermore, many states loose valuable tax revenues, as counterfeit goods move through informal markets where taxes and duties are seldom paid. Counterfeiting has significant negative impacted on pharmaceutical businesses with adverse implications on the growth of the s pharmaceutical ector. It is against this background that this paper empirically investigated the effects of counterfeits on performance of independent community pharmacies in Nairobi country, Kenya.

1.2 Statement of the Problem

Counterfeit drugs 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. Performance of pharmaceutical firms is critical to their sustainability and growth. Independent community pharmacies in Kenya particularly in Nairobi City County are growing at a rapid pace contributing immensely towards country's gross domestic product. Independent community pharmacies growth in Nairobi City County was 2.3 percent in 2017 with net annual revenue of $50 million (Ng'ethe, 2017). However, performance of independent community pharmacies in Nairobi City County started declining in the years 2018 and 2019 generating $47 million annual revenue sales and $45.4 million annual revenue sales respectively (Kalekye & Kariuki, 2020). The declining performance of independent community pharmacies has largely been attributed to influx of counterfeit drugs in the industry, which is yet to be proven empirically.

Developing countries like Kenya are target of counterfeit drugs. In Nairobi, an estimated 30% of drugs sold are fake or counterfeit, accounting for an annual loss of more than 10 billion shillings (Ng'ethe, 2017). The proliferation of counterfeit drugs and pharmaceuticals has been attributed to the rising deliberate deaths, disabilities and injuries to consumers, loss of revenue to both genuine drug manufacturers, distributors and county government and also greatly contributes to the high cost of public healthcare (Ng'ethe, 2017).

Different studies have been conducted however, the focus vary. For instance a study by Bashir *et al.* (2019) looked into community pharmacists' perceptions, awareness and practices regarding counterfeit medicines. Marete (2014) investigated anti-counterfeiting strategies adopted by pharmaceutical manufacturing firms in Kenya and organizational performance, while Said (2016) investigated the effect of counterfeit drugs on distribution of pharmaceutical products in Mombasa County. Indeed, the aforementioned studies did not delve into how counterfeits impact on performance of independent pharmacies. In view of this discrepancy, there is need to ascertain the effect counterfeits have on pharmacies performance in order to provide practical evidence that may inform policy in the county and country at large. If this is not addressed, increased counterfeiting of pharmaceuticals could continue negatively impacting performances in the sector. This is a dangerous precedent for the economy and health system of the whole country.

1.3 Objectives of the study

1. To determine effect of risks associated with counterfeit drugs on performance of independent community pharmacies in Nairobi County.

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2. To assess effect of potential legal suits on performance of independent community pharmacies in Nairobi County.
3. To determine the role of drug quality control surveillance on performance of independent community pharmacies in Nairobi County.
4. To establish effect of regulatory policies on counterfeit drugs and performance of independent community pharmacies in Nairobi County.

1.4 Conceptual Framework

The study used a conceptual framework that indicates relationship between independent variables (risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance), regulatory policies as moderator variable and performance of independent community pharmacies as the dependent variable.

