# RESPONSES OF PHARMACEUTICAL IMPORTERS TO THE CHALLENGE OF ILLEGAL TRADE IN PHARMACEUTICALS //

TY OF MAINE

BY
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#### DECLARATION

This project is my original work and has not been submitted for a degree in any other university.

Signature Manya

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This project has been submitted for examination with my approval as the university supervisor.

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#### **DEDICATION**

To my Dad and Mum, Mr. Joseph Opiyo and Mrs. Barbara Opiyo. Thank you for the sacrifice, guidance and support you have given me throughout my life. I hope this makes you proud because you have always instilled in me the value of hard work. and to my daughter Nadia who gives me the inspiration to achieve my goals always.

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May God Almighty bless you all abundantly and give you a gracious life.

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#### **ABSTRACT**

The study set to explore the responses of pharmaceutical importers to the challenge of illegal trade in pharmaceuticals. It was founded on the premise that pharmaceutical firms are facing several challenges owing to the liberalization of the industry. The study set to find out the challenges these firms were facing, specifically as a result of illegal importation of their products and their medicines being counterfeited. It also identified how the different firms responded to these challenges.

The research was done by conducting a survey and the findings confirmed that illegal trade in pharmaceutical products is a growing problem that needs to be addressed. The challenge that was faced most was that firms had their profit margins reduced as a result of illegal trade. It was followed by their having to address product quality to their customers. Firms were also forced to lower their medicine prices in order to compete with these illegal medicines. In analyzing the causes of illegal trade, the study revealed that lack of proper legal and regulatory structures was seen as the major cause for people to engage in illegal trade. Other causes included the desire for higher profit margins by some players in the industry and the high cost of medicines.

As a result of the findings, the recommendation made to the Pharmacy and Poisons Board which is charged with regulating and controlling the industry, was that random monthly inspections be conducted to identify illegal chemists and those engaging in illegal trade. It was also recommended that control at customs be enhanced to prevent illegal products getting into the country and that the government should enact and enforce tougher criminal penalties for those found trading in illegal medicines.

The recommendations to the pharmaceutical importers was that as major stakeholders in the industry, they should support the Pharmacy and Poisons Board with human or financial resources for conducting regular inspections in chemists to ensure that drugs stocked are from authorized and licensed suppliers. More importantly they should set their medicine prices to suit the economic situations of different markets and should review their prices to make their medicines

more affordable and easily accessible to their customers. They should also carry out public awareness campaigns to enlighten the public on the dangers of illegal medicines.

#### **CHAPTER ONE: INTRODUCTION**

#### 1:1 Background

The pharmaceutical industry in Kenya plays a crucial role in the healthcare sector. The industry is comprised of local manufacturers, franchise importers who are involved in distribution, multinational companies, wholesalers and retailers of drugs (Aseto, 2002). The Kenya Pharmaceutical Review (2005), states that Kenya has 36 pharmaceutical manufacturers and 5262 drug distribution outlets and pharmacies.

Pharmaceutical firms like other business firms operate like open systems and therefore depend on the external environment for their survival. Following liberalization of the pharmaceutical industry in 1991 through an act of parliament, there was an increase in the number of pharmaceutical companies in the Kenyan market either through direct investment or through franchise holders. This liberalization has contributed to unfair trade practices in the industry. Many countries in Asia, which manufacture generic drugs, flooded the Kenyan market surpassing the capacity of the Pharmacy and Poisons Board (P.P.B) for quality surveillance. The legislation of the Industrial Property Act in May 2001, which legalized parallel importation of Human Immuno- Deficiency Virus drugs, has also been misinterpreted by some players in the industry and used to engage in illegal trade.

Kenyan pharmaceutical firms continue to face several challenges from illegal trade in pharmaceuticals. A number of chemists run by pharmacists have been forced to close down as a result of losing the market battle to the unscrupulous dealers of illegal trade. For licensed importers who pay taxes, drug registration and license fees to the government, their profit margins are reduced because they face competition from illegal traders who import and market the same products without incurring extra costs. Illegal trade in pharmaceuticals poses serious threats to the economy of a country. It also puts risk to human life and public health when drug quality is compromised.

## 1.1.1 Organizational Responses

With the environment continuously changing, an organization's survival and success will occur when it creates and maintains a match between its strategies and the environment and also between its internal capabilities and the strategies. Strategic response requires organizations to change their strategies to match the environment and also to transform or redesign their internal capabilities to match these strategies. Ansoff and Mc Donnell (1990) state that strategic responses by an organization involve changes in the firm's strategic behaviors to ensure success in the transforming future environment. They further say that the choice of the response will depend on the speed with which a particular threat or opportunity develops in the environment.

While managers are faced with the responsibilities of managing the internal activities in the firm, the firm's immediate external environment poses another set of challenges or opportunities and threats. The challenges faced may come in form of competitors at a time when a firm is enjoying monopoly or it may be customers whose wants and needs are continuously changing. They must strategically respond to these challenges.

According to Porter (1980), organizational responses reflect a firm's competitive position in the industry and a fast changing environment may force the firm to change its position. He asserts that a competitive position can be created around cost leadership, differentiation of products or services and focused strategy. Many firms sometimes adopt more than one approach. Porter further says that a firm that continuously invests to gain competitive advantage by improving its relative cost position and by differentiation will be difficult to challenge successfully.

Pharmaceutical firms respond to environmental changes in different ways. One of the approaches used has been the formation of mergers and acquisitions. Mbau (2000) says that in order to gain a competitive advantage. Glaxo Wellcome acquired the Egyptian company Amoun Pharmaceuticals and then merged with SmithKline Beecham to become GlaxoSmithkline. Other multinational companies may respond by transferring their marketing functions to Kenyan agents

to save costs while others may invest heavily in research and development to create new products and hence invent new markets.

## 1.1.2 The Pharmaceutical Industry in Kenya

Pharmaceutical firms in Kenya are mainly involved in manufacturing and marketing of medicinal substances or distribution of the same from multinational companies who engage in research and development of the products. Mbau (2000) categorizes 31% as manufacturers, 59% as distributors and 9% as both. The pharmaceutical manufacturing sector in Kenya is the biggest in the COMESA region. It has over 30 local manufacturers with an investment of over USD 50 million. They have the capacity to manufacture 90% of the drugs on the Kenya Essential Drugs List and are a key supplier to medical stores in the region including Tanzania and Uganda (Kenya Pharmaceutical Review 2005).

Vinayak (2001) identifies two categories of pharmaceutical drug importers. Multinationals, which are companies involved in research and development of pharmaceutical products. They import finished products and may undertake all marketing functions on their own or assign distribution to local agents. The second category that he identifies is Kenyan Agents. These are local firms that import and market finished pharmaceutical products. They enter into contractual arrangements with multinational companies or other companies that are involved in manufacturing of drugs.

The Kenyan pharmaceutical market is estimated to have a total annual turnover ranging between USD 80 and 130 million (Kenya Pharmaceutical Review, 2005). The Government of Kenya drug expenditure on the other hand is between USD 20 to 30 million. The private sector therefore which includes mission hospitals and non-governmental organizations has by far the biggest share of the market. The sector is regulated and controlled by the Ministry of Health (M.O.H), the Pharmacy and Poisons Board (P.P.B) and the National Quality Control Laboratory (N.Q.C.L). Whereas a research done by the Ministry of Health in 2005 established that Kenya has 36 pharmaceutical manufacturers and 5262 drug distribution outlets and pharmacies, the

Official Journal of the Pharmaceutical Society of Kenya (2006) lists only 607 registered retail pharmaceutical outlets.

Managers in the industry today continue to deal with the many challenges facing them because financial access to essential medicines is inequitable and restricted in all sectors. Some challenges posed to the industry arise from the high cost of drugs, increased imports of generics, reduced government expenditure on health, increased customer demands and pressure on pricing from Health Management Organizations and other stakeholders. The Kenya Association of Pharmaceutical Industry (K.A.P.I), which was formed in 1991 brings together all pharmaceutical companies involved in research and development of drugs together with their principal agents to tackle the challenges facing the industry. Its key function is to collate views of member companies and present them as a unified body to its stakeholders who include key government ministries, regulatory bodies like the P.P.B. the Kenya Bureau of Standards, the Kenya Revenue Authority and the Kenyan Police Force among others.

