



FACTORS CONTRIBUTING TO SUBSTANDARD MEDICAL PRODUCTS IN KENYA

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ABSTRACT

The medical supplies sector is key to functional health care systems worldwide. This sector is currently facing numerous challenges in its mandate to provide quality and efficacious products. Statistics estimate that over 25% of the medical products consumed developing countries are substandard. The study evaluated factors contributing to proliferation of substandard medical products in Kenya. The factors examined include regulation, supply chain, handling and storage, demand and workmanship. It was carried out in Kiambu and Ruiru Districts. A descriptive survey research design was applied on a target population of 44 assorted medical outlets. Respondents were conveniently sampled using a questionnaire and data analyzed using SPSS. Findings were presented in form of frequency distribution tables, charts and percentages. The study revealed absence of industry policy and guiding documents in majority of operators and that cooperation between stakeholders was loose. Demand was rated as 'very important' motivation fueling circulation of substandard medical products. On workmanship, it was confirmed that quality variation between manufacturers is significant. On ICT use, only about half of the respondents employed ICT tools in service and majority was satisfied with how authorities were employing technology to confront the problem of substandard products.

Key words: *Functional Healthcare, Efficacious Products, Quality Variation*

BACKGROUND OF THE STUDY

Quality medical products play a central role to good healthcare. However, assuring provision of these products is continually coming under challenge with more cases of substandard medical products being reported (WHO, 2006). The products are generally required to meet a criteria of three key parameters namely safety, effectiveness and quality. It is in view of these three and the reality of the consequences implied if any of them is breached that the World Health Organization emphasizes the need for adequate control over their manufacture, storage, distribution and even use (Andreas, 2002).

Substandard medical products can cause serious problems including increased disease incidence (morbidity), death, engendering of drug resistance and subsequent loss of drug effectiveness, loss of confidence in health systems, economic loss to patients, their families, health systems, manufacturers and traders in good quality medicines, adverse reactions resulting from incorrect ingredients among others (Anon, 1997). Examples in time include the emergence of the Extra Drug resistant-Tuberculosis (EXDR-TB), and relegation of previously effective sulfa-based anti-malarials commonly referred to as SPs (Fansidar and Metakelvin), and the now seriously threatened Artemisinin based antimalarial regimens (Julian, 2009).

Although it is difficult to obtain precise figures, it is estimated that about 10% of medicines in the global market are substandard with an estimated over 25% of that occurring in developing countries (WHO, 2006). In 2006, European statistics showed a particularly strong increase of drug counterfeit seizures (Sanofi-Aventis, 2010). At the European customs, a total of 2.7 million of drug units were seized, representing a growth of 384% compared to 2005, while in many developing countries in Africa, parts of Asia, and parts of Latin America had areas where more than 30% of the medicines on sale were counterfeit.

Globally, emphasis on the development, manufacture, distribution and use of high quality medical products is nowadays a continuous campaign, spear headed by the World Health Organization and implemented by various international and national level authorities like the

Food and Drugs Administration (FDA) of the United States and the Pharmacy and Poisons Board (PPB) of Kenya. Even so, that has not led to full realization of the ultimate goal of eliminating substandard medical products from the market.

The Centre for Medicines in the Public Interest in the United States in 2005 had projected those substandard drugs sales would hit US\$ 75 billion globally by 2010 and still continue growing representing increase of more than 90%. This could be true today going by the number of substandard drugs seizures around the globe.

In Kenya, it had been estimated in 2007 that up to 30% of medicine on sale was substandard (Mbogo, 2008). A memorable recent case in Kenya involved recall of Anti-Retroviral manufactured by a well-known pharmaceutical giant owing to patients and health workers complaints involving funny experiences after use of the product and irregularities in the appearance and texture of the product (Plus News, 2011).

STATEMENT OF THE PROBLEM

According to Keuffel (2005), the pharmaceuticals industry rates among the most stringently regulated industries that entrepreneurs can think of venturing into, yet it has been so difficult to curb the dealership in substandard medical products. These products are an insidious threat to global health, and the risk they pose has been largely underestimated to date. Apart from failing to cure disease, they can cause mental and physical harm and even death (Boateng, 2007). Some are made and distributed by criminal gangs, who are attracted by the high profit margins of the trade, with many using fake Western addresses to impress patients and doctors in poor countries (Givering, 2007). Further, the products are often hard to identify for good ones, and their ineffectiveness may be revealed only when a life has been put at risk (Sanofi-Aventis, 2010).

A World Health Organization (2006) report between January 1999 and October 2000 relating to 46 confidential reports on substandard drugs from 20 countries indicated that 60% of cases of substandard medical products originated from developing countries while the remaining 40% were reported by developed countries. The

consequences for such figures especially in developing countries are dire, as it is for example estimated that about 700,000 deaths occur yearly due to substandard Malaria and Tuberculosis drugs (Julian, 2009). Data published by The United Kingdom National Statistics on its website revealed that deaths related to drug poisoning in England and Wales has been on a steady increase between 1993 and 2008, from an average of one thousand to three thousands per annum.