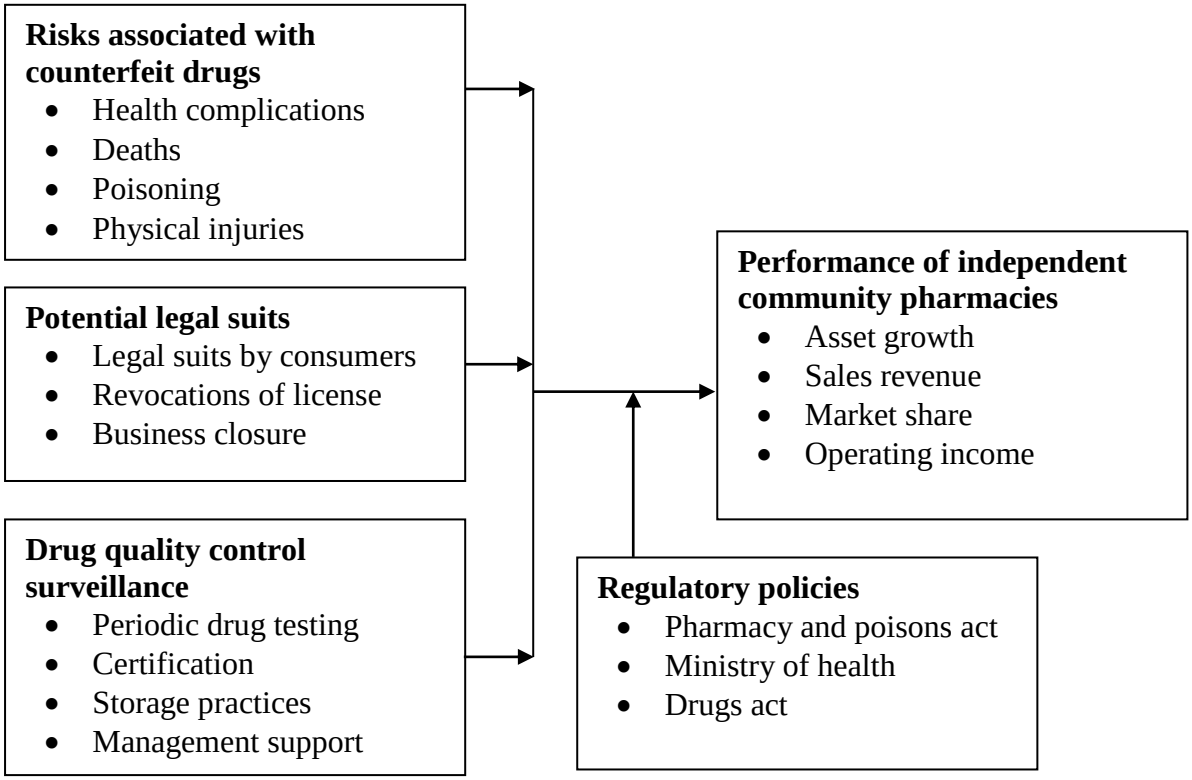

Figure 1: Conceptual framework

The conceptual model presented in Figure 1 depicts the relationship between the independent variables of the study namely risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance, regulatory policies as the moderator variable and performance of independent community pharmacies as the dependent variable. Operationalization of the variables is conducted as indicated in the conceptual framework. The conceptual framework proposes that risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance have significance effect on performance of independent community pharmacies.

2.0 Literature Review

2.1 Review of Theories

The main theory anchoring the paper is Neoclassical Theory of Consumer Demand. In addition, the paper is also supported by Aarker's Brand Equity Model and Normative Theory of Market-Failure.

2.1.1 Neoclassical Theory of Consumer Demand

Neoclassical Theory of Consumer Demand was popularized by Alfred Marshall as cited by Humphrey (1996). Demand theory is an economic principle relating to the relationship between consumer demand for goods and services and their prices in the market. Demand theory forms the basis for the demand curve, which relates consumer desire to the amount of goods available (Reisman, 2013). As more of a good or service is available, demand drops and so does the equilibrium price. Demand is simply the quantity of a good or service that consumers are willing and able to buy at a given price in a given time period. People demand goods and services in an economy to satisfy their wants, such as food, healthcare, clothing, entertainment and shelter (Reisman, 2002).

According to Moscati, (2007), demand is the preparation and ability to purchase a range of quantities at a range of prices. Consumers purchase goods that satisfy wants and needs that generate utility (Barr & Cuthbertson, 1991). Those goods that generate more utility are more valuable to consumers and thus buyers are willing to pay a higher price (Bentham, 2005). The ability of consumers to pick one unit of one type of differentiated commodity is important to determine the situations in which discrete change in prices leads to some consumers switching brand or mode, while others change the magnitude of their consumption (Katzner, 2015). If each additional unit of a good is less satisfying, then a buyer is willing to pay less, as such the demand price declines (Lee & Keen, 2004). This inverse law of demand relation between demand price and quantity demanded is a direct implication of the law of diminishing marginal utility. This theory is relevant to this study in that as demand for pharmaceutical products increases, the counterfeiters bring more of their products into the market. This is true to the fact that the prices for original branded products are deemed to be high thus encouraging counterfeiting.

2.1.2 Aarker's Brand Equity Model

Aaker (1991) provided the most comprehensive brand equity model which consists of five different assets that are the source of the value creation. These assets include: brand loyalty; brand name awareness; perceived brand quality; brand associations in addition to perceived quality; and other proprietary brand assets such as, patents, trademarks, and channel relationships. Based on Aaker's model, Al-Abdallah and Abo-Rumman (2013), brand loyalty generates value by reducing marketing costs and leveraging trade. Loyal customers expect the brand to be always available and entice others advising them to use it.

Brand awareness is a key and essential element of brand equity which is often overlooked (Sun & Ghiselli, 2010). Brand awareness has different level; at the recognition level, it can provide the brand with a sense of the familiarity as well as a signal of substance, commitment and awareness and at the recall level, it further affects choice by influencing what brands get considered and selected. For many companies, brand awareness is pivotal and it underlies the strength of successful brands (Aaker, 2009). Brand awareness plays an important role in most of conceptual models of brand equity. Brand awareness generates a high level of purchase,

mainly because consumers are likely to buy those brands they are familiar with enhancing the firm's profitability and sales (Jalilvand, Samiei & Mahdavinia, 2011). Aaker (1991) explained that perceived quality provides value by providing a reason to buy, differentiating the brand, attracting channel member interest, being the basis for line extensions, and supporting a higher price. In other words, perceived quality is the consumer's judgment about a product's overall excellence or superiority.

Aarker's Brand Equity Model is relevant to the study because pharmaceutical marketers can evaluate these assets to arrive at the brand's equity. Brand equity can enhance the efficiency and effectiveness of marketing programs. A promotion, for example, will be more effective if the brand is familiar and if the promotion does not have to influence a sceptical consumer of brand quality. Further, brand awareness, perceived quality and brand associations can all strengthen brand loyalty by increasing customer satisfaction and providing reasons to buy the product, thus firm performance or profitability. However, it is the same brand awareness and perceived quality attached to a particular pharmaceutical product that attracts counterfeits. Pharmaceutical products perceived to be of good quality and also bearing a marketing brand name often attracts unscrupulous manufacturers, distributors and retail sellers who want to reap profits from that particular item. Thus, counterfeiting emerges.