#### 1.1.3 Illegal Trade in Pharmaceuticals

According to the World Health Organization (W.H.O), for the majority of the Kenyan population, geographical access to public health facilities is not assured. Private for profit health facilities and registered retail pharmacies are not evenly distributed within the country. 71% of retail pharmacies are located in five main urban areas serving approximately 18% of the population (Kenya Pharmaceutical Review, 2005). As a result, many patients resort to illegal drug sellers to purchase medicine where neither quality of medicines sold nor pharmaceutical advice given is assured.

Illegal trade in the pharmaceutical industry may involve trade in counterfeits or illegal importations. Counterfeits are imitations of existing brands and usually infringe on patented trademarks. Illegal imports on the other hand are defined as products that may be genuine or imitations that have not been licensed for sale in a country. They are imported into a country by

unscrupulous businesspersons without proper authorization because control at customs is difficult or customs officials are corrupt.

While illegal pharmaceutical products sometimes have the correct amount of active ingredients, in many cases they have no active ingredients, may have the incorrect amount of active ingredients or they may have the wrong active ingredients. They also sometimes have fake packaging, different size or color of the product. W.H.O reports that trade in illegal pharmaceuticals may represent 10% of global medicines trade in some countries and up to 20-30% in Asia.

The Pharmacy and Poisons Board (P.P.B), which was established by an act of parliament in 1957 controls the profession of pharmacy and the trade in drugs and poisons. Its responsibilities include monitoring the market for the presence of illegal/counterfeit medicinal products. According to the P.P.B website, only 1100 of the estimated 8000 drugs in Kenya are listed as registered. A report by the Ministry of Health attributes increased number of unlicensed illegal pharmacies to an increase in illegal imports and counterfeits in the Kenyan market.

The Center for Medicines in the United States projects illegal medicine sales to reach USD 75 billion in 2010, a 92% increase from 2005. Factors that favour the circulation of counterfeit medicines and illegal imports include the global trend towards liberalization making customs control more difficult, ill equipped legal systems to tackle the problem, inadequate penalties for engaging in the trade and increased demand for medicines while patients are forced to pay out of their pockets hence their tendency to look for cheaper products while unable to differentiate genuine from fake products. The British Medical Journal (2002) states that all measures that reduce the profit margins for trading in illegal pharmaceuticals such as reducing the price and increasing the availability of genuine, quality assured drugs will make illegal trade in pharmaceuticals a less attractive criminal activity.

#### 1.2 Research Problem

Only about 30% of the Kenyan population has access to essential drugs and other health commodities (Kenya Pharmaceutical Review, 2005). The poor majority who lack access to essential medicines look for cheaper products even if it means purchasing them in illegal chemists. These illegal chemists obtain their drugs from unauthorized suppliers and 'hawkers' of medicines.

Counterfeit medicines and illegal imports pose a serious health problem to an individual consuming them and to the economy of a country. They may not be able to treat an ailment, may cause undesirable side effects, have the risk of building up drug resistance and may even cause death to patients. Pharmaceutical firms therefore have to deal with the threat posed to their survival by these drugs. They lower their profit margins because are illegally imported into the country and fill the demand of genuine quality drugs. They also affect employment opportunities because when profit margins are reduced, firms retrench their workers instead of employing and they compromise quality of genuine products. If a patient consumes counterfeit drugs and suffers from the undesirable side effects or even death, a pharmaceutical company may suffer losses from legal action taken by the patient. It may also have to deal with damage to its reputation before it can prove that the drug was sourced from illegal trade. The government on the other hand suffers loss of revenue from loss of taxation, drug registration and licensing fees.

The challenge is fast growing yet no previous research on pharmaceutical firms has addressed the issue. Previous research has focused on Marketing Practices in the Industry (Ndiho, 2001, Vinayak, 2001, Naikuni, 2001, Misumi, 2003, Ronoh, 2002), Strategic Implications of H.I.V (Wamalwa, 2002, Aseto, 2002, Rarieya, 2001, Muraah, 2003), Analyzing Industry Financial Sources (Lesiew, 1998), Sales Force Motivation (Obado, 1991), The Use of Business Process Reengineering (Munyiri, 2000), The Use of Competitive Intelligence Systems (Muiva, 2001), Export Trade in the Industry (Kinuthia, 2002) and Strategic Planning Practices in the Industry (Sagwa, 2002, Mwangi, 2003). The research questions addressed are, what are the challenges arising from illegal trade in drugs? And secondly what are the responses of pharmaceutical importers to these challenges?

#### 1.3 Research Objectives

- i. To identify the challenges arising from illegal trade in pharmaceuticals
- ii. To establish the responses of pharmaceutical importers to these challenges

#### 1.4 Importance of the Study

It is anticipated that the findings of the research will be of value to the following groups:

- i) The Pharmaceutical firms can learn from what other firms are doing to counteract these challenges and also develop better strategic management practices.
- Scholars, academicians and other researchers can use it as a guide for further research on challenges in the industry.
- Other pharmaceutical bodies like the Kenya Association of Pharmaceutical Industry, the Pharmacy and Poisons Board, the Pharmaceutical Society of Kenya may benefit from the findings and recommendations of the study.

#### **CHAPTER TWO: LITERATURE REVIEW**

#### 2.1 The Concept of Strategy

Strategy has been defined by many authors in various ways. It stems from the Greek word 'Strategos' which means the art of the General Commander in Chief (Ng'ang'a, 2004).

Hax and Majluf (1996) define strategy as a multi dimensional concept that embraces all the critical activities of the firm. It provides it with a sense of unity, direction and purpose as well as facilitating the necessary changes induced by its environment. It is meant to provide guidance to the organization so that it can achieve its objectives while responding to the opportunities and threats in the environment.

Johnson and Scholes (2002) on the other hand, define strategy as the direction and scope of an organization over the long term. It is intended to achieve advantage for the organization through its configuration of resources within a changing environment and to fulfill stakeholder expectations. Its purpose is not only to enable a firm to beat its competitors over the long term but to satisfy its customers.

Pearce and Robinson (2002) define strategy as a firm's 'game plan'. They further say that strategy reflects a company's awareness of how to compete, against whom, when, where and for what and that by strategy, managers mean their large-scale future oriented plans for interacting with the competitive environment to optimize achievement of organization objectives. In formulating and implementing an organization's strategy, managers have to make certain decisions to achieve their objectives. The decisions facing a business have to be made strategically and will require strategic planning and management. Strategic planning is therefore key for every manager due to the changing nature of environment and the high degree of competition. Mwaura (2001) recommends that firms develop methods of collecting competitor intelligence by undertaking serious market analysis so as to formulate appropriate and effective strategies.

It is essential for managers to monitor the extent to which the actions they are taking and their decisions are achieving the goals and objectives of the organizations while meeting stakeholders' expectations. This requires strategic management that encompasses strategic analysis, strategic choice and strategy implementation. Johnson and Scholes (2002) distinguish three levels that strategy can exist at in an organization. These include corporate strategy which is concerned with the overall purpose and scope of an organization, business unit strategy which focuses on how to compete successfully in a particular market and operational strategy which looks at how the different parts of an organization will work effectively towards achieving the corporate and business level strategy.

Thompson (1997) defines corporate strategy as the range of products and services offered by an organization and the number of different industries and markets in which it competes. It also touches on resource allocation to different parts of the organization and is the responsibility of the top management and senior executives. It looks at the businesses that exist and analyses which ones should be added or disposed off.

In the pharmaceutical sector, many multinational companies have their corporate strategies defined by the parent companies or manufacturers of the drugs because they may provide the resources required for the marketing function. They decide on product diversity and geographical coverage after careful analysis of the perceived needs of the market. Hax and Majluf (1996) state that corporate strategy deals with the decisions that by their nature should be addressed with the fullest scope encompassing the overall firm.

Hill and Jones (2001) state that the business-level strategy of a company encompasses the overall competitive theme that a company chooses to stress, the way it positions itself in the market place to gain a competitive advantage and the different positioning that can be used in different industry settings. Business level strategy is concerned with achieving a competitive advantage in the market. It analyses new opportunities created in the market and threats presented by competitors and how to counteract them. Some companies today base their competitive advantage on price while others base it on differentiation where they offer unique or high quality products at premium prices.