In Nigeria, over 39 children died in the year 2008 from poisoning by a substandard teething preparation manufactured with a car coolant diethylene glycol instead of its cousin propylene glycol (Obina, 2008). Profit wise, in 2002, pharmaceuticals ranked as the most profitable sector in the United States, topping the Fortune 500 ranking of America's top industries. The pharma industry topped all three of Fortune's measures of profitability three decades in a row then with profits increased by a margin of 32%, while overall profits of Fortune-500 companies declined by 53% (Gottlieb, 2002). This trend was maintained in 2004 in the United State with a return on investment of 17% (Barlett, 2004). Though no substantive information could be found appertaining to the profitability Kenya margins enjoyed by dealers in medical products, a points of sell inquiry at retail level in the year 2010 found a subsidized anti-malarial regimen supposed to be sold for 40KES retailing at between KES 80 and 240 KES in most pharmacies (Gathura, 2010). This puts the profit margins for this particular product between 100 and 600%.

The potential profitability of trade in medical products, the relative rampancy of substandard among the products and the clearly serious consequences associated with them present a unique combination of factors that pose a real threat on healthcare management and economics. These necessitated the need for research in the area.

OBJECTIVES OF THE STUDY

- I. To find out if the current industry regulation system contributes to substandard medical products in Kenya.
- II. To investigate whether the supply chain practices contribute to substandard medical products in Kenya.
- III. To find out if handling and storage contribute to substandard medical products in Kenya.
- IV. To determine whether demand contributes to substandard medical products in Kenya.
- V. To find out whether workmanship and technology use contribute to substandard medical products in Kenya.

JUSTIFICATION OF THE STUDY

It is widely acknowledged that however good the healthcare service providers could be, quality of drugs used in treatment can frustrate treatment and lead to debilitation or even death of patients and in due course falsely project doctors, pharmacists and even institutions as incompetent or bogus. (Boateng, 2007) While the consequences associated with use of substandard medicines are clearly and obviously dire and more often insidious, no comprehensive study had so far been done in Kenya to assess the extent of the problem or the factors leading to rampancy of these products.

The value of the study can perhaps emerge more clearly if the goal is reframed as a question: What are the benefits of arresting the factors contributing to the trade in substandard medical products? .In order to arrest the driving factors, they will have to be clearly identified and confirmed in the first case.

The study aimed to confirm or disapprove the significance the factors so identified above to contribute to refining of working current approaches, as well as finding new and better approaches to eliminating substandard medical products and stumping out their effects. This study was envisaged to add to the body of knowledge on the factors contribution of substandard medicines. It could also provoke

debate on how to improve the quality of drugs and health care and open frontiers for further research.

SCOPE OF THE STUDY

The study focused evaluating the factors contributing substandard medical products in Kenya mainly through perception of practitioners in medical field – especially pharmacists/pharmacy attendants, doctors and clinical/medicine practitioners. The population consisted of 960 medical outlets in Kiambu and Kasarani districts.

LITERATURE REVIEW

The World Health Organization (WHO) in a fact sheet (N^o275) published in January 2010 identifies High prices, Sophistication of clandestine drug manufacture, Inefficient cooperation among stakeholders, Lack of regulation by exporters within free trade zones, Lax free trade zone agreements and lax quality control for drugs made for export as the key contributors to the trade in substandard medicines among others. Many studies of various designs have been carried out on the topic of substandard medical products and the findings do paint a grim picture indeed. In the United States in 2009, a study by Bio Med Central Nephrology (MBCN) involving review of 5,373 medication orders for Drug Related Problems (DRPs) over a 10 month period found out that 33.5% of DRPs were medication-dosing problems or adverse drug reactions, while 13.5% of the cases patients claimed non- treatment. This study however didn't proceed to attribute DRPs to a particular problem e.g. substandard medicine, mal-diagnosis or mal-administration of drugs.

The Associated Chambers of Commerce and Industry of India (ASSOCHAM) estimations in 2008 indicated that 20% of medicines circulating in India were fake, and that India supplies up to 75% of fake medicines sold around the world. The lethal trade was estimated to be growing at about 25% per annum (Sinha, May 2008).

In Africa, a study published by Reuters in mid-2008 on tests of 195 different packs of malaria drugs sold in six African cities showed that 35 % of them either did not contain high enough levels of active ingredient or did not dissolve properly. Dissolution rate is important because it is a simulation of how the drug product might behave when ingested (Kibwage, 1999). Slower or poorer dissolution characteristics means that lesser of the drug molecule will be absorbed in to blood stream thus affecting achievement of desired therapeutic effects.

i. Regulation

The Afro-regional meeting of the World Health Organization in 2006 with Medicines Regulatory Authorities (MRA) unanimously agreed that proliferation of harmful, inefficacious, counterfeit or substandard medicines on the national and international market is the outright the consequence off ailed regulation. A study conducted by the WHO Regional Office in 2004 showed that 90 per cent of MRAs in the region lack the capacity to carry out all their regulatory functions and cannot guarantee the quality, efficacy and safety of medicines (UNIDO, 2010).