2.1.3 Normative Theory of Market-Failure

Normative theory of market failure was proposed by Dollery and Worthington (1996). The normative theory of market failure predicts that regulation will be instituted to improve economic efficiency and protect social values by correcting market imperfections. Research into the markets is at the center of economic sociology (Fligstein, 2001). Over the past three decades sociologists have investigated almost every type of market using a variety of theoretical premises (Oatley & Nabors, 1998). All this research however, starts from an assumption of the legality of the market exchange (Pisano, 2015).

The most relevant market failure giving rise to trademark protection arises from asymmetric information (Devlin, 2010). For many goods, consumers do not have enough information to ascertain the quality of a potential purchase. A trademark guarantees that a product or a service originated with a particular producer (Fink, Maskus & Qian, 2016). This is valuable information to consumers because it reduces both uncertainty and the costs of searching for particular quality levels. Indeed, producers compete by establishing a reputation for different levels of quality (Dollery & Worthington, 1996). In turn, trademarks serve as an indication of product quality, a crucial support for functioning markets. Thus, trademarks, geographical indications, and similar rights enable high-quality producers to distinguish themselves in the market, supporting investments in improved product or service quality.

This theory is relevant because it supports that the market failure in the pharmaceutical Industry in Kenya is due to the lack of proper regulations. The drug distribution network in Kenya is in a state of chaos because it consists of open markets, patent medicine stores, community pharmacies, private and public hospitals, wholesalers/importers and pharmaceutical manufacturers. Deceptive counterfeiters copy trademarks, logos, and designs to confuse consumers into believing they are buying the legitimate product. In the presence of information asymmetries, deceptive counterfeiting is virtually certain to reduce economic welfare. Those who discover they bought a fake good realize less consumption value than the price they paid for it. Rational consumers, aware that fake goods are on the market but are indistinguishable from originals, are unwilling to pay the full price of a high-quality good.

This problem undermines the incentive for producers to invest in higher quality and may destroy markets for high-quality goods.

2.1.4 Theory of Reasoned Action

Theory of reasoned action (TRA) was proposed by Ajzen and Fishbein (1980). The theory of Planned Behavior states that individuals have systematic access to knowledge and they take rational decisions solely based on the knowledge they absorb (Fishbein & Ajzen, 1980). The theory suggests that an individual's behavioral intention is a function of the individual's attitude about the behavior and subjective norm (Marcketti & Shelley, 2009). It is made up of three constructs namely behavioral intention, attitude, and subjective norm. Behavioral intention is defined as the individual's relative strength of intention to perform a behavior (Huang, 2017). According to the theory of moral reasoning and competency**,** moral reasoning comes into play when an individual is faced with an ethical dilemma. Attitude comprises of the various beliefs about the outcomes of performing the behavior multiplied by the assessments of these outcomes (Kim & Karpova, 2010). Subjective norm comprises of the perceived expectations from the individuals and the intentions to comply with these expectations (Huang, 2017). Individual's voluntary behavior is predicted by the attitude toward the behavior in question and how it is assumed that other people would view them if the behavior is performed.

Theory of reasoned action is relevant to the study in understanding human behvaiour when it comes to creating and consuming counterfeit products. It is the human behavour that pushes certain firm to manufacture items even if they are not observing standards and qualities required. The desire for profits and high revenues push some drug distributers and manufacturers to produce and sell products even disregarding regulations. Likewise, the dire of higher profits among drug distributers and sellers entices them to acquire drugs from unrecognized manufacturers just because they are selling them cheaply. Moreover, consumers' desire for cheap or affordable products may push them to buy counterfeit products.

2.1.5 Theory of Minimum Quality Standards

Theory of Minimum Quality Standards was proposed Akerlof in 1970. Theoretical justification for minimum quality standards was first established by Akerlof (1970) when he showed in the context of the used auto market that informational asymmetry could lead to market failure. Subsequently, Leland (1979) presented a more general information theoretic analysis of markets with asymmetric information. Leland (1979) concluded that in such markets: quality would be supplied at sub-optimal levels; minimum quality standards mayor may not be socially desirable, depending on certain demand and supply characteristics which he identified; and a professional group or industry if allowed to set its own standards, could set such standards too high or too low, but that "on balance, there is some reason to expect too-high standards to be the more likely case.

In markets with asymmetric quality information, quality deterioration may occur as indicated by Akerlof (1970), resulting in a "lemons" market. Such deterioration, often cited as justification for minimum quality standards and occupational licensing, was concluded by Leland (1979) to be a general phenomenon in markets with asymmetric quality information. Support is found for Leland's conclusion that a "lemons market" is a general phenomenon in competitive markets characterized by asymmetric information, as well as the conclusion that

a minimum quality standard mayor may not be socially desirable in such markets (Garella & Petrakis, 2008).