While pharmaceutical companies involved in research and development will base their competitive advantage on differentiation, today they face stiff competition from companies manufacturing generic products that base their competitive advantage on price. Some strategies used by companies to enhance their competitive position may involve mergers and acquisitions or collaboration with other stakeholders in the industry mainly suppliers and distribution agents.

According to Thomas and Strickland (1998), operational strategies look at how the various functions in an organization will work effectively to achieve the corporate and business level strategies in terms of resources, processes and people. Managers at this level address issues of efficiency and effectiveness of production, marketing and distribution systems. They also look at the quality and extent of customer service. Here the marketing department will inform customers about new products in the market and the distribution department must supply the products to the customers when it is required. It is notable that successful organizational strategies will depend greatly on the activities undertaken and the decisions made at the operational level.

## 2.2 Organizational Responses

Pearce and Robinson (2002) state that due to the rapid changes in the environment, managers have the responsibility of ensuring their firm's capacity for survival. A firm's manager must therefore analyze and understand the impact of the external environment on the organization if he wants to achieve strategic success. Environmental scanning also referred to as competitive intelligence is the rigorous approach to collecting, analyzing and communicating information about the competitors' activities, market changes that are occurring, changes related to supply of raw materials and other issues that could affect organizational responses.

Ansoff (1981) argues that all environments are tending towards more turbulence, complexity and uncertainty and hence there is a need to be a responsive learning type of organization. In response firms must be innovative, must search for weak signals and must constantly analyze the



environment for clues. A firm must become a learning organization that can respond quickly and flexibly to the changing needs of the environment.

Many organizations in the pharmaceutical industry have taken steps to respond to the challenge of illegal trade in pharmaceuticals. Some firms have changed the packaging of their products by either reducing or increasing the size of products in the pack. Ng'ang'a (2004) reports that GSK responded to the challenge of counterfeits of their drug Halfan by covering it with a special seal called a hologram which is not easy to imitate. Other firms differentiate their products from illegal imports by changing the color of the package. Others will respond by lowering their medicine prices. Many firms also send their marketing representatives to inform their customers on the presence of illegal imports and counterfeits and to discredit them.

#### 2.2.1 Strategic Responses

According to Grant (2005), survival and success for an organization occurs when an organization creates and maintains a match between its strategy and environment and also between its internal capability and the strategy. An organization needs to harness both its tangible and intangible assets to maintain a strategic fit between its strategy and environment. If this fit is not realized then a strategic gap exists.

Within the pharmaceutical industry, responses to changes in the environment have been varied. There has been a trend towards coalition formation. Here firms within a coalition cooperate with specific other group members to enhance their competitive position in the industry. Mergers and acquisitions are forms of coalition formation for competitive advantage. Companies will merge so that they can acquire economies of scale when it comes to research and development and when it comes to the marketing functions. Examples here include the merger between Zeneca Pharmaceutical and Astra International to become AstraZeneca (Wamalwa, 2002). Sanofi merged with the French company Synthelabo Laboratories to become Sanofi-Synthelabo. This later merged with Aventis Pasteur to form Sanofi-Aventis.

Other strategies used are collaboration strategies. Collaboration involves building relationships with other stakeholders for example suppliers and distribution systems to acquire information on product movement. Porter (1980) states that strategic responses reflect a firm's competitive position in the industry and a fast changing environment may force the firms to change its position. He further suggests three generic competitive strategies, which a firm can use to develop a competitive edge over its competitors in a competitive environment. A firm can develop a strategy of overall cost leadership, differentiation strategy or focus strategy.

Clark (2000) states that cost leadership requires that a firm has more economies of scale. It enables a firm to compete favorably through low costs especially when dealing with customers who are cost conscious. To achieve overall cost leadership in an industry, a firm can adopt certain functional policies and resort to aggressive construction of efficient scale facilities, vigorous pursuit of cost reductions, tight cost and overhead control, avoidance of marginal customer accounts and cost minimization in areas of research and development, sales force and advertising (Porter 1980). To be successful, an organization requires a high relative market share or favorable access to raw materials.

Baker (1997) states that firms that respond to competition through differentiation modify their products to make them more appealing to their target customers. Here firms position themselves as unique and different from competitors. These customers as stated earlier are willing to pay premium prices for high quality or unique products. In the pharmaceutical industry many multinational companies adopt the differentiation strategy. They invest in research and development to come up with innovative products, which are unique and will cost more to the customer. On the other hand manufacturers of generic products cut themselves out as having cost leadership.

Clark (2000) says that differentiation requires that a firm make its products different from those of its rivals in terms of quality, branding, aesthetics, durability and taste among other things. He continues to state that differentiation always works since it means the degree of substitutability is reduced. Firms that adopt differentiation in response to changing environments have to invest continuously in research and development. Differentiation targets customers who will buy a

product because of the additional features without being concerned about the price. As a result these customers enable a firm achieve competitive advantage because of their loyalty to a brand.

According to Pearce and Robinson (2002) differentiation is where the business creates differential advantage through having features or services that are different from others in the market. Firms that use differentiation want to be unique in ways that appeal to the customer. They also look at sustainability of the competitive advantage. When firms are competing fiercely, differentiation will give some that much needed competitive advantage.

Porter (1980) states that when the environment changes, some firms will respond by focusing on a particular market segment, product category or particular buyers. These are firms that use focused strategies. They will identify certain market segments that they want to serve and then adopt either cost or differentiation strategy to meet the needs of that particular market. Multinational giant Novo-Nordisk whose products are distributed by Phillips Pharmaceuticals in Kenya cuts out a niche as serving the diabetic segment throughout the world. They research and develop products for patients suffering from diabetes mellitus and market these products in many markets. To serve the market segment well, they not only come up with innovative products for sustaining the ailment but they offer diabetic education to help the patient observe his nutrition and take care of his body.

Mwangi (2003) observes that over the past ten years companies have been adjusting their strategies with the changing environmental conditions. He continues to say that previously, many of the pharmaceutical companies adopted a dominant business structure in the Kenyan market. For example Astra Zeneca Pharmaceuticals grew through its dominance in the gastrointestinal product sector with their product Losec, Bayer through its antihypertensive product Adalat and Eli Lily through their antibiotic Ceclor. Due to technological advancements, these companies have increased their range of products to serve other market segments.

Johnson and Scholes (2002) while analyzing strategic responses of organizations to changes in the environment noted that strategic alliances, collaborations and joint ventures are becoming increasingly popular. These strategies involve two or more organizations sharing resources and activities to pursue a strategy. Nganga (2004) observes that GlaxoSmithKline (GSK) following liberalization of the pharmaceutical industry in Kenya collaborated with Cosmos limited a local indigenous generics manufacturer. Cosmos was granted a voluntary license to manufacture ARVs namely Combivir (Lamivudine and Zidovudine), Retrovir (Zidovudine) and Epivir (Lamivudine). Under the collaboration Cosmos would manufacture and sell these products in Kenya and would in turn pay 5% of sales for these drugs as royalties to GSK.

Multinationals will form strategic alliances and acquire companies in order to gain entry into certain markets. In the aviation industry, airlines form strategic alliances in response to changing environmental conditions. They do this to expand their route networks and to acquire the image of being global in order to gain a competitive advantage (Wachira, 2003). Some strategic responses that may be used by multinational pharmaceutical manufacturers include re-locating their entire operations to other more investment friendly countries, closing their manufacturing plants, franchising their sales and marketing operations and starting to manufacture generic brands. Manufacturers of generic drugs may respond by starting to manufacture unpatented molecules, investing in research and development, starting parallel importation or changing completely to distributorship (Wamalwa, 2002).

## 2.2.2 Operational Responses

Operational responses specify how the firm will use its operational capabilities to support the business and corporate strategy. According to Hayes (1996), a company's operation strategy begins with a statement specifying how it proposes to create for itself that chosen form of competitive advantage. Galbraith (1967) found that firms can be either fitting their environments or shaping their environments to suit them. He found that many firms were not so much adapting to their environment as actively adapting it to suit them. They would for example eliminate markets.

By internalizing part of the environment by vertical integration through taking over other firms, a firm is able to make what was a part of its environment into a part of the firm. Firms can also control markets by getting bigger through horizontal integration or by advertising or effective

branding and product differentiation. Firms can also make agreements with their rivals that reduce competition or with their suppliers to effectively suspend threats that come from the environment.