It is estimated that 30 per cent of countries in the world have inadequate medicines regulation or none at all. According to UNIDO (2010), there is a significant difference between rich and poor countries in their ability to regulate the quality of medicines. In developed countries, national drug-regulatory authorities (DRAs) authorize medicines for use on the basis of their demonstrated safety, efficacy, and quality. Following authorization, or 'registration', health authorities proceed to monitor the market in order to detect and remove any poor-quality, falsified, or unregistered medicines. This involves expenditure of significant resources for the sake of protection of patients (Gopakumar, 2010).

In the absence of effective medicines regulation, substandard medicines may be widely traded and consumed. Although the prevalence of substandard medicines in developing-country markets is unknown largely due to a lack of complete and reliable data, anecdotal evidence

suggests that they are widely available (Mango, 2009).

The ministry of medical services published the Kenya National Pharmaceutical Policy in 2008 (KNPP 2008) detailing among other things good prescription and dispensing practices, Appropriate Medicine Use (AMU), Information, Education and Communication to the public on matters pharmaceuticals. As it is now, the document is yet to be implemented. Further to that, there seems to be a problem in adherence to the code of pharmacy practice by practitioners in Kenya. A survey by *Synovate* involving 203 pharmacies across the country revealed that about three quarters (73%) of them did not ask for a prescription before selling what should be “prescription only” drugs.

While anti-counterfeiting laws enacted in Kenya include those for medical products, they tend to focus on trade mark infringement issues - effectively tending to address intellectual property rights leaving out issues related to medicine quality, safety and efficacy that are not matters of intellectual property law as they are separate to counterfeiting. They are therefore issues for laws regulating drug safety (CEHURD, 2010). Considering all the above regulatory challenges, the study aimed to find out if regulation has contributed to substandard medical products in Kenya.

ii. Supply Chain

It is a common saying in supply chain management that ‘a chain is as strong as its weakest link’ implying that in an interdependent system, if something goes wrong at one point, the whole system may get upset (Tailor, 2008). Similarly in a pharmaceutical supply chain interlinked by a number of players, it is important that they all act in a concerted manner to attain synergy in eliminating the ills of the chain.

Whereas developed countries are very stringent with their local quality standards for medical products, they have not been equally aggressive in emphasizing similar standards for export products

especially to poor countries (Anon, 1997). Onwudinjo (2009) argues that lack of adequate cooperation between exporters and authorities especially within free trade zones, lax free trade zone agreements and lax quality control for drugs made for export has made it easy for substandard drugs to enter the supply chain. Moreover, many pharmaceutical companies are hesitant to share information about incidents of sub standards with local law enforcement officials/agencies or international agencies for fear that their statements could be obtained through the discovery process in litigation and used against them later: “You knew about the problem, but failed to do anything...”. To date, almost all of the information available to the public has come from international agencies such as the WHO, law enforcement organizations such as the Federal Bureau of Investigation, Interpol and activist groups (WHO, 2006).

Parallel importation (PI), also called gray-market importation is the importation of goods produced genuinely under protection of a trademark, patent, or copyright, under circulation in a market to another without the authorization of the local owner of the intellectual property right, i.e. while the patent is still effective (Maskus, 2001). It could occur due to inadequate regulation. Parallel importation goes hand-in-hand with patent busting - where manufacturers openly start manufacturing generics of products before their patent is lifted (Maskus, 2001).

In Kenya, the Efficiency monitoring Unit (EMU) in July 2011 reported a number of imported drug generics were still validly registered for sale in Kenya despite indications from the National Quality Control Laboratory (NQCL) that the drugs had failed crucial tests (Gatonye, 2011). It was further reported that the drugs which included antibiotics were readily available to end users. The report also revealed that the Pharmacy and Poisons Board (PPB) was sometimes in the dark over drug imports as it was discovered that not all the medicine imported were captured in its records as 235 pharmaceutical import entries captured at the Kilindini port by the Kenya Ports Authority were missing in the Pharmacy and

Poisons Board records. Another report by the same body (EMU) released on March 2011 also indicated that in some cases import permits were issued after drugs had already landed in the country (Emeka, 2011).