Theory of Minimum Quality Standards is important in monitoring quality of products. In theory, large pharmacy chains can also test products before or after acquiring them, but the incentive to do so is likely weak especially if neither consumers nor regulators can discover quality problems and link them to chain identity. Minimum quality standards is adopted in many fields including drug manufacturing industry to check quality, typically in response to the existence of imperfect information and the perceived need for consumer protection. For products, minimum quality standards have been applied to such diverse items as medical drugs. In addition, occupational licensing is applied to regulate drug production.

2.2 Empirical Literature

Counterfeit medicines are among the counterfeit products with the greatest potential for harming the health of consumers. The production of pharmaceuticals is heavily regulated in order to ensure product compliance with the highest quality and safety standards (Fadlallah *et al.*, 2016). All drugs must undergo clinical trials before being marketed in order to test their efficiency, verify their quality and exclude the potential existence of side effects on patients. These institutional and technical measures are meant to work as a safety valve to guarantee the quality of medicines (Omer, 2018). Counterfeit products do not respect any of these regulations and requirements. Despite the existence of controls, counterfeit products exist in the market, creating consequences ranging from ineffective therapeutic results to severe health problems or death.

The adulteration and fraudulent manufacture of medicines is a common problem, vastly aggravated by modern manufacturing and trade. Before considering the various elements of the problem, the term "counterfeit drug" should be defined (Laaksonen, Duggan & Bates, 2010). According to the 1992 World Health Organization (WHO) definition, a counterfeit drug is a pharmaceutical product that is deliberately and fraudulently mislabeled with respect to identity and/or source (Blackstone, Fuhr & Pociask, 2014). The WHO further clarifies that this definition applies to both branded and unbranded medicines, the so-called generics, and it includes products "with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. This definition stresses out the adulteration, inappropriateness, illegality and by extension, the danger of these products.

Counterfeit drugs increase costs to patients, health systems creating marketing inefficiencies. Medicines are expensive; patients and governments waste money on ineffective ones (Fadlallah, *et al.*, 2016). Lingering illnesses decrease productivity, causing workers to forgo pay and spend more on treatment. Through encouraging antimicrobial resistance, illegitimate medicines reduce the effective life of a drug (Ng'ethe, 2017). Society must bear the cost of drug development, an expense that increases as drugs become more complex. Substandard and falsified medicines undermine confidence in the health system and in all public institutions.

In many ways, the trade in illegitimate pharmaceuticals further erodes the distribution of genuine products in the market. Consumption of counterfeit drugs diverts revenue from genuine beneficiaries to criminal dealers undermining market structure of pharmaceutical products (Yorke, *et al.*, 2019). As a consequence, genuine producers and distributers loose revenue to fraudulent drug dealers resulting to market failures (Mhando, Jande, Liwa, Mwita

& Marwa, 2016). Markets for post-experience goods are particularly prone to failures related to information asymmetry. More specifically, producers and consumers have access to different degrees of information about the product, which leads to inefficient market outcomes.

With the rising cases of counterfeit products, ultimate risks on consumers are eminent. The perceived risk of consuming particular product is anchored on trust between and supplier or distributor (Alfadl, Ibrahim & Hassali, 2012). Perceived risk as risk in terms of consumer awareness about the negative impact in product purchase. The perceived risk of consumers relates to the financial, performance, prosecution, time and social risks (Khalid & Rahman, 2015). Because the consumers' perceptions of quality hold them, therefore, their perceived risk to buy negatively influences their attitude towards buying counterfeit products (Quintal, & Phau, 2014; Chiu, Lee, & Won, 2014).

Counterfeit products may often attract law suits attributed to injury or harm to the consumer. As a consequence, many independent community pharmacies who knowingly or unknowingly sell or distribute drugs find themselves being suit in the court of law and other bodies mandated to oversee over the production, distribution and consumption of medical products (deKieffer, 2016). More often when found culpable, the independent community pharmacies have their license revoked. All these occurring affect the efficient operations of the pharmaceutical enterprises ultimately hindering their performance (Currais, Rivera & Rungo, 2018).

The credibility of pharmaceutical products including drugs and other medical facilities is dependent on the capability of various regulatory bodies and producers to undertake drug quality control surveillance (Aminu & Gwarzo, 2017). Quality control surveillance ensures that quality and safe drugs are produced and marketed. Drug quality control surveillance calls for resources, infrastructure and trained personnel to assure the quality of drugs produced and imported medicines, to carry out regular surveillance for substandard and falsified medical products, and to carry out effective law enforcement measures against criminal or negligent offenders (Bate, Jin & Mathur, 2015). During, quality control surveillance process, drugs are subjected to laboratory testing to ensure that they meet laid standards of quality and safety (Petersen, Held & Heide, 2017). If a drug, upon laboratory testing in accordance with the specifications it is claimed to comply with fails to meet those specifications, then it is classified as a substandard drug.

However, managing counterfeits is often a challenge especially if regulations are weak (Lallerstedt, 2019). Having regulations per se is an insufficient deterrent unless there is significant market surveillance, strong enforcement, and sufficient penalties for those who are caught breaking the rules (Swathi, *et al.,* 2020). The policies and regulations on drug production and distribution are poorly implemented and adhered to both by those in authorities and product supplier.