Clark (2000) observes that firms can respond by choosing to manage the environment. He gives an example in the early 1980's when everyone started wearing light cotton trousers rather than jeans, some firms responded by lowering their prices. The Levi-Strauss Corporation instead of lowering their prices initiated the largest advertising campaign which was so successful that sales of jeans were restored.

Slack and Lewis (2002) say that operations strategy is the collective concrete actions chosen, mandated or stimulated by corporate strategy. It is implemented within the operational function. This operations strategy binds the various operations decisions and actions into a cohesive consistent response. It does this by linking firm policies, programs, systems and actions into a systematic response. It looks at the competitive priorities chosen and communicated by the corporate or business strategy. Wit and Meyer (1998) point out that changes in the international operating environment have forced multinationals to optimize global efficiency, national responsiveness and world wide learning simultaneously. For most companies, this new challenge implies not only a fundamental strategic reorientation but also a major change in organizational capabilities.

When it comes to firms responding to competition, they differentiate their products so that fewer direct comparisons can be made and substitutability is thereby reduced. To encourage loyalty, firms offer loyalty inducements that add value to their products. Firms also collaborate to reduce the possibility of price wars that could destroy them. Even a firm with lower costs than its rivals cannot guarantee to win a price war. Firms put a lot of strategic effort into avoiding price competition and focus instead on non-price competition such as branding and styling. They create new products and thus invent new markets through research and development activities or by focusing on particular segments of the market.

Gagdon (1999) observes that operations strategy should integrate recent theories from the resource based view of strategic management and emphasize on the dynamic development and leveraging competencies and capabilities in order to set new business diversification strategies. Firms can respond to the environment through the resource-based view that focuses on the strengths-weaknesses component of SWOT analysis. It does this by identifying valuable, non-substitutable, non-immitable firm level competencies as the basis of superior performance.

Organizational capabilities reflect the firm's ability to respond effectively on the basis of its internal strengths and weaknesses to external opportunities and threats. Dynamic capabilities include special company strengths to cope with the shifting character of the environment. This approach focuses on the key role of strategic management in appropriately adapting, integrating and reconfiguring company strengths towards changing environments.

Ng ang a (2004) in looking at the strategic responses of GlaxoSmithkline (GSK) following liberalization of the pharmaceutical industry in Kenya, observed that in 2003 GSK finally bowed down to constant pressure from the government, World Vision, Medecins Sans Frontiers and other lobby groups to reduce the cost of Antiretrovirals (ARVs) by about 90%. In the wake of the government allowing Lords Healthcare a local pharmaceutical distributor for a number of Indian generics to start importing generic ARVs from Cipla in India, GSK responded by reducing prices to patients not only to uphold social responsibility but to remain competitive as well.

Gilgeous (1995) observes that many companies in the United Kingdom embrace reliability of services as a strategy to survive in the competitive business environment. Marketing plays a critical role here. Kotler (1996) says that marketing plays a role in defining the business mission and in analyzing the environment. The marketing department is concerned with developing of programs and operating plans that are linked with strategic plans.

Today's market is very competitive therefore firms have to outperform the competition by offering quality products and better customer service. Many firms will respond to competition in the business environment with an aim of remaining competitive. Firms must produce products that customers consider have valuable features. The marketing department must understand what

the customer requires while the distribution department must supply the products when required and in the right form.

#### 2.3 Counterfeit Products

According to the World Customs Organization (W.C.O), counterfeiting and piracy of products have grown dramatically in the last ten years. This is because global trade has significantly increased following the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS Agreement of 1994). Aseto (2002) states that the TRIPS Agreement requires that all World Trade Organization members pass intellectual property laws that provide patent protection with a minimum 20-year term. The minimum provisions of the agreement are now not enough to meet the current growth of illegal trading.

Trade in counterfeits is not limited to pharmaceutical products but extends to many other products like vehicle and aircraft parts and general household goods like toothpastes and electronics. It has affected global trading hence affecting national economies, inward investments and public health. Russian president Vladimir Putin recently raised serious concerns about counterfeit medicines in Russia. Calling the pharmaceutical market situation 'extremely negative' he noted that the turnover in counterfeit medicine is beginning to pose a real threat to the health of the nation and the widespread presence of counterfeit goods undoubtedly discredits Russia as a reliable business partner (B.B.C Monitoring International Reports, February 2006).

Experience shows that any product can be counterfeited. In the pharmaceutical industry branded and non-branded generics are widely targeted as well as over the counter drugs. Dr. Howard Zucker, Assistant Director General for Health Technology and Pharmaceutical W.H.O. in a congress held in Rome on February 2006 states that 'people don't die from carrying a fake handbag or wearing a fake t-shirt, but they can die from taking counterfeit medicine'.

In the last decade there has been a sharp increase of uncontrollable Internet trade. Consumers purchasing goods directly from Internet websites do not know where the counterfeit goods they are buying are manufactured. One of the possible sources for counterfeiting is theft. A major

pharmaceutical robbery resulted in the theft of USD 100,000 worth of prescription drugs from a Hamilton Pharmacy. The theft included painkillers, controlled substances and other brand – name medications (Hamilton Spectator 2006). Other sources are unauthorized persons, who hawk medicines from pharmacy to pharmacy, and suppliers and manufacturers that lack proper documentation.

The World Customs Organization states that customs has a crucial role in leading a successful fight against counterfeits. This is because it is concerned with monitoring the movement of goods, conveyances and people across borders. The border still offers the best opportunity for governments to intercept bulk consignments of counterfeit and pirated products. The best time to intercept shipments of counterfeit goods is when they are being exported, but not many administrations examine exports.

Counterfeit products pose a threat to all industries because the trade is growing fast. Bale (2006) describes it as a low risk high returns on investment business because in many countries the risks of prosecution and penalties given for counterfeiting are inadequate. Many countries in Africa are affected because regulatory structures are weak and control is difficult. Counterfeit medicines have also entered the supply chain because medicine prices vary greatly worldwide and we have increased parallel trade due to liberalization. Counterfeit medicines reduce the profit margins of genuine quality drugs and 'bad drugs' drive 'good drugs' out of local circulation.

#### 2.4 Illegal Importations

Illegal importation of products is the illegal importation of specific branded products or generics. by unlicensed distributors from one country's market into another. This has been confused with parallel importation, which according to the European Union is legal importation of specific branded drugs by licensed distributors from one country's market into another. Parallel importation is not only legal but is strongly encouraged as national policy in some European Union countries including countries with a strong research based pharmaceutical industry. This is because these countries strive to overcome all the legal and policy issues associated with legalizing drug importation.

Parallel importation of specific drugs was legalized in Kenya in May 2001 after the legislation of the Industrial Property Act (Wamalwa, 2002). This followed the 1999 declaration of Human Immuno Deficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) as a national disaster. The aim was to increase the availability of these drugs to HIV/AIDS sufferers in Kenya and to enable their cheaper accessibility.

Kanavos, Gross and Taylor (2002) observe that in the United States of America, it is illegal to import prescription drugs either for personal use or for resale except under very limited circumstances. This is unlike within the 15 member states of the European Union and other Western European countries that allow commercial importation of pharmaceuticals. Although there is big public support by Americans for legalizing drug importation from certain countries, the government has not authorized importation of prescription drugs arguing that the high cost of ensuring the safety of imported medicines would outweigh the small benefit that consumers would derive from their reduced prices.

Pharmaceutical firms in Kenya today have to deal with the problem of illegal importation of medicines by unlicensed importers and distributors. A large percentage of illegal imports into the Kenyan market are from Asian markets, like India, Pakistan, Thailand and the United Arab Emirates. Illegal importation has been favored by the global trend towards free international commerce that makes their movement easier and customs control more difficult. It is important to note that illegal imports unlike counterfeits may be genuine products even though they have not been licensed for sale in a country.

Many illegal importers are said to do 'briefcase' importation of medicines when they travel to Asian countries and source the products from licensed distributors claiming it is for personal use. The growth in illegal importation is as a result of the big disparities in medicine prices in different markets or different countries. Illegal medicine importers will strive to source the medicines in markets with reduced prices. They will not pay duty on the imports and will then resale them to unlicensed or unscrupulous businesspersons who sell them to the patients at the recommended retail prices in that market.

