Factors Influencing the Influx of Counterfeit Medicines in Kenya: A Survey of Pharmaceutical Importing Small and Medium Enterprises within Nairobi

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Abstract

Purpose: The proliferation of counterfeit medicines is one of the most pressing issues facing pharmaceutical SMEs in Kenya. As a result of counterfeiting, the SMEs lose revenues and profits, jobs are lost and customers are forced to pay higher prices for genuine products due to financial losses. Counterfeiting has received little attention in research in spite of its development, scope and consequences on firms, on governments and on brands. While most studies have focused on how to control the supply side of counterfeits, few studies have investigated the influencing factors of increased influx in counterfeited medicines.

Design/methodology/approach: The study adopted descriptive survey research design. The annual list from the Pharmacy and Poisons Board of registered pharmaceutical importing companies was used as sampling frame. Primary data was collected using a questionnaire and interview schedule. The study used both qualitative and quantitative techniques in analyzing data. Factor analysis, correlation analysis and regression analysis were used to determine the relationship between the independent variables.

Findings: 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 existed 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.

Practical implications: The study concludes that pharmaceutical companies should protect all their products with Kenya Intellectual Property Institute to avoid IPR infringement by the counterfeiters. Further, SMEs importing genuine branded products should develop better marketing strategies to entice the consumers to purchase genuine products and not the counterfeit version. The importers should employ pricing strategies that discourage counterfeiters from importing their products.

Originality/value: The study is among the few that have been carried out to investigate the motivating factors of medicine counterfeiting and is likely to be of great benefit to the players in the health sector including the pharmaceutical SMEs, the government agencies as well as the consumers.

Key Words: Counterfeiting, Health & Economic effects, SME

1.0 Introduction

Counterfeiting is defined as the manufacture, production, packaging, re-packaging, labeling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods (GOK, 2010).

It is an infringement upon protected intellectual property rights or imitation thereof so that the other goods are calculated to be confused with the original one (Otieno-Odek, 2010). Counterfeits of almost anything can be found, from apparels to pharmaceuticals, electrical goods, bleach and dyes, books and food. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. According to the World Health Organization (WHO) definition, what makes a medicine counterfeit is the deliberate or intentional (criminal) nature of the mislabeling of a product.

Counterfeiting of drugs as a 'problem' was first mentioned at the WHO conference of experts on the 'Rational use of the drugs' held in Nairobi in1985 (WHO, 2005). The Federal Bureau of Investigation(FBI) calls counterfeiting the crime of the 21st century (United Nations Interregional Crime and Justice Research Institute [UNICJRI], 2003). Trafficking of counterfeit goods has become one of the world's largest and most rapidly growing criminal enterprises, with the International Anti-Counterfeiting Coalition (IACC) estimating a value of more than US\$ 600 billion annually (IACC, 2009).

The Center for Medicines in the United States projected illegal medicine sales to reach USD 75 billion in 2010, a 92% increase from 2005. The World Health Organization (WHO) estimates that of the 1 million malaria deaths that occur in Africa each year, 200,000 are the result of counterfeit anti-malarial drugs (WHO, 2003). Harris, Stevens and Morris (2009) state that counterfeit drugs for tuberculosis and malaria kill 700,000 people every year in Africa.

In Kenya, the most common products counterfeited are dry primary cells, Bic Ball Point Pens, cosmetics, pharmaceutical products, toothpaste products, and certain brands of cooking oils, mobile phones, electronic equipment, juices and detergents (GOK, 2010). Kenya Association of Manufacturers [KAM] (2008) estimated that the counterfeit penetration ranges up to 40 percent for some items. The association claims that counterfeits cost Kenyan Small and Medium Enterprises (SMEs) 50 billion shillings (\$650 million) and the government 19 billion shillings (\$250 million) in taxes in 2008. KAM (2010) estimates that the Kenyan manufactures in general lose up to 30 per cent in revenue and 27 per cent jobs.