Abzakh, Ling and Alkilani (2013) looked at the impact of perceived risks on the consumer resistance towards generic drugs in the Malaysia pharmaceutical industry by focusing on financial risk, performance risk-technology, performance risk-infrastructure, physical risk, time risk, social risk, and psychological risk. The findings of this research showed in indicate that only two independent variables (performance risk-technology and physical risk) are in positive relationship with consumer resistance towards generic drug. On the other hand, financial risk, performance risk-infrastructure, time risk, social risk, and psychological risk

do not have significant relationships with the consumer resistance towards generic drugs. The study did not illustrate potential consumer risk as a result of consuming counterfeit drugs.

Sholy, Gard, Williams and MacAdam (2018) studied pharmacist awareness and views towards counterfeit medicine in Lebanon. The study used convenience sampling and selected pharmacists based on their willingness to participate and used a questionnaire. The study highlighted the need for additional counterfeited medicines awareness campaigns with an emphasis on the role that pharmacists have in protecting patients from using counterfeited medicines. In addition, there is a need for an official counterfeited medicines definition that distinguishes between the different types of counterfeiting.

Khalid and Rahman (2015) conducted a study on word of mouth, perceived risk and emotions, explaining consumers' counterfeit products purchase intention in a developing country: implications for local and international original brands. In this study, an empirical approach is accepted that practices survey research to examine the consumers' purchase behavior towards counterfeit products. Using non-probability convenience sampling technique, a self-administrated questionnaire was designed and distributed among 500 respondents in Islamabad, Lahore and Peshawar city of Pakistan. Results show that, except perceived risk, the word of mouth and emotions positively influence consumers' counterfeit products purchase intentions. However, the study focused on counterfeit products in Pakistan whose regulatory jurisdictions on counterfeiting may be different from those in Kenya hence the need to undertake the current study.

Nsimba (2019) studied problems associated with substandard and counterfeit drugs in developing countries. Review of various literatures through Pub-Med, Medline, Google and Internet search to retrieve and download published materials was done by the author of this review paper. Counterfeit or substandard (poor quality) drugs pose threats to society; not only to the individual in terms of the health side effects experienced, but also to the public in terms of trade relations, economic implications, and the effects on global pandemics. It is vital for suppliers, providers, and patients to be aware of current trends in counterfeiting in order to best prepare for encounters with suspicious products. Furthermore, this is an issue that needs to be continually dealt with on national and international policy levels.

deKieffer (2016) studied potential liability for counterfeit medications. Counterfeit drugs usually enter the market through diversion. Once the drugs have entered the market, they are still difficult to detect because they appear like the real drug, and they are often destroyed through ingestion. Potential liability faced by wholesalers cost them huge law suits. That litigation has raised the awareness of wholesalers and others about the potential liability of buying drugs in the secondary market.

Pisani (2017) studied public health and socioeconomic impact of substandard and falsified medical products. The papers reviewed in this study provide data for 88 of the 194 WHO Member States. It was revealed that most countries from developing world lacked drug quality control surveillance systems to secure the quality of the medical products in the national supply chain. There is need to study drug quality control surveillance situation in Kenya.

Petersen, Held, Heide and Difäm-EPN Minilab Survey Group studied (2017) surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. The highest proportion of substandard and falsified medicines was found in Cameroon (7.1%), followed by the Democratic Republic of Congo (2.7%) and Nigeria

(1.1%). Antimalarial medicines were most frequently found to be substandard or falsified (9.5% of all antimalarials). Surveillance for poor-quality medicines can be carried out by local organizations in low-and middle-income countries using a simple, low-cost technology. Such surveillance can identify an important subgroup of the circulating substandard and falsified medical products and can help to prevent them from causing harm in patients.

Kibwage (2018) studied counterfeiting of drugs and the necessity of quality control systems in developing countries. In Kenya, the quality control functions are carried out by the Drugs Analysis and Research Unit (DARU) and the National Quality Control laboratory (NQCL). The data presented in this paper represents samples analyzed by the two laboratories during the period 1980-2007. In both laboratories, the handling of samples has been similar. The failure rates still remain unacceptably high, especially with anti-infective agents, which have serious implications in development of multi-drug resistance and treatment failures. Surveillance of counterfeits still remains poor and many cases still go undocumented due to low vigilance. There is need for stepping up market surveillance through infrastructure development and capacity building in the country.

Miller and Goodman (2017) studied whether chain pharmacies perform better than independent pharmacies. The study measured the quality of history taking, therapeutic management and advice giving against national (Government of India) and international (WHO) guidelines. The performance of chains and independent shops was strikingly similar for most areas of assessment. Results from Bengaluru suggest that it is unlikely that chains alone can solve persisting quality challenges. However, they may offer a potential vehicle through which to deliver interventions.