The highlighted cases bring afore the issue of cooperation within and between government agencies responsible for enabling and enhancing the fight against substandard medical products .These directly point to loopholes within the medicals supply chain that could be exploited by unscrupulous traders to make a killing financially by flooding the market with substandard products to the detriment of innocent end users. In addition, it also sabotages genuine efforts by the government and other players geared towards disease treatment and eradication of some infectious diseases. The study sought to investigate whether the supply chain contributes substandard medical products in Kenya.

iii. Handling and Storage

All materials and products undergo natural decay of a nature specific to their composition i.e. they are unstable (Zumdahl, 2006). The opposite of this nature is called stability. For drugs and related products, it is defined as their capacity to remain within established specifications and to maintain their identity, strength, quality, and purity throughout their shelf life (Rhodes, 2008).

The quality of medical products depends in part on proper storage and distribution practices, using methods that protect product integrity from handling and changes in temperature throughout the distribution chain (USDQIPandCollaborators, 2007) .

Although the storage conditions are relatively constant, the distribution environment can vary greatly, especially when a drug product is shipped between various climatic zones (FDA, June 1998). Seasonal changes, mode of transportation, and the number of drop-off points are also variables that need to be considered within the medical supply chain (Boateng, 2007).

The United States pharmacopoeia has detailed standards for “Good Storage and Shipping Practices for Pharmaceuticals” including labeling to indicate recommended storage conditions, warehouse monitoring and profiling of environmental conditions to identify where specific products can and cannot be kept, qualification of transport vessels e.g. vehicles and containers - and package performance and evaluation under elements of shock and vibration among others (USPconvention, 2006) .

According to The USDQIP and Collaborators (2007), the quality assurance component of distribution should follow the receipt of procured medicines at the port of entry, clearance through customs, and transportation from a central warehouse to depots and health facilities where they are stored and dispensed to patients, ensuring swift clearance through customs at the port of entry as critical to preventing deterioration of their quality, especially in countries classified as climatic zone IV (territories with very high temperature and humidity).

Risha et al (2003) also argues that the quality of drugs imported into developing countries having a tropical climate may be adversely affected if their formulations have not been optimized for stability under these conditions.

In Rwanda, a report publicized in the American Journal of Tropical Medicine and Hygiene in September 2009, focusing on antihypertensive drugs revealed that 2 out of 10 formulations were substandard at purchase and that 8 of 10 formulations became substandard after 6 months of storage under accelerated conditions for a combined criteria of drug content and invitro dissolution test (Twagirimukiza et al, 2009).With Kenya estimated to be importing 95% of its raw materials for pharmaceutical manufacturing and over 70% medical finished products,(EPZ Authority, 2005), there is significant risk of importing formulations that are not optimized for tropical climatic conditions besides other concerns like physical damage to packages. Moreover, it is difficult to detail other possible quality alterations during transportation and storage without laboratory testing.

iv. Demand

The World Health Organization launched the concept of Essential Drugs (EDs) in 1977 as one of the eight pillars of its Primary Healthcare Strategy and effectively developed a model Essential Drugs List (EDL) as a guide for the development of national and institutional essential medicine lists. Essential Drugs are defined as "those drugs that satisfy the primary health care needs of the population." (WHO, 2011). They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness and intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford (WHO, 2010). The essential drugs concept is applicable in all countries and at various levels including national, provincial, and district and even hospital level.

Given the international, national, geographical and demographic differences in disease preferences and patterns, there are obviously differences in essential drug requirement (WHO, 2009). This means that there is a possibility of unscrupulous dealers targeting to supply bogus essential medicines because there is a particular need for such- i.e. demand driven supply (DDS). For example in relation to this, there have been arguments questioning the seriousness of the swine flu pandemic in 2010 (Enserink, 2010). This is risky because vaccines developed during emergency times do not undergo complete testing to confirm their safety and efficacy (Salinsky, 2006). Research revealed that fake Artesunate- an antimalarial was endemic in South-East Asia in at the time corresponding to its high demand (Dodorp et al 2004).

The World Health Organization classifies Kenya's Malaria endemic, for which reason there is an almost constant high demand for anti-Malaria drugs. This could be the reason for which unscrupulous dealers imported fake anti-malarial in 2009 worth 800 MKES, which the government seized and destroyed (Gatonye, 2009). Research by WHO (2010) has shown that medical counterfeiting is primarily motivated by its potentially huge profits- and "counterfeiters are

adept at quickly adjusting to different contexts and products for which they can make the most money". The increasing demand for medicines in Kenya could act as a stimulant to the trade in substandard medical products. The study engaged to find out if demand contributes to substandard drugs in the Kenyan context.

v. Workmanship and Technology

The quality a product depends on among other things the level of workmanship applied. Development of new drugs is a rigorous multistep exercise classified into two three major steps: discovery, pre-formulation and formulation. (Gennaro, 2000). New product development requires investment of a tidy sum of money and time too. Before a new drug product (NDP) is authorized for marketing, a patent is normally already in force for sometimes periods as long as 20 years depending on the country in order to allow the developer to recoup the cost research and development of the NDP (Shadlen, 2010). After the patents lapse, other manufacturers are then free to take on manufacturing similar formulations- and here lies the challenge (Basheer, 2008).