Kenyan pharmaceutical firms face several challenges from illegal imports. A number of chemists run by pharmacists have been forced to close down as a result of losing the market battle to the unscrupulous dealers who do 'cargo' (The Weekly Advertiser, June 2005). The practice of illegal trade in pharmaceuticals means that an unlicensed pharmaceutical distributor or person/s without obtaining proper authorization, will import any drug from any country, whether the drug that is being imported is identical to the drug that is locally sourced, that is it may contain the same active ingredient and is produced by the same manufacturer or the two conditions may not be as required. For the legal importers of drugs who pay taxes, drug registration and license fees, it means reduced profit margins because the market demand is satisfied by these illegal imports. Illegal imports may also pose serious threats to human life and public health when drug quality is compromised.

#### 2.5 Illegal Pharmaceuticals Trade in Kenya

The Weekly Advertiser; June 2005 in its report on 'Bogus Medicine Cartel' reported that unscrupulous dealers have swarmed the Kenyan Pharmaceutical industry with cheap drugs of questionable quality. Members of the thriving black market cartel are said to be minting millions from selling drugs at prices even lower than the manufacturers. These dealers of illegal trade take advantage of the porous borders and entry points combined with corrupt customs officials who lack understanding on the significance of trade in illegal drugs. A number of chemists run by pharmacists have been forced to close down as a result of losing the market battle to the unscrupulous dealers of illegal trade. Among the chemists that have closed shop include Laureatte Pharmacy, Sigma Chemists, Eros Chemists and Super Pharmaceuticals.

The Pharmacy and Poisons Board in Kenya, which falls under the Ministry of Health, is charged with the responsibility of registration of drugs and monitoring of the market for the presence of illegal and counterfeit medicinal substances. Dr. Yano the legal officer of the P.P.B. sights some limitations that the board faces that make it unable to fight this illegal trade. He says they lack funds to conduct effective post marketing surveillance and impromptu inspection of chemists across the country. They carry out only two inspections in a year and some illegal chemists will

close down for two months when they know inspections are on. He also says the boards records are still manual and its officials are developing a software, including a website. This will make all information on drugs registered in the country readily available to the public.

llegal traders of pharmaceuticals target both branded and generic products. They target expensive drugs especially antibiotics and fast moving drugs like Deep Heat and Viagra the drug for erectile dysfunction. One of the factors that has catalyzed this trade is the big disparity in prices of medicine in different markets. For example four tablets of Viagra 50mg that stays in the body for three hours is sold by the importer to wholesalers at Kshs. 2,340 who in turn sell to retail chemists at Kshs 2,600. The same packet is available in the black market for less than Kshs. 2,000. Fastum gel 50gm an analgesic gel manufactured in Italy and imported to the Kenyan market by Phillips Pharmaceuticals retails at Kshs. 600. In the United Arab Emirates illegal traders source it for only Kshs. 200.

The Weekly Advertiser further discloses that industry sources attribute illicit medicines trade to be dominated by airline staff. Mombasa port and Kenya Airport Authority workers, carjackers and thieves working in chemists who have specialized in illegal importation or smuggling of drugs. Nganga (2004) states that GSK in striving to address the challenge of illegal trade ensured that trade prices of drugs in the East African region are largely the same so that it is not any more profitable to smuggle them across the borders back to Kenya.

Apart from the disparities in prices of drugs being a cause of illegal trade. Mwatu (2006) says that other factors that favor their circulation is that legal systems are often not well equipped to deal with the extremely serious consequences of counterfeit medicines. Penalties for illegal trade are also often inadequate to act as a deterrent. The Kenya Association of Pharmaceutical Industry chairman says that selfish interests such as greed and the desire for higher profits margins drive illegal trade in pharmaceuticals. Lack of alternative employment in an economy like Kenya's, which is still struggling, may also be a cause for people to engage in illegal trade.

On matters to do with illegal trade, pharmaceutical importers may liase with Ministry of Health inspectorate officials in apprehending and charging importers or distributors of these products in

court. Other ways of tackling this problem has been to run media campaigns to alert consumers and discredit the quality of these drugs to the public. Ng'ang'a (2004) says that in 2003, GSK ran a campaign for their antihistamine Piriton and in 2004 for their analgesic Panadol to highlight the difference between their branded products and other counterfeits. He also says that GSK fought counterfeits of its antimalarial drug Halfan by incorporating a transparent seal or Hologram that could not be reproduced easily. This has greatly reduced Halfan counterfeits from Asia.

**CHAPTER THREE: RESEARCH METHODOLOGY** 

3.1 Research Design

The research was carried out by conducting a survey. A survey was most appropriate because we were trying to find out from pharmaceutical importers the challenges they are facing as a result of illegal trade in pharmaceuticals. Secondly we wanted to know the strategic responses of various importers to these challenges. Survey as a research design has been used by other researchers, for example Aseto (2002) and Wamalwa (2002).

3.2 Population

The Kenya pharmaceutical review (2005), states that Kenya has 36 pharmaceutical manufacturers and 5,262 drug distribution outlets and pharmacies. The Kenya Medical Directory 2004 lists 144 manufacturers and importers of pharmaceutical products. The population of focus in this study was firms in Nairobi that import and distribute pharmaceutical products.

3.3 Sampling Design

The target sample size was 50 out of the pharmaceutical firms involved in drug importation. They were selected by probability or random sampling. The sampling frame took the form of pharmaceutical firms in Nairobi that import and distribute pharmaceutical products (See appendix). This list was extracted from the Kenya Medical Directory (2004) from a list of 144 manufacturers and importers of drugs.

3.4 Data Collection Method

This involved the use of questionnaires to collect primary data. The target respondents of the research were marketing managers of the firms. The questionnaire was divided into three

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sections. The first section was to enable us obtain demographic data about the firm. The second section was used to identify the challenges pharmaceutical importers were facing as a result of illegal trade. The third section was to determine the strategic responses of the firms to these challenges. The questionnaire contained both open and close-ended questions and also structured and unstructured questions. The questionnaire was filled through personal interviews with the respondents where possible and where not possible was delivered to the respondents office or sent via electronic mail for filling and a collection date agreed upon.

## 3:5 Data Analysis Method

Since the data collected was largely quantitative, descriptive statistics was used to analyze it. These included frequency distribution, percentages and mean scores. Percentages were computed to analyze the profiles of the firms, to determine the frequencies of various challenges and responses to the challenges. Mean scores were used to determine the extent of various factors as a cause for illegal trade.

## CHAPTER FOUR: DATA ANALYSIS AND FINDINGS

#### 4.1 Introduction

This chapter presents data analysis and findings of the study from questionnaires completed by the respondents. The respondents were marketing managers and sales supervisors of the various pharmaceutical importers. The findings are presented in the order of the objectives using mean scores and tables with percentages and frequencies.

The chapter will be divided into three sections. The first section has profiles of the firms studied. In the second section, the challenges due to illegal trade in pharmaceuticals are presented and this is related to the first objective. The third section addresses the second objective, which is the responses of the various pharmaceutical importers to the challenge of illegal trade.

#### 4.2 Profiles of Pharmaceutical Firms Studied

50 Pharmaceutical importers were targeted for the study, but only 47 responded. The findings are for the ones that responded.

Table 4.1: Year of establishment

Year	Frequency	Percentage
1966 – 1975	6	12.7
1976 - 1985	14	29.8
1986 – 1995	10	21.3
1996 – 2006	17	36.2
Total	47	100

The findings in Table 4.1 show that out of the pharmaceutical importers who responded, 17 have been in operation for 10 years or less while only 6 have been in operation for over 30 years.

Table 4.2: Size of organization based on monthly sales turnover (2006)

Monthly sales	Frequency	Percentage
Below Kshs 10m	14	29.8
Kshs 11-50m	16	34.0
Kshs 51-100m	8	17.0
Kshs 101-500m	6	12.8
Over Kshs 500m	3	6.4
Total	47	100

Table 4.2 shows that 30 out of the firms that responded have monthly sales of Kshs 50 million and below while only 3 have sales above Kshs 500 million.

Table 4.3: Kind of products imported

Product type	Frequency	Percent
Prescription only	16	34.1
Pharmacy only	1	2.1
Both	30	63.8
Total	47	100

The findings in Table 4.3 show that majority of the firms studied import both prescription and pharmacy only products. Only one firm imports pharmacy only products.