Besançon, Humbert and Pedersen (2019) studied legal and regulatory framework for community pharmacies in the WHO European Region. This report provides an overview of existing components and provisions of the legal and regulatory framework for community pharmacies and their activities in Europe. It presents the diverse approaches to community pharmacy licenses and to establishment of new pharmacies and their ownership. It also details the framework for community pharmacy operating requirements (including opening hours, workforce, premises and equipment, services provided and identification of a community pharmacy) and the types of activity undertaken. Adoption of provisions from one country to another needs a full analysis of advantages and disadvantages and adoption into the local context and adjusted to the coherence of the national framework.

Omer (2018) studied some aspects of fake and counterfeiting of drugs: Sudan Case. The investment law approved recently has good statements and rules on the above strategy in particular to pharmacy regulations. The study reveals the need for further research to find out how efficient the regulatory authorities at both federal and state levels are. The splitting of the drug regulatory authority between two ministries and the marketing of unregistered medicines by public drug suppliers (namely the CMSPO, and RDFs), and NGOs undermine the quality of medicines and ultimately jeopardise the health of the people taking medication.

Ng'ethe (2017) conducted a study on the effects of counterfeits on sales and distribution of pharmaceutical products in Nairobi County, Kenya. The study undertook a cross sectional survey approach of the major pharmaceutical distributors in Nairobi County. 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 remediated measures in the industry to curb the practice. The study concluded that there's need to strengthen the various laws relating to counterfeits in Kenya.

3.0 Research Design and Methodology

The study applied descriptive survey design. By using descriptive survey design method, the study was able to determine the effect of counterfeit drugs on performance of independent community pharmacies in Nairobi County. The study population was 423 licensed independent community pharmacies in Nairobi City County with a total of 1850 owners/operators (Pharmacy and Poisons Board report, 2020). The selected regions of Nairobi City County (Nairobi CBD, Embakasi, Westlands, Kasarani, Nairobi West and Dagorethi) have the highest cases of influx of counterfeit drugs as per the Pharmacy and Poisons Board report of 2020.

Yamane formula was used to calculate sample size of 329 operators comprising 156 operators where stratified random sampling technique was used to select 156 operators from Nairobi CBD, 54 from Embakasi, 31 from Westlands, 40 from Kasarani, 26 from Nairobi west and 22 from Dagoreti. Data were collected using structured questionnaires. Statistical Package for the Social Sciences (SPSS) software version 25.0 was used to organize code and analyze information and generate quantitative report. The data was analyzed using descriptive statistics, correlation and regression analyses. Correlation was used to establish the association between risks associated with counterfeit drugs, potential legal suits, drug quality control surveillance and performance of independent community pharmacies in Nairobi County. Regression analysis helped determine relationship between counterfeit drugs and performance of independent community pharmacies in Nairobi County. A critical p value of 0.05 was used to determine whether the individual variables are significant or not. The multiple regression model estimated is;

$$\mathbf{Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \epsilon}$$

Where;

Y = Performance of independent community pharmacies

X_1 = Risks associated with counterfeit drugs

X_2 = Potential legal suits

X_3 = Drug quality control surveillance

In the model, β_0 = the constant term while the coefficient $\beta_i = 1\ldots.3$ were used to measure the sensitivity of the dependent variable (Y) to unit change in the predictor variables X_1, X_2, and X_3 The error (ϵ) term capture the unexplained variations in the model.

To test the moderating effect of drugs' regulatory policies on counterfeit drugs and performance of independent community pharmacies in Nairobi County, the study adopted Kenny and Baron (1986) moderating technique. The change in coefficient of determination (R^2) was used to confirm moderating effect of regulatory policies on counterfeit drugs and performance of independent community pharmacies in Nairobi County. Therefore, the model estimated is;

$$\mathbf{Y = \beta_o + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_5 M + \beta_6 C.M + \epsilon}$$

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Where;

X_1, X_2, X_3, X_4 = Independent variables

M = Moderating Variable (regulatory policies)

C = Composite function of X_1, X_2, X_3, X_4 (Counterfeit drugs)

C.M = Moderator Multiplied by the Composite of Counterfeit drugs (Interaction Term)

4.0 Presentation, Discussion and Interpretation of Findings

The analysis of the study involved correlation and regression analysis. Interpretation and discussion of results are also presented.

4.1 Correlation Analysis

Table 1 shows result output of the Correlation Analysis.

Table 1: Correlation Matrix

		Performance of independent community pharmacies	Risks associated with counterfeit drugs	Potential legal suits	Drug quality control surveillance
Performance of independent community pharmacies	Pearson Correlation	1.000			
	Sig. (2-tailed)				
Risks associated with counterfeit drugs	Pearson Correlation	-.697**	1.000		
	Sig. (2-tailed)	0.000			
Potential legal suits	Pearson Correlation	-.425**	.272**	1.000	
	Sig. (2-tailed)	0.000	0.000		
Drug quality control surveillance	Pearson Correlation	.532**	-.425**	-.228**	1.000
	Sig. (2-tailed)	0.000	0.000	0.000	

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

Results in Table 1 indicated that there was a significant negative association between risks associated with counterfeit drugs and performance of independent community pharmacies (r=-.697, p=0.000<0.05) implying that risks arising from dealing with counterfeit drugs and performance of independent community pharmacies move in opposite direction, that is; as risks associated with counterfeit drugs increases, performance of independent community pharmacies decreases and vice versa. There was a significant negative association between potential legal suits and performance of independent community pharmacies (r=-.425, p=0.000<0.05). A significant positive association between drug quality control surveillance and performance of independent community pharmacies (r=.532, p=0.000<0.05) was established.