The earliest counterfeit medicines encountered in Kenya were skin preparations (GOK, 2008). Newer cases of counterfeit medicines were those of anti-malarial drugs including Duo-Cotexcin (dihydroartemisinin-piperaquine tablets that lacked piperaquine). Others included common antibiotics and fast moving analgesics. Kibwage, (2008) observes that the most frequently counterfeited medicines in Kenya are expensive life style medicines such as hormones, analgesics, antibiotics, steroids and antihistamines. Anti-malarial drugs, anti HIV/AIDS, anti-cancer and anti-viral, antibiotics are among the most counterfeited drugs found in developing countries (Dahiya, 2008). Medicines 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 (Mehta, 2006).

1.0 Statement of the Problem

Kenyan pharmaceutical SMEs continue to face several challenges from illegal trade in pharmaceuticals products. There are incalculable financial costs to the reputation of these pharmaceutical importing SMEs and the public health systems as a result of counterfeits. The SMEs 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); government loses valuable tax revenues, as counterfeit goods move through informal markets where taxes and duties are seldom paid; and both public and private actors have to bear the costs of policing, crime prevention, detection and law enforcement (Opiyo,2006). 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 and pharmacist, and potentially modern medicine or the pharmaceutical industry in general (Opiyo, 2006).

While most studies have focused on how to control the supply side of counterfeits, few studies have investigated the influencing factors of increased influx in counterfeited medicines, (Albers, 1999). Opiyo, (2006), identified three of such factors as weak legal framework, consumers' attitude towards counterfeit medicines and higher prices charged on imported drugs.

This still leaves a wide gap of researchable area and it is in view of this gap, that this study was constructed to explore other factors that influence the influx of counterfeit medicines in Kenya. The study sought to meet the following research objectives;

- 1. To investigate how legislation influences influx of counterfeit medicines in the Kenya's pharmaceutical SMEs.
- 2. To determine the extent to which genuine medicines' brand equity influences influx of counterfeits into the pharmaceutical SMEs.
- 3. To investigate whether the pricing strategy of medicines influences the influx of counterfeit medicines in pharmaceutical SMEs.
- 4. To establish to what extent perceived risks of counterfeit medicines influences their influx into the pharmaceutical SMEs.

1.3 Theoretical Review

1.3.1 Theory of Reasoned Action (TRA)

The TRA was proposed by Ajzen and Fishbein (1980). It is made up of three constructs namely behavioral intention (BI), attitude (A), and subjective norm (SN). The theory suggests that an individual's BI is a function of the individual's attitude about the behavior and SNs (BI ¼ A þ SN). BI is defined as the individual's relative strength of intention to perform a behavior. Attitude comprises of the various beliefs about the outcomes of performing the behavior multiplied by the assessments of these outcomes. SN comprises of the perceived expectations from the individuals and the intentions to comply with these expectations. In short, an individual's volitional (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.

1.3.2 Theory of planned behaviour (TPB)

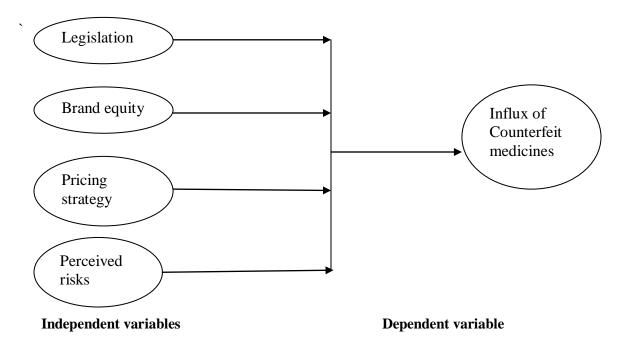
The TPB was created to account for the weakness in the TRA. With the addition of the perceived behavioural control (PBC) construct (Notani, 1998), PBC is defined by Ajzen and Madden (1986) as a "persons beliefs as to how easy or difficult performance of the behaviour is likely to be". Beliefs about resources and opportunities are often viewed as underlying factors influencing PBC. Therefore, as well as having positive attitudes toward purchasing a product and having social reasons to do so (SN), PBC should be able to additionally predict intentions of knowingly purchasing counterfeit luxury brands based on the perceived ease or difficulty associated with this behaviour. If an individual perceives he or she has control over performing behaviour, the individual is more likely to form strong intentions to perform the behaviour and vice versa (Notani, 1998; Rivis and Sheeran, 2003; Armitage and Christian, 2003; Armitage and Conner, 2001; Ajzen, 2002).