Similar formulations of a drug made by the other manufacturers also called "Generics" are supposed to have the same active ingredient, strength, dosage form and route of administration as the brand name or reference product, but not necessarily the same inactive ingredients. Further to that, as a requirement for marketing authorization, bioequivalence (i.e. similarity in blood levels) to the reference product must be demonstrated and the product must pass all quality tests of the brand product.

According to Helendes (1993), Pharmaceutical equivalence of generic drugs may be affected by many factors including variations in the non-active ingredients, the source of active ingredients (for example plants growing in different parts of the world produce ingredients varying in quality), and the processing method. In addition, studies have shown that in some cases, pharmaceutically equivalent formulations can have different bioavailability leading to faster or slower absorption rate with resultant clinical significance

(Mikati, 1992). If the inputs for drug manufacture are of good quality, then the manufacturing method (i.e. the level of expertise employed) becomes the major determinants of quality of generic products. Some manufacturers formulate products that marginally meet requirements just to save cost (Oles, 1992). Quality problems related to poor workmanship commonly manifest in multiple products (Andreas, 2002). These may include adverse drug reactions, drug product recalls and real-time changes in drug product characteristic (lack of stability at recommended conditions).

The Hansard (July 2004), reported a Pharmaceutical manufacturing company supplied substandard Paracetamol tablets that contained rotting chalk. The consignment was worth Ksh160 million, and had already been distributed to health centers across the country but had to be recalled when the scam was blown up in the media. This, together with a myriad of other complaints on substandard products by the company led to its closure by the PPB in July 2011 (PPB, 2011).

In developed countries, ICT has enabled unique and sophisticated ways of seeking treatment through online medical consultancy and enhanced the concept of medical tourism (Hill, 2007). Online prescription of drugs is also common. A study carried out in the United States by the alliance for safe online pharmacies (ASOP) in 2010 indicated that illegal online pharmacies had provided about 36 million Americans (about 1 in 6 Americans) with prescription medication via the Internet without a valid prescription thus exposing them to the potential of taking counterfeit and substandard medications.

An online survey by Helium marketing Inc. published in November 2010 found 93% (996 out of 1071 respondents) strongly believe that product packaging influences consumer buying behavior. The defective "Hot" condoms discovered in Kenyan shops for example were very convincingly well packaged and attractively labeled beyond suspicion of many- even regular users (Onyango, 2009 Nov.)

Computer-aided design has made it easier than ever for unscrupulous manufacturers and patent busters to make near exact copies of a product of interest without easily attracting attention (Rago, 2006). The study sought to find out whether workmanship and technology contribute to substandard medical products in Kenyan market.

RESEARCH METHODOLOGY

The study adopted a cross sectional study design in which a subset of the population is selected and used to obtain information to help answer research questions (Sekaran, 2010). Cross sectional study is often used to assess the preference of acute or chronic problem conditions, or to answer questions about the cause of a problem or results of an intervention (Schinder, 2006). The study adopted convenience sampling, a non-probability sampling technique where individuals that happen to be most accessible to the researcher are included as participants. It is most suitable when the processes the researcher is testing are assumed to be basic and universal such that they can be generalized to the population (Orodho, 2008). This is the case with medical outlets where for instance government facilities are supplied by the Kenya Medical Supplies Agency (KEMSA), while the rest of the outlets are supplied by a few wholesalers, most of whom have their headquarters in Nairobi.

FINDINGS AND DATA ANALYSIS

I. Industry Regulation

The study sought to find whether industry relevant regulations, policies and guidelines used as operation references were available with operators in either soft or hard copies. Majority of operators (68.6%) did not have them while the remaining 31.45% had the documents that they knew of. These majorly included the pharmacy and poisons act and the Good Distribution Practices code.

Table1: Availability of Policies and Guidelines within Medicals Trade Industry

Legend		
	F	%
Know of but don't have policies	24	68.6
Have	11	31.4
Total	35	100

Information as to the adequacy of the law in addressing the quality ailments of the industry- and if it is uniformly enforced was also sought. 54% of respondents were of the opinion that the law was adequate to deter the trade in substandard medicals while 60% were confident with the uniformity of its enforcement. On average therefore, 57 % were satisfied with adequacy and mode of enforcement of regulations while the remaining 43% were of opposite opinion.