Table 4.4: Number of products imported

Product No.	Frequency	Percentage
Less than 10	13	27.7
11-20	14	29.8
21-30	1	2.1
30 & above	19	40.4
Total	47	100

Table 4.4 shows that of the firms that responded, 19 imported at least 30 products.

Table 4.5: Presence of strategic management department

Strategic Mgt Dept	Frequency	Percentage
Yes	29	61.7
No	18	38.3
Total	47	100

Table 4.5 shows that 29 out of the 47 firms that responded have a strategic management department.

## 4.3 Challenges of Illegal Trade

This section addresses the first objective that sought to determine the challenges firms face as a result of illegal trade. It also identifies the possible causes of trade in illegal pharmaceuticals. Structured questions were used to collect data for this section and it was analyzed using frequencies and percentages.

Table 4.6: Causes of illegal trade in pharmaceuticals

Causes	Mean	Standard Deviation
High medicine prices	3.5	1.27
Lack of legal and regulatory structures	4.38	0.87
Lack of alternative income generating activities	2.39	1.0
Desire for higher profits	4.0	1.08

The respondents were asked to rate the extent to which certain factors were a cause for illegal trade in pharmaceuticals. This was to enable us make recommendations after identifying possible causes of illegal trade. Data analysis was done using mean scores on a scale where 1=Not a cause at all and 5=Very great cause

The findings show that lack of legal and regulatory structures, which has a mean score of 4.38 and desire for higher profit margins with a mean score of 4.0, are considered to be the greatest causes of illegal trade in pharmaceuticals.

Table 4.7: Challenges due to illegal trade

Challenges	Frequency	Percent
Lower product price	20	42.6
Address product quality	30	63.8
Reduced profit margins	47	100
Retrenchment	5	10.6
Lower product price and reduced profit margins	25	53.2
Lower product price and address product quality	15	63.8
Lower product price and retrenchment	4	8.5
Address product quality and reduced profit margins	30	63.8
Reduced profit margins and retrenchment	5	10.6
Address product quality and retrenchment	3	6.4
Lower price, address quality and reduced profits	12	25.5

This addresses the first objective which sought to determine the challenges firms faced as a result of illegal trade in pharmaceuticals. The respondents were asked to tick appropriately the challenges faced from the ones given and also to provide alternative challenges faced. Analysis was done using frequency distribution and percentages. The higher the percentage, the more frequently the challenge was faced.

The findings as shown in Table 4.7 is that many firms faced more than one challenge. The greatest challenge faced by all firms studied was reduced profit margins followed by firms having to address product quality. The least faced challenge was retrenchment of workers.

Table 4.8: Extent of effect of illegal imports on firms' sales.

Extent of effect		
on sales	Frequency	Percent
Not at all	8	17.0
To a less extent	3	6.4
Moderate extent	24	51.1
To a great extent	7	14.9
To a very great extent	5	10.6
Total	47	100.0

Table 4.8 presents findings on the extent to which illegal imports has affected the firms sales. 24 out of the 47 respondents felt that illegal imports has affected their firm's sales to a moderate extent. Over 70% of the respondents felt it had affected their sales from moderately to a very great extent.

Table 4.9 Extent that counterfeits have affected firms sales

Extent of effect on sales	Frequency	Percent			
Not at all	30	63.8			
To a less extent	3	6.4			
Moderate extent	8	17			
To a great extent	4	8.5			
To a very great extent	2	4.3			

Table 4.9 presents findings on the extent to which counterfeits have affected the firms sales. 30 out of the 47 respondents felt that counterfeits have not affected their firm's sales at all while 29.8% said it had affected their firms' sales from moderately to a very great extent.

## 4.4: Firm Responses to Challenges

This section addresses the second objective which sought to determine the responses of the pharmaceutical importers to the challenge of trade in illegal pharmaceuticals. The respondents were asked to tick appropriately from the responses given and also to provide alternative responses to their challenges. Data here was analyzed using frequencies and percentages. The higher the percentages, the more common was the response.

Table 4.10: Responses to the challenge of illegal imports

Responses	Frequency	Percent
Sensitize customers only	47	100.0
Withdraw product from market	1	2.1
Reduce medicine prices and change product packaging	12	25.5
Reduce medicine prices and change product color	2	4.3
Reduce medicine prices and sensitize customers	20	42.6
Change product packaging and change product color	1	2.1
Change product packaging and sensitize customers	12	25.5
Change product brand name and sensitize customers	2	4.3
Change product color and sensitize customers	3	6.4

N = 47

All the 47 firms surveyed faced the challenge of illegal imports. Table 4.10 shows findings on the responses. All the firms responded by sensitizing their customers about the presence and effects of illegal pharmaceutical products while 20 of the firms also lowered their prices in response. Only one firm responded by withdrawing the product from the market and only one by changing the product color and packaging.

Table 4.11 Responses to the challenge of counterfeits

Responses	Frequency	Percent
Sensitize customers	9	56.3
Reduce price and change packaging	2	12.5
Reduce price and change color	1	6.3
Reduce price and sensitize customers	2	12.5
Change packaging and sensitize customers	2	12.5

N = 16

Table 4.11 shows that, only 16 out of the 47 firms studied faced the challenge of counterfeits. 9 out of these firms responded by informing their customers about the presence of the counterfeits.

## **CHAPTER FIVE: CONCLUSION**

#### 5.1 Summary, Discussions and Conclusions

Here the results of the study are summarized, discussed and conclusions drawn. They are presented in order of the objectives of the study. The first objective sought to identify the challenges faced by pharmaceutical importers as a result of illegal trade in pharmaceuticals. The results indicate that all of the pharmaceutical importers studied face the challenge of illegal imports of their drugs and only 34% face the problem of counterfeits.

The findings show that many of the firms face more than one challenge. The challenge that was faced by all firms was reduced profit margins. This was followed by firms having to address product quality. This may have been the result of customer complaints on drug efficacy and side effects. The results confirm the views shared by World Customs Organization and Dr Harvey Bale in an International Conference concerning trade in illegal pharmaceuticals. This view is that illegal trade affects national economies, inward investments and public health when drug quality is compromised.

The other challenge faced was that many firms were forced to lower the prices of their medicines in order to compete with counterfeits and drugs sourced illegally. As earlier discussed, illegal trade in pharmaceuticals is a low investment high returns trade. Those involved incur fewer costs compared to authorized importers. Illegal traders fight the market battle on low cost leadership and this may force their competitors to lower their medicine prices. We can conclude from the findings of the research that illegal importation of drugs is a major problem for pharmaceutical importers in Kenya and that whereas pharmaceutical firms face the challenge of counterfeits, it is not to a great extent.

The research also sought the opinion of the respondents on what they considered as the greatest cause of illegal trade in pharmaceuticals. By understanding the causes, pharmaceutical importers and other stakeholders may find solutions to the challenges by addressing the possible causes. Lack of proper legal and regulatory structures with a mean score of 4.38 was said to be the

greatest cause for illegal trade. The other great cause with a mean score of 4.0 was said to be the desire for higher profit margins by some players in the industry.

The Pharmacy and Poisons Board in Kenya, is charged with regulating and controlling pharmaceutical importers and with quality surveillance of all drug imports. The board as stated in previous chapters admits to lacking adequate resources to address the challenges. This explains why many of the respondents thought that lack of proper legal and regulatory structures was a very great cause for illegal trade.

High medicine prices were considered by nearly 30% of the respondents as a very great cause for illegal medicines trade. There is a big disparity in the prices of medicines in different markets of the world. Unscrupulous businesspersons take advantage of this to manufacture fakes that look similar to original brands and sell them at a lower or similar cost. They will also try and source medicines from other markets even when they are not authorized to do so. The research may therefore concur with what the British Medical Journal (2002) states that all measures that reduce the profit margins for illegal trade in pharmaceuticals such as reducing the price and increasing the availability of genuine quality assured drugs will make it a less attractive criminal activity.

The second objective sought to determine the responses of pharmaceutical importers to the challenges of illegal trade. The most commonly used strategy to address both illegal importations and counterfeits was sensitizing customers concerning them. Other strategies that scored highly were reduction of medicine prices followed by changing the product packaging while sensitizing the customers. This goes to confirm what Porter (1980) says that customers are very valuable to any business and an organization must maintain a match between its strategies and the environment. Many firms will sensitize their customers because when customers are aware of the presence and dangers of drugs being obtained from illegal sources, they will purchase drugs only from authorized distributors and importers. Pharmaceutical firms highlight the differences between their medicines and illegal imports or counterfeits.