1.3.2 Theory of Moral Reasoning and Competency

Moral reasoning comes into play when an individual is faced with an ethical dilemma. Kohlberg (1976) categorized three stages which an individual encounters when faced with ethical dilemmas. At the preconventional level (Stages 1 and 2) an individual's reasoning is based on expected personal consequences such as reward and punishment. Stages 3 and 4 focus on maintaining and adhering to the expectations of reference groups and societal values. At the post-conventional level (Stages 5 and 6), there is a clear effort to define moral principles and values, whilst still maintaining and adhering to the values of one's reference group and society (Nill and Scultz, 1996). This stage is about finding a balance between what is morally acceptable to the individual and which fits in with his/her social environment. Consumer choices are generally influenced by behaviours considered appropriate and therefore normatively approved, whilst others are seen as inappropriate and hence restricted (Gupta, 2004). The theories mentioned above in combination with the literature review have aided in the development of the conceptual framework development outlined below.

1.4 Conceptual Framework

In this study the conceptual framework is based on four independent variable namely legislation, brand equity, pricing strategy and perceived risk and the dependent variable being influx of counterfeit medicines.



1.4.1 Legislation

The term may refer to a single law, or the collective body of enacted law. Legislation forms the basis for drug regulation both in Kenya and internationally (GOK, 2010). For it to be effective, legislation must be complemented with effective law enforcement. Governments need to develop strategies to reduce corruption and criminal activity and promote inter-sectoral cooperation between regulatory authorities, police, customs services and the judiciary to effectively control the drug market and enforce drug regulation (Rukwata, 2010).

1.4.2 Brand Equity

The extent to which a brand is considered as symbolic or functional influences consumers' willingness to purchase counterfeit brands. Symbolic brands are often used as vehicles for interpersonal communication and as expression of an individual's self-concept and need for social conformity (Chaudhry & Majumdar, 2006). It is a sad case for owners of genuine products as the organization has invested huge amounts of money in designing, marketing and manufacturing their products, while counterfeit producers use the brand names without having to design or incurring marketing costs but yet able to reap the profits (Gieske, 2004).

1.4.3 Pricing Strategy

Pricing is one of the most important elements of the marketing mix, as it is the only mix, which generates a turnover for the SMEs; the other three P's represent variable cost of the SMEs. The pricing strategy employed by many counterfeiters follows similar strategies as those employed by genuine brand owners. In non deceptive counterfeiting, penetration pricing strategy is employed and the driving force is the reduced price advantage of the counterfeit medicine over the higher price of the genuine drug (Opiyo, 2006). In deceptive counterfeiting, the gist of the strategy is to sell the counterfeited product at similar prices as those of fast moving genuine brands. Waters (2008) considers this a competitive strategy that takes advantage of the large market share of popular brands.

1.4.4 Perceived risk

Perceived risk is one of the main explanatory variables in consumers' behaviour in making a choice between purchasing a genuine product or a counterfeit one (Gabbott, 1991; Boustani, 1993; Mitchell, 1999). Perceived risk comprises of multidimensional constructs namely financial, social, physical, and psychological and time risks (Mitchell & Boustani, 1993; Campbell & Goodstein, 2001; Mandel, 2003).

1.5 Methodology

The study adopted descriptive survey research design that tried to explore the factors that influence the influx of counterfeit medicines. Phau and Teah (2009), in their study on antecedents and outcomes of attitudes towards counterfeits of luxury brands, asserted that this type of research design is appropriate in getting answers from respondents who participate through answering questions that are asked. The design was selected for this study because it provided numeric descriptions of the population and described events as they are, as they were or as they will be (Oso & Onen, 2009).