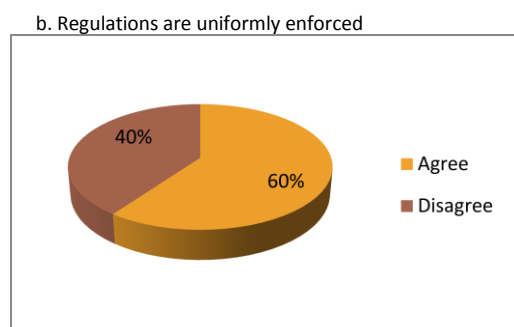
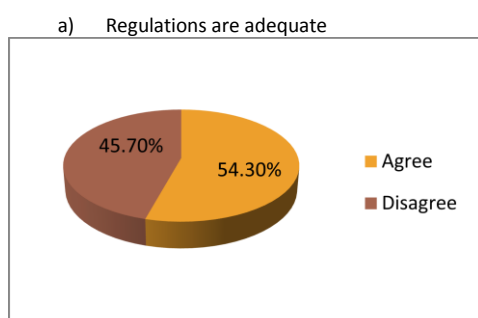


Figure 1: Pie Charts of Adequacy and Uniformity of Regulations Enforcement

The findings agree with the Afro-Regional Medicines regulatory Authorities (MRA) – WHO(2006) that proliferation of harmful, inefficacious, counterfeit or substandard medicines on the national and international

market is has a serious element of regulatory failure. The significant 43% who are of the opinion the law is inadequate and sloppily enforced concur with CEHURD(2010) that most regulatory approaches are more inclined to intellectual property and trademark infringement issues than quality issues.

That majority respondents do not have industry policies and guidelines implies that they cannot be put into practice when operators do not know what they contain. Some of the reasons cited by the significant 43% include unilateral approach by authorities, corruption and apparent empathy to manufacturers and wholesalers. The efficiency Monitoring Unit (EMU) findings in March 2011 where import permits were issued to importers after drugs had already landed in the country corroborate this.

II. Supply Chain

The study sought to determine if cooperation among various stakeholders in the medicals supply chain was adequate to benefit the war on substandard medical products. Majority of respondents (71%) were of the opinion that only essential cooperation for business operations takes place, while another estimated 28% described cooperation in the industry as loose and distant.

Table 2: Description of Cooperation within the Supply Chain

Response	f	%
Cooperation is :	Adequate and balanced	2 5.7
	Just to enable businesses to run	25 71.4
	Loose/Distant	8 22.9
	Total	35 100%

Insight was sought into communication preferences especially in essence of overlapping sensitive issues like substandard products. The study revealed that majority of respondents (80%)

would rather to talk to their suppliers than to the government regulatory authority(11%) or to manufacturers (9%). Reasons cited for supplier communication preference were intended replacement of defective products (92%) and easy accessibility (86%).

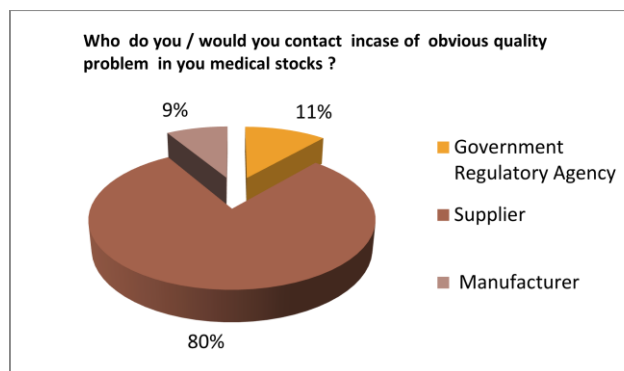


Figure 2: Pie Chart of Communication Preferences within the Supply Chain

These findings concur with the WHO (2006), and Gatonye (2011) all of whom point that non-cooperation within the supply chain is one of the key contributing factors enhancing the trade in substandard medical products .Onwudinjo (2009)'s argument, that lack of adequate cooperation between dealers and authorities has especially made it easy for substandard products to enter the supply chain is also corroborated. The apparent lack of a balanced multilateral and mutually beneficial cooperation that could enable active tackling of the problem of substandard medical products within the context of supply chain was confirmed. The averseness to communicating to the regulatory authority and manufacturers especially impedes the fight because authorities wouldn't get crucial information, while manufacturers could be unduly exonerated from responsibility for quality.

III. Handling and Storage

Relative abundance of encounters with Products Damaged during Transportation (PDDT) or Spoiled during Storage (PSDS).It was revealed that approximately 9% of respondents frequently encountered PDDT, while about 3% frequently encountered PSDS.

A cumulative percent of 94% had at least experienced PDDT, with a 92% having experienced PDDS. Only about 5.7 % and 8.5% respectively had never encountered PDDT and PDDS respectively.

Table 3: Products Damaged during Transportation and Spoiled during Storage

	Damaged during transportation			Spoiled during storage			Total %	RT%
	f	%	Cum.%	f	%	Cum.%		
Frequently	3	8.6	8.6	1	2.9	2.9	11.5	5.9
Occasionally	13	37.1	45.7	15	42.9	45.8	74.0	38.1
Rarely	17	48.6	94.3	16	45.7	91.5	94.3	48.6
Never	2	5.7	100	3	8.5	100	14.2	7.4
Total	35	100		35	100		194	100

Actions preferred in event of encounter withproducts damaged during transportation or spoiled during storage were inquired on. The majority (77.1%) favored returning the goods to the supplier for replacement. 51.4% return the goods anyway whether or not they expected replacement and a significant 34.3% destroy the goods. However, only 22.9% indicated of keepingrecords of the actions taken.