More than 50% of pharmaceutical importers who face the challenge of illegal trade have reported varying degrees of success in addressing the challenges. These successes may be attributed to the

different strategies used to address the problem. For example customer awareness about drugs sourced from illegal trade and highlighting the difference in quality has achieved some success for some firms. Changing product packaging to differentiate counterfeits from genuine products has also achieved success for some firms. Nganga (2004) confirms this in his study on GlaxoSmithkline response to the challenge of its drug Halfan facing counterfeits. They introduced a special seal on it called a Hologram, which is not easily imitated and this has resulted in a reduction in the counterfeits of the drug from Asian markets.

#### 5.2 Limitations of the study

There are a number of limitations that may have affected the results of the study. They include the following:

The research was conducted using predetermined questions that may have limited the respondents' responses. Not all the targeted respondents answered the questionnaires and this reduced the response rate to 94%, also some of the respondents did not answer all the questions. We also note that a sample size of 50, which relied on random sampling, can affect results and limit generalizations. Lastly the study was conducted with pharmaceutical importers in Nairobi and may not reflect characteristics of importers in other areas.

#### 5.3 Suggestions for further Research

Illegal trade in pharmaceuticals is a problem that has not been largely studied or addressed in Kenya. This is because owing to its illegal nature it may not be easy to detect the extent to which it affects trade in pharmaceutical products. The researcher suggests that further studies be carried out in a bigger number of firms outside Nairobi and also on the extent to which the Pharmacy and Poisons Board has addressed the problem. Research on illegal trade can also be done in other industries to establish the extent of the problem in non-pharmaceutical industries.

### 5.4 Recommendations for Policy and Practice

From the findings and conclusions of the research, illegal importation of pharmaceutical products and counterfeits are a genuine and growing concern for pharmaceutical importers. The

esearcher makes recommendations to the Pharmacy and Poisons Board, which regulates and ontrols the industry, to the pharmaceutical importers and to the government.

P.P.B should take the lead and prioritize the fight against illegal trade in pharmaceuticals. Xu 2002) in addressing the challenge of counterfeits in China recommended strengthening of drug aspection teams to effectively tackle the problem. P.P.B should conduct random monthly aspections to identify illegal chemists in operation and to charge those trading in illegal imports. The penalties should be heavy fines and withdrawal of their licenses for a specified period.

Pharmaceutical importers in trying to address the challenges should address the cost of their medicines to their customers. They should try to standardize the prices of medicines in different markets. In embracing social responsibility they should set and review drug prices while looking at the economic conditions of particular markets. Pharmaceutical importers should also carry out bublic awareness campaigns nationally to sensitize the public on the presence and dangers of burchasing drugs from illegal sources. They should also consider setting aside a budget to support the P.P.B with personnel or financial resources to help carry out random and regular inspection of chemists.

K.A.P.I representatives should push the government to enact and enforce laws that address illegal trade in pharmaceuticals. The government should enact and enforce tougher criminal penalties for those found engaging in illegal trade. Control at customs should also be enhanced to tackle the problem at the source of entry and to prevent illegal products getting into the country. This is because the government also suffers loses of revenue when customs officials and other unscrupulous business people sneak in illegal products into the country. Illegal trade in pharmaceuticals affects the economy of a country and puts human life at risk because it can have serious consequences when drug quality is compromised.

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#### **APPENDICES**

#### Appendix 1: Letter to Respondents

University of Nairobi,
Faculty of Commerce,
Department of Business Administration,
P.O Box 30197,
NAIROBI.
17<sup>TH</sup> July 2006.

Dear Respondent,

I am a postgraduate student at the University of Nairobi, at the Faculty of Commerce. In order to fulfill the degree requirements. I am undertaking a research project on strategic practices followed by pharmaceutical firms in Kenya. The study is titled "Responses of Pharmaceutical Importers to the Challenge of Illegal Trade in Pharmaceuticals."

Your organization/company, which falls within the population of interest, has been selected to form part of this study. This therefore is to kindly request you to assist me collect data by filling out the accompanying questionnaire or according me an opportunity to come and assist you fill it.

The information/data will be used exclusively for academic purposes. My supervisor and I assure you that the information you give will be treated in strict confidence. At no point will the name of your organization appear in the final report. A copy of the research project with suggestions will be made available to your organization on request.

Your cooperation will be highly appreciated.

Yours faithfully,

OPIYO JACQUELINE

MBA Student

DR. MARTIN OGUTU

Supervisor and Lecturer, UON.

# Appendix 2: Questionnaire

## Part A: Demographic Data

1.	Name of the company
2.	Designation of respondent
3.	How long have you been operating in Kenya?
4.	Which countries do you import drugs from?
5.	What kind of products do you import to Kenya?
	Prescription only medicines ( ) pharmacy only ( ) both ( )
6.	What is the current total number of employees?
7.	What is the relative size of your organization on the basis of
	sales turnover (2005)?
8.	Does the firm have a strategic management department?
	( ) Yes ( ) No
9.	If no, which department deals with strategy formulation
	and implementation
10.	Do you have a sales and marketing department?
	( ) Yes ( ) No
11.	. Who owns the firm? Individual ( ) family members ( ) board ( )
12	Who is the director of the firm?
13	Which of the following are involved in the formulation of the organization's strategies?
	(Tick appropriate ones)
	Parent company/drug manufacturing company ( )
	Chief Executive officer ( )
	Head of sales and marketing department ( )
	Strategic manager ( )

17	in your organization	ai structure,	wnat is th	e posi	tion of	the str	ategic n	nanager in	relatio
	to other functional he	eads?							
		Higher	same		low	er			
	Finance	( )	( )		(	)			
	Marketing	( )	( )		(	)			
	Human resource	( )	( )		(	)			
Pa	rt B								
1.	How many pharmac	ceutical produ	icts do yo	u impo	ort into	the Ke	nyan ma	arket?	
	*******************		• • • • • • • • • • • •					• • • • • • • • • • • • •	• • • • • • •
2.	How many times in	a year do you	carry out	impo	rtation	of drug	s?		
	( ) once in a year (	) more than	once a ye	ear (	) less t	han one	e a yea	r	
3.	Do you face the prob	blem of illega	l imports	of you	r drug	S			
	Yes ( ) No (	)							
4.	Do you face the pro-	blem of your	medicines	being	count	erfeited			
	Yes ( ) No (	)							
5.	In your opinion,	rate the ex	tent to v	vhich	each o	of the	followi	ng is a ca	use fo
	illegal imports and o	counterfeits. U	Jse a 5-po	int sca	le whe	ere: -			
=No	t a cause at all 2= A le	ess Cause 3=	Moderate	Cause	4=Gr	eat Cau	se 5=	Very great	cause
				1	2	3	4	5	
i)	High medicine price	es		( )	( )	( )	( )	( )	
ii)	Lack of proper legal	l and regulato	ry	( )	( )	( )	( )	( )	
	structures to deal wi	ith the problem	m						
iii	) Lack of alternative i	income gener	ating	( )	( )	( )	( )	( )	
	activities								
iv	) Greed/ desire for his	gher profit ma	argins	( )	( )	( )	( )	( )	

6. Do	es your firm	have a system for	or track	king and	analyzing	g the percentage	e of your
med	licines being co	ounterfeited?					
( )	Yes No	( )					
7. Does	your firm have	a system for trac	king an	d analyzir	ng the per	centage of illegal	limports
for yo	our products?						
()	Yes No	( )					
8. How	many of your	drugs have illegal	imports	?			
( ) le	ess than five	( ) greater than fi	ive ( )	cannot ac	curately t	ell	
9.How	many of your d	lrugs have been co	ounterfe	ited?			
( ) le	ess than five	() greater than 5	( )	can not to	ell with ac	ccuracy	
10. You	ur counterfeited	d medicines have t	he follo	wing feat	ures (plea	se tick)	
- Sam	e packaging		( )				
Diff	erent packagin	g	( )				
Sam	e color of table	et	( )				
Diff	erent color of	ablet	( )				
Same	e size of drug		( )				
Diffe	erent size of dr	ug	( )				
Same	e retail price		( )				
Lowe	er retail price		( )				
High	er retail price		( )	)			
11. To wh	at extent has ill	legal imports affec	ted you	ır firm's sa	ales?		
Use a	5- point scale	where;					
I= Not a	t all 2=To a le	ess extent 3=Mode	erate ex	ktent 4=To	o a great	extent 5=To a	very great
extent							
	1	2	3		4	5	
	( )	( )	( )	(	( )	( )	