The target population was the pharmaceutical importing SMEs in Kenya and was provided by PPB. The population of study was the 61 pharmaceutical importing SMEs located in the city of Nairobi and having been in existence for over seven years, (GOK, 2010). The target respondents were the pharmacists or marketing managers running these firms because they were assumed to possess past and present knowledge of counterfeit medicines and therefore best placed to offer valuable information to the study.

A questionnaire, interview schedule and document analysis were used for collecting data in this study. The primary data was obtained from the data collected through the questionnaire and interview schedule. The secondary data was collected from past document reviews and relevant articles. The questionnaires contained both open and close-ended questions and also structured and unstructured questions. Nordin (2009), in his study on consumer attitude towards counterfeit products in Malaysia recommends use of questionnaires because of time saving and confidentiality.

Pilot test was conducted to test validity and reliability of research instruments using five pharmaceutical importing SMEs that were randomly selected. For this study, both qualitative and quantitative data analysis techniques were used with assistance of Statistical Packages for Social Sciences (SPSS).

Qualitative analysis involved coding and organizing collected data into themes and concepts that address the research questions, (Mugenda & Mugenda, 2003). Quantitative data analysis consisted of measuring values which were analyzed using descriptive analysis such as central tendencies like mean, median and mode and measures of dispersion such as range, standard deviation and variance (Kothari, 2004). To test the relationships that presuppose a relationship between criterion and response variables, data coded was extracted using factor analysis method, a statistical approach that involves finding a way of condensing the information contained in a number of original variables into a smaller set of dimensions (factors) with a minimum loss of information (Hair, 1992).

1.6 Research Findings and Discussions

In the study, a total of 61 questionnaires were administered to the marketing managers or the company pharmacists or their equivalents of each pharmaceutical importing SMEs in Kenya. 49 questionnaires were successfully filled, returned and taken as a sample. This gave a response rate of 80.3%. This response rate was favorable according to Mugenda and Mugenda (2003) in which they assert that a 50% response rate is adequate, 60% good and above 70% rated very well. Further, Nordin (2009) in his study on consumers' attitude towards counterfeit products in Malaysia stated that, a response rate of above 70% is adequate for satisfactory research findings. The findings of the pilot test showed that the calculated Cronbach's reliability alpha was 0.785 which implied that the questionnaire was reliable.

Table 1.0 illustrates the results of correlation analysis that determined the strength of relationship between the independent variables and the influx of counterfeit medicines. The findings indicate very weak (.049) relationship between the influx of counterfeit medicines and legislation, a weak positive (.286) relationship between influx and branding equity, weak positive (0.093) relationship between influx and pricing, while influx had a weak positive (.026) relationship between influx and penalty influence.

Further, logit regression analysis was done because the dependent variable was dichotomous to determine the linear relationship between the influx of counterfeits and legislation, brand equity, pricing strategy and perceived risk. The findings are tabulated in tables 2 and 3.

Model summary- The -2 log likelihood statistic is 47.509 it measures how poorly the model predicts the factors leading to the influx of counterfeits medicines Kenyan pharmaceuticals SMEs- the smaller the statistics the better the model. **The Cox & Snell R square-** Shows the predicting power of the model, the factors under study affects the influx of counterfeits medicines in Kenyan Pharmaceuticals.

Variables in the Equation- shows the out of the regression is

Ln (Odds) = 3.804 + .088 Perceived Risk + .059 Pricing Strategy - .227 Brand equity + .044 Legislation.

The model can be used to predict the odds that the factors under investigation influence the influx of counterfeit medicines in Kenyan pharmaceuticals. The odd for the prediction is $ODDS = e^{a+\beta 1X1+\beta 2X2+\beta 3X3+\beta 4X4}$. If the subject is the factors affects the influx of counterfeit medicine (Influx =1), then the ODDS is $e^{3.084+.088+.059-.227+.044}$ =3.8953. This shows that the perceived risk, pricing strategy, brand equity and legislation are 3.8953 times likely to influence the influx of counterfeits medicines in the Kenyan pharmaceuticals SMEs. Further, the beta coefficients among legislation (.044), brand equity (.227), pricing strategy (.059) and perceived risk (.088) were all positive.