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4.2 Regression analysis

Table 2 presents the model summary results.

Table 2: Model Fitness

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.774[a]	.599	.594	.58653

a. Predictors: (Constant), drug quality control surveillance, potential legal suits, risks associated with counterfeit drugs

From the results on Table 2, risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance are adequate explainers of performance of independent community pharmacies supported by R square of .599. This implies that risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance explain 59.9% of performance of independent community pharmacies. Community pharmacies have both an important responsibility of distributing drugs and medicines to consumers and monitoring the ongoing safety of medicines. Network drug stores are perceived by individuals from general society as an essential, fundamental piece of the wellbeing administrations in their nation, are known to be helpfully open spots where sound, target guidance on medical problems can be acquired and early identification of Adverse Events done. However, more often, independent community pharmacies have the tendency of not adhering to some set pharmaceutical regulations and guidelines giving room to the emergence of counterfeit drugs. Table 3 gives the results of the analysis of variance (ANOVA).

Table 3: Analysis of Variance

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	139.154	3	46.385	134.832	.000[b]
	Residual	93.229	271	.344		
	Total	232.382	274			

a. Dependent Variable: Performance of independent community pharmacies

b. Predictors: (Constant), Drug quality control surveillance, Potential legal suits, Risks associated with counterfeit drugs

The outcomes of the analysis of variance show that the general model was statistically significant. Further, the outcomes suggest that risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance are satisfactory indicators of the performance of independent community pharmacies. This was supported by an F statistic of 134.832 and calculated p value<0.05. Fake drugs are items purposely and falsely created as well as mislabeled as for character and additionally source to make it give off an impression of being a certified item. Counterfeit drugs are mostly of low quality but of low price to attract customers. Counterfeit drugs duplicate genuine drugs denying genuine dealers optimal revenue. The regression of coefficient table is presented in Table 4.

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Table 4: Multiple Regression Model

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
a	(Constant)	4.479	.320		13.984	.000
	Risks associated with counterfeit drugs	-.465	.038	-.526	-12.135	.000
	Potential legal suits	-.317	.057	-.223	-5.539	.000
	Drug quality control surveillance	.282	.047	.258	6.020	.000

a. Dependent Variable: Performance of independent community pharmacies

Basing on the predictive model, risks associated with counterfeit drugs (β=-.465) had the highest negative effect on performance of independent community pharmacies, followed by potential legal suits (β=-.317). Drug quality control surveillance had the highest positive effect (β=.282) on performance of independent community pharmacies. The results also revealed that risks associated with counterfeit drugs and performance of independent community pharmacies have a negative and significant relationship (β=-.465, p=0.000<0.05). The regression of coefficient implies that if risks associated with counterfeit drugs increases by one unit, the performance of independent community pharmacies decreases by .465 units.

The results also revealed that potential legal suits and performance of independent community pharmacies have a negative and significant relationship (β=-.317, p=0.000<0.05). The regression of coefficient implies that if potential legal suits increase by one unit, the performance of independent community pharmacies decreases by .317 units. The results also showed that drug quality control surveillance and performance of independent community pharmacies have a positive and significant relationship (β=-.282, p=0.000<0.05). The regression of coefficient implies that if drug quality control surveillance increase by one unit, the performance of independent community pharmacies increases by .282 units.

4.3 Moderating effect of regulatory policies on counterfeit drugs and performance of independent community pharmacies

The fourth objective established the effect of regulatory policies on counterfeit drugs and performance of independent community pharmacies in Nairobi County. All the autonomous factors were directed by the variable administrative strategies to give a composite (association term). The outcomes introduced in Table 5 shows the model readiness for a relapse model after balance.

Table 5: Model Fitness

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.780[a]	.609	.602	.58115

a. Predictors: (Constant), interaction term, potential legal suits, risks associated with counterfeit drugs, Drug quality control surveillance, regulatory policies

The R^2 before moderation was 59.9% but after moderation the R^2 improved to 60.9%. This implies that regulatory policies ensure that guidelines and procedures in the manufacturing of genuine drugs. Genuine drugs may attract good sales revenue thus enhancing performance of

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independent community pharmacies. Further the moderating term has significance with P value 0.000<0.05. Results of the ANOVA

Table 6: Analysis of Variance

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	141.532	5	28.306	83.812	.000[b]
	Residual	90.851	269	.338		
	Total	232.382	274			

a. Dependent Variable: Performance of independent community pharmacies

b. Predictors: (Constant), Interaction term, potential legal suits, risks associated with counterfeit drugs, drug quality control surveillance, regulatory policies

The outcomes of the analysis of variance show that the model was statistically significant after introducing the moderator. Further, the outcomes suggest that risks associated with counterfeit drugs, potential legal suits and drug quality control surveillance and moderator (regulatory policies) are satisfactory indicators of the performance of independent community pharmacies as supported by an F statistic of 83.812 and p value less than 0.05. The regression of coefficient table is presented in Table 7.