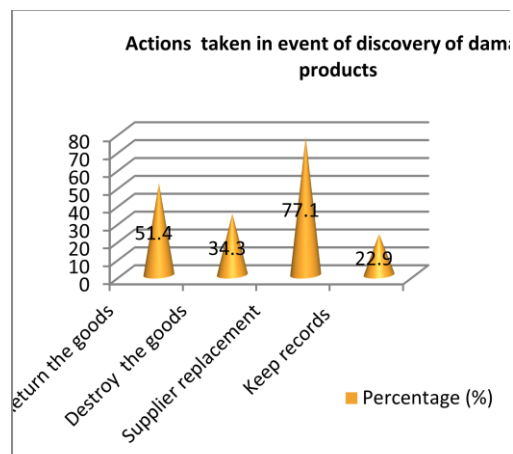


Figure 3: Actions Preferred in Event of Product Damage during Transportation

The study also out to determine whether medical products transportation /delivery system was consistent with the precautions necessary to maintain quality. Findings whereas depicted in figure 4.5.Majority (77%) of respondents were positive on the integrity of transportation system

while the remaining 23% were of the opposite opinion

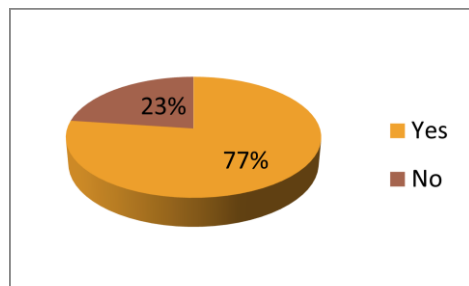


Figure 4: A Pie Chart on Effectiveness of Medicals Transportation System

On reading of labeling and literature information which normally has a direct bearing on proper handling and storage of medical products, it was revealed that majority (60%) always read literature information while the remaining significant 40% occasionally does so.

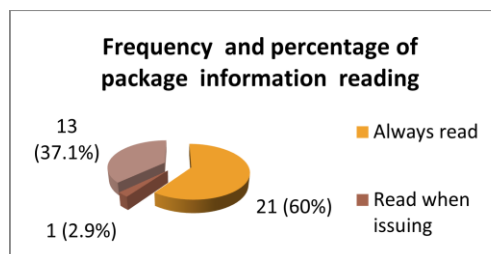


Figure 5: A pie Chart on Reading of Label and Literature Information

On adequacy and clarity of handling and storage information on packages and other provided literature, majority of respondents (77.1%) were of the opinion that the information is adequate/clear, 20% indicated it is not always find it so as a significant number lacked products literature, while the remaining 2.9% indicated that instructions were largely inadequate and kind of ambiguous. The net implication of the findings on products damaged during transportation and spoiled storage respectively can be said to be significant enough to contribute to substandard products. The lack of expeditious clearance system for medical imports, importers and distributors without elaborate cold chain delivery systems, slackness in keeping of records, the lack of literature in packaged products, ambiguities in product literature, indifference to reading product

literature key to proper handling and storage are some of the pointers to that.

IV. Demand

The study set to find out in the first instance the level of importance that respondents attributed to demand as a possible motivator to the trade in substandard medical products. A Likertscale of 1 to 5 with 1 implying most important and 5 not important was used. Majority (71.43% on cumulative) were of the opinion that demand is an important motivator to the trade in substandard medical products. 11% placed it mid-way while the remaining 14% thought it is not important at all.

Table4 :Importance of Demand in the Trade in Substandard Medicals

	Frequency	P ercent	Cumulative percent
Very Important	1	14	4
		0.00	40
	2	11	3
		1.43	71.4
Not Important	3	1	2
		.86	9
	4	4	1
		1.42	9
	5	5	1
		4.30	100.

On occurrence rate of anomalies in as products categorized as fast moving, 11% encounter substandard products often in the category, 37 % do occasionally encounter them and a narrow majority of 51% indicated they rarely encounter substandard products in the category.

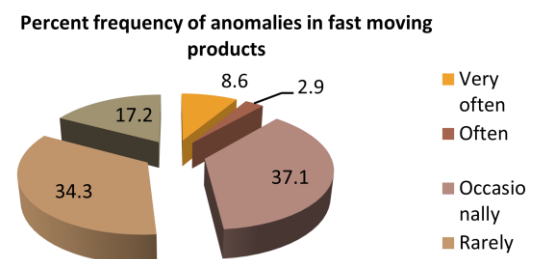


Figure 6: Frequency of Anomalies in Various Categories of Fast Moving Products

An index to identify the category most empirically affected with substandard products called

Movement related Substandard Medicals Index (M_rSMi) was developed on account of product movement (Movement/Demand Factor/MF), observed frequency of substandard products Defect factor/DF) and the number of categories (n). Five levels of defects were employed for this purpose: Very often (DF = 5), Often (DF =4), occasionally (DF=3), rarely (DF = 2), Very rarely (DF = 1).