1.7 Conclusions

From the findings of the study, data analysis and interpretation of interview and questionnaire responses from the 49 pharmaceutical importing SMEs based in Nairobi revealed other 13 key components that were found to have influence on the four variables. These were: Pricing, Risk, Perception, Legislation, Brand, Value, Quality, Complaints, Damage, Consumer Ignorance, Tactics, Protection and Penalties. The various factors studied showed to differ in extent to which they influenced the influx of counterfeit medicines.

The findings above support that legislation has an effect on the influx of counterfeit in Kenyan pharmaceutical SMEs. The correlation analysis however indicates very weak positive relationship (0.049). The findings also show that brand equity influences the influx of counterfeit medicine in Kenyan pharmaceuticals SMEs. A weak positive relationship (0.286) was noted. Never the less, it was suffice to say a relationship existed. This implied that brand equity of medicines could positively influence the influx of counterfeit medicines in the Kenyan Pharmaceuticals and as such the importance of popular brands to be protected against infringement.

The study further showed that pricing strategy influences the influx of counterfeit medicine in Kenyan pharmaceuticals SMEs. A weak positive relationship existed (0.093). Further, the findings above also show that consumers buy counterfeit medicine over genuine ones if there is a price advantage, discounted prices of genuine brands reduces counterfeiting and counterfeit medicines are usually not sold at the same prices as the genuine ones. This implies high prices of medicines may prompt the consumers to purchase counterfeit medicines.

The findings also show that perceived risks influences the influx of counterfeit medicine in Kenyan pharmaceuticals SMEs. The relationship analysed was however very weak (0.002). Overall, the findings above show that there is a high probability that the counterfeit medicines do not work and that the risk undertaken when counterfeits are purchased is very high.

1.8 Recommendations

In view of the findings of the study, the following recommendations are made to the SMEs: In order to develop appropriate countermeasures it becomes necessary to understand the phenomenon of counterfeiting as a whole and, in particular, the reasons why people buy counterfeit goods. Pharmaceutical companies should protect all their products with Kenya Intellectual Property Institute to avoid IPR infringement by the counterfeiters. Further, all cases of counterfeiting should be reported to the regulatory authorities for action.

SMEs importing genuine branded products should develop better marketing strategies to entice the consumers to purchase genuine products and not the counterfeit version. By knowing that attitude plays a role in determining the purchase intention of a customer, marketers can work on finding ways to change consumers' attitudes and beliefs.

The importers should charge affordable prices so as to reduce the market for counterfeit commodities. Over-pricing thus creates potential for hyper-profits for counterfeiters. In this regard, leading brands should consider their pricing strategy very carefully to avoid from being taken advantage of by counterfeiters.

The SMEs may further consider educating general public on the effects of counterfeit products and what they need to check before purchasing any medicines. They also need to be informed of the risks associated with counterfeit medicines as well. This will create awareness among the general public and may positively help address to this menace.

1.9 Areas of Future Research

Further research may be carried out to investigate the influencers of influx of counterfeit medicines among all the pharmaceutical importing companies including the multinationals as well as those located in other parts of the country.

Influx of counterfeit **Penalty Perceived** medicine Legislation branding pricings Influence Risk Influx of counterfeit medicine 1 Legislation 0.049 1 branding .286 .370 pricings 0.093 0.128 0.113 1 **Penalty Influence** 0.026 .477 0.214 0.135 1 0.23 **Perceived Risk** 0.002 .428 .459 .346 1

Table 1.0 Correlation Analysis Results

Table 2: Model Summary Results

-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
47.509a	0.134	0.199

a. Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

	В	S.E.	Wald	Sig.	Exp(B)
Legislation	0.044	0.112	0.156	0.693	1.045
Brand equity	-0.227	0.105	4.647	0.031	0.797
Pricing Strategy	0.059	0.073	0.645	0.422	1.06
Perceived risk	0.088	0.139	0.403	0.525	1.092
Constant	3.804	5.19	0.537	0.464	44.887

Table 3: Variables in the Equation Results

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