12. To wha	at extent has coun	terfeits affecte	ed your firm			
Use a	5- point scale who	ere;				
I= Not at	all 2=To a less	extent 3=Mod	derate extent	4=To a great	extent 5=To a	very great
extent						, 0
	1	2	3	4	5	
	( )	( )	( )	( )	( )	
			, ,		` '	
13. Tick w	hich problem you	ır firm has had	to deal with	as a result of il	llegal imports ar	nd
counte						
i) Addres	ss product price					
Reduce	e product price	15		( )		
	se product price					
	•			( )		
ii) Addres	ss product quality			( )		
	, and a second			( )		
iii) Reduce	ed profit margins			( )		
,	- Promo mangano			( )		
iv) Retren	chment			( )		
v) Others	(Please specify)			` /		
Part C						
l. Has voi	ur organization ad	dressed the nr	oblem of illeg	al imports?		
	s ()No	aressed the pr	obtem of meg	ai imports.		
	ur organization ad	dressed the no	oblem of some	nterfeits?		
	s ( ) No	dressed the pr	objetii of coul	neriens?		

3. Indicate the extent to which the following havillegal imports and counterfeits.  Use a 5-point scale where;	ve partic	ipated i	in addres	sing	the challenges	of
1= Not at all 2=To a less extent 3=Moderate ex	ctent 4=	To a gr	eat exter	nt S	5=To a very gr	eat
extent		Ü			, 0	
	1	2	3	4	5	
The marketing representatives	( )	( )	( )	( )	( )	
The customers	( )	( )	( )	( )	( )	
The media	( )	( )	( )	( )	( )	
The government, Pharmacy & Poisons Board	( )	( )	( )	( )	( )	
4. Which of the following strategies has your firm	ı used to	addres	s the chai	lleng	e illegal impor	rts?
(Please tick)						
Reduce medicine prices	( )					
Change product packaging	( )					
Change brand name of product	( )					
Inform customers about them	( )					
Others (Please specify)						
						• •
					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
***************************************						• •

5. Which of the follow		our firm us	sed to addre	ess the challenge	e of counterfei
medicines? (Please tick)	)				
Change brand name of p	roduct		( )		
Change product packaging	ng		( )		
Sensitize customers abou	at them		( )		
Others (Please specify)					
	* * * * * * * * * * * * * * * * * * * *				
	• • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •	* * * * * * * * * * * * * * * * * * * *
*************************					
6. Has your company co					
illegal imports and counte					
( ) Yes ( )	No				
7. When did your compan	y last reduc	e medicine p	rices?		
				• • • • • • • • • • • • • • • • • • • •	
Rate the following in o	rder of impo	ortance			
			Less import	tant Not import	ant at all
Drug distributors	( )	( )	( )	*	
Medical practitioners	( )	( )	( )	· · ·	
Retail chemists	( )	( )	( )		
Patients	( )	( )	( )	( )	
9. Does your company inc	corporate so	cial responsi	bility in its po	` '	
(	No	1	, and the second		
` '					

10. To	what extent does your company incorpora	te ti	he fo	ollo	win	g w	hen	ma	rke	ting	its ]	prodi	ucts?
Use a	5-point scale where;												
1= No	ot at all 2=To a less extent 3=Moderate ex	tent	4=	То	a gr	eat	ext	ent	5	=To	a v	ery	great
extent													
		1		2		3		4		5			
i.	Price reduction	(	)	(	)	(	)	(	)	(	)		
ii.	Giving of discounts on purchase	(	)	(	)	(	)	(	)	(	)		
iii.	Giving of bonuses on purchase	(	)	(	)	(	)	(	)	(	)		
iv.	Distribution of pharmaceutical gifts to	(	)	(	)	(	)	(	)	(	)		
	retail chemists												
11. W	ho informs your customers about counterfei	t pro	oduc	ts?	(Ple	ase	tick	()					
	Your medical representatives	(	)										
	The medical practitioners	(	)										
	The medical advertisements	(	)										
	All of the above	(	)										
12. W	hich of the following has your company dor	ne to	ado	lres	s the	e ch	alle	nge	s of	ille	gal	imp	orts?
(1	Please tick)												
	Change product brand name	(	)										
	Change product packaging	(	)										
	Change product color	(	)										
	Withdraw product from market	(	)										
Other	s (Please specify)												
					• • • • •								
			• • • • • •										
	***************************************		••••								• • • • •		
*****						• • • •							

13. If have done the considerations in (11), to what extent have you been successful in
addressing the challenge of illegal imports?
( ) very successful ( ) Successful ( ) a little successful ( ) not successful at all
14. Which of the following has your company done to address the challenges of
counterfeits? (Please tick)
Change product brand name ( )
Change product packaging ( )
Change product color ( )
Withdraw product from market ( )
Others (Please specify)
15. If have done the considerations in (14), to what extent have you been successful in
addressing the challenge of counterfeit medicine?
( ) very successful ( ) Successful ( ) a little successful ( ) not successful at all

\*)

# Appendix 3: List of Pharmaceutical Importers in Nairobi that were used in Survey.

- 1. Abbott Laboratories
- 2. Assia Pharmaceuticals Limited
- 3. Astrazeneca
- 4. Aventis Pasteur SA (E.A)
- 5. Bayer East Africa Ltd
- 6. Beta Healthcare International
- 7. Boehringer Ingelheim
- 8. Bristol Myers Squibb Company
- 9. Cadila Pharmaceuticals (E.A) Ltd
- 10. Caroga Pharma Kenya Ltd
- 11. Eli-Lilly (Suisse) SA
- 12. Europa Healthcare Ltd
- 13. Framin Kenya Ltd
- 14. Galaxy Pharmaceuticals Ltd
- 15. GlaxoSmithKline
- 16. Glenmark Pharmaceuticals Ltd
- 17. Goodman Agencies Ltd
- 18. Harleys Limited
- 19. Highchem Pharmaceuticals Ltd
- 20. Intas Exports Ltd
- 21. Janst Healthcare International
- 22. Jos. Hansen & Soehne (E.A) Ltd
- 23. Kulal International Ltd
- 24. Lords Healthcare Ltd.
- 25. Menarini International
- 26. MacNaughton Ltd
- 27. Madawa Pharmaceuticals Ltd
- 28. Medisco Ltd

- 29. Medox Pharmaceuticals Ltd
- 30. Merck Sharp and Dohme
- 31. Metro Pharmaceuticals
- 32. Novo Nordisk
- 33. Omaera Pharmaceuticals Ltd
- 34. Pfizer Laboratories Ltd
- 35. Pharma Specialities
- 36. Pharmacia Africa Ltd
- 37. Prisma Pharmaceuticals Ltd
- 38. Rhino Kenya Ltd
- 39. Roche Products Ltd
- 40. Sai Pharmaceuticals Ltd
- 41. Sanofi-Synthelabo (K) Ltd
- 42. Schering Africa GMBH
- 43. Solvay Pharmaceuticals
- 44. Sphinx Pharmaceuticals Ltd
- 45. Sunpar Pharmaceuticals
- 46. Wessex Pharmaceuticals Ltd
- 47. Wockaine Kenya Ltd
- 48. Wockhardt (Europe) Ltd
- 49. Zadchem Pharmacy Ltd
- 50. Zeneth Pharmaceuticals

## Appendix 4: Abbreviations

AIDS - Acquired Immune Deficiency Syndrome

ARV's - Anti RetroVirals

BBC - British Broadcasting Corporation

COMESA - Common Markets for East and Southern Africa

E.A - East Africa

GSK - GlaxoSmithkline

HIV - Human Immuno Deficiency Virus

KAPI - Kenya Association of Pharmaceutical Industry

LTD - Limited

MOH - Ministry of Health

NQCL - National Quality Control Laboratory

PPB - Pharmacy and Poisons Board

S.A - South Africa

SWOT - Strengths Weaknesses Opportunities Threats

USD - United States Dollar

WCO - World Customs Organization

WHO World Health Organization