Table 7: Regression of Coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	4.582	1.183		3.873	.000
Risks associated with counterfeit drugs	-.474	.126	-.536	-3.775	.000
Potential legal suits	-.351	.112	-.247	-3.123	.002
Drug quality control surveillance	.190	.103	.173	1.846	.066
Regulatory policies (Moderator)	-.087	.401	-.088	-.218	.827
Interaction term	.062	.110	.206	.561	.576

a. Dependent Variable: Performance of independent community pharmacies

The R^2 prior moderation was 59.9% but after moderation the R^2 improved to 60.9%. This is an implication that regulatory policies ensure that guidelines and procedures in the manufacturing of genuine drugs. Genuine drugs may attract good sales revenue thus enhancing performance of independent community pharmacies. Risks associated with counterfeit drugs and potential legal were negatively related with performance of independent community pharmacies. Drug quality control surveillance was positively but insignificantly related performance of independent community pharmacies. However, regulation policies (moderator) had a negative but insignificant relationship with performance of independent community pharmacies. Managing counterfeits is often a challenge especially if regulations are weak. Having guidelines in essence is a lacking hindrance except if there is huge market observation, solid implementation, and adequate punishments for the individuals who are discovered disrupting the norms. The policies and regulations on drug production and distribution are poorly implemented and adhered to both by those in authorities and product

supplier. The results agree with Fadlallah *et al.* (2016) who studied methodologies and frameworks level mediations to battle or forestall sedate duplicating and saw that laws and enactment need as explicit to fake medications, including penalties and how to identify counterfeit drugs.

5.0 Conclusions

The study concludes that risks associated with counterfeit drugs badly undermine the performance of independent community pharmacies by damaging their reputation and scaring customers aware. Moreover, the risks may result to customer harm; loss of revenue by purchasing uncertified drugs and medicines that end up being confiscated. These e risks pose significant dangers to the performance and subsequent performance of the independent community pharmacies.

Conclusion can be made further that potential legal suits affects performance of the independent community pharmacies. Counterfeit products may often attract law suits attributed to injury or harm to the consumer. As a consequence, many independent community pharmacies who knowingly or unknowingly sell or distribute drugs find themselves being suit in the court of law and other bodies mandated to oversee over the production, distribution and consumption of medical products.

The study further concludes that drug quality control surveillance is essential in ascertaining quality of drugs and medicines supplied to retailers and consumers. The credibility of pharmaceutical products including drugs and other medical facilities is dependent on the capability of various regulatory bodies and producers to undertake drug quality control surveillance. Quality control surveillance ensures that quality and safe drugs are produced and marketed.

It was also concluded that regulatory policy may help reduce high cases of counterfeit drugs and medicine influx into the market. Supply laws and guidelines on the production and delivery of pharmaceutical products may help minimize high influx of counterfeit drugs through penalties, fines and license revocations.

6.0 Recommendations

It was established that most independent community pharmacy operators could not identify counterfeit products. The study recommends for the need of awareness training on counterfeit drugs trough workshops, seminars organized by community pharmacy operators in conjunction with relevant product quality monitoring authorities like Kenya Bureau of Standards, Kenya Poisons Board. Community pharmacy operators may then be sensitized about the various risks associated with counterfeit drugs and how it may impact the performance of their business.

The study established that potential legal suits for dealing with counterfeit drugs undermine the performance of independent community pharmacies. The study recommends that there is need for the independent community pharmacies to ascertain the credibility of suppliers of drugs and medicines by checking their registration details and license from Kenya Bureau of Standards and Kenya Poisons Board. Independent community pharmacies should undertake the process on periodic times and every time they are receiving any supplies. This will ensure that independent community pharmacies do not end up receiving drugs and medicines from uncertified suppliers and risk potential legal suits from consumers who get harmed by consuming their products.

The study established that drug quality control surveillance may help detect counterfeit products. Drug quality control surveillance may also help in monitoring quality of drugs and medicines produced during manufacturing. The study recommends that the independent community pharmacies may need to have their own laboratories fully equipped with reagents to check the quality and credibility of drugs and medicines supplied. However, some independent community pharmacies may not afford to have lab services to test the quality of drugs and medicines supplied, they ask for help from Kenya Bureau of Standards and other quality certification bodies willing to enter into agreement with.

The study established that regulatory policies may help reduce high cases of counterfeit drugs and medicine influx into the market by implementing and enforcing drug and medicine supply guidelines and procedures. Though there are clear guidelines and procedures guiding the production, distribution and supply of drugs and medicines, their subsequent enforcement and implementation is a problem. The study recommends for enhanced enforcement and implementation of laws and policies relating to drug production, distribution and consumption. Government, producers, distributers and consumers may need to work in collaboration to ensure effective implementation of relevant drug policies.

There is high proliferation of counterfeit goods into the market despite the existing measures. Further research may attempt to explore the channels that facilitate high influx of counterfeit products into the market. Factors contributing to high influx of counterfeit products may also be investigated. Further research may also entail studying effects of counterfeit drugs on country's healthcare system and economy.

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