MF was based on the number of categories with the fastest moving category assigned a factor of 7, backwards to the least moving with a factor of 1. A constant factor of 48.6/100 (0.486), derived from summing the 37.1, 2.9 and 8.6 (anomaly frequency on figure 6) and dividing by 100 was applied purposely to reflect the empirical probability for possible encounter of substandard product in the fast moving category. The Movement related Substandard Medicals Index, M_rSMi was then calculated using the formula:

$$M_rSMi = \frac{MF \times DF \times 0.486}{n}$$

The M_rSMi indices calculated and tabulated in table 5 showed that among the seven categories, anti-infectives were leading on likelihood of finding substandards with an index nearly 30% more than that of pain relieve agents and nearly five times that of most other products. Though four categories didn't register concerns, it doesn't actually mean that the likelihood of finding substandards among them is null because lack of high demand also mean that products may stay longer in shelves and get spoiled.

Table: 5: Movement Related Substandard Medicals Index

Category	f	Movement Factor (MF)	Defect Frequency Factor (DF)	M _r SMi	Relative M _r SMi (M _r SMi/2.43)x 100%
Anti-effectiveness	24	7	5	2.43	100
Pain relief agents	9	6	4	1.67	68
Cosmeceuticals	2	5	3	1.04	42.8
Family planning	0	4	2	0.555	22.8
Recreational use products	0	4	2	0.555	22.8
Neutraceuticals	0	4	2	0.555	22.8
Chronic disease	0	4	2	0.555	22.8

In the study, costliness and high demand were also compared to determine stronger motivator for dealership in substandard medical products between the two. To achieve that, frequency of substandard products in the two categories was assessed. Demand emerged as the superior driver of substandard medical products at 57% to costliness at 17%. 26 % of respondents tied the two factors.

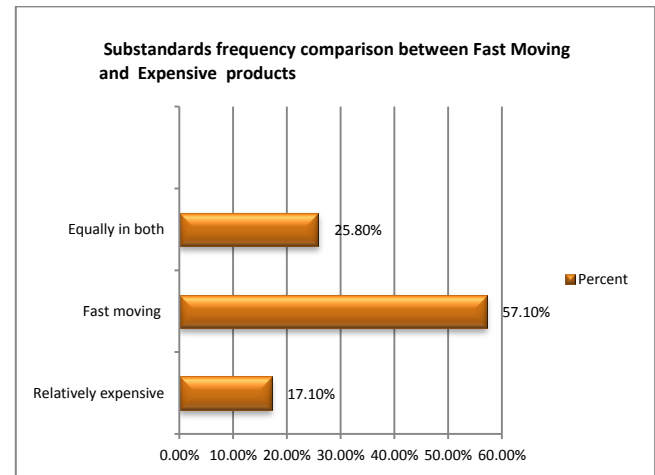


Figure 7: Occurrence Rate of Substandard: Fast Moving versus Expensive Products

Generally on demand, majority (71%) were of the opinion that demand is a key motivator to the trade in substandard medical products as 48% indicated having encountered substandard in the high demand products category with 11% doing so frequently. Anti-infectives led in demand related occurrence of substandards with pain management agents in second place. These findings agree with Dodorp et al (2004) and UNIDO (2010) that attribute increased level of substandard medicines in the market with demand.

V. Workmanship and Technology

Enquiry was made as to whether quality variation between manufacturers of especially generic drugs were significant enough to bar free substitution, and whether users have at any times preferred products on basis of manufacturers. Majority of respondents (51%) indicated that differences between manufacturers were significant while 83% affirmed that users have

shown product preference based on the manufacturer.

Table 6: Quality Variation between Manufacturers and Consumer Preferences

Quality differences between manufacturers are significant	Consumers prefer products from certain manufacturers	
	f	%
Yes	18	51%
No	17	49%
Total	35	100

The level of application of ICT tools e.g. mobile phones and internet in service delivery by operators in the medical supplies sector was also examined. It was revealed that about 46% used ICT frequently, 31% used it occasionally. The remaining approximate 23% do not or rarely use it. A majority of 68.6% were satisfied with how regulatory authorities were employing ICT as a tool to counter substandard medical products. Availability of a website for the regulatory authorities including a pharmacy vigilance portal for reporting problems related to medical products e.g. adverse reactions and substandard suspects was cited as an example. Those in disagreement cited absence of the most popular technology tool (mobile phone) in the picture in order to leverage its wide availability to gear up the fight against substandard medical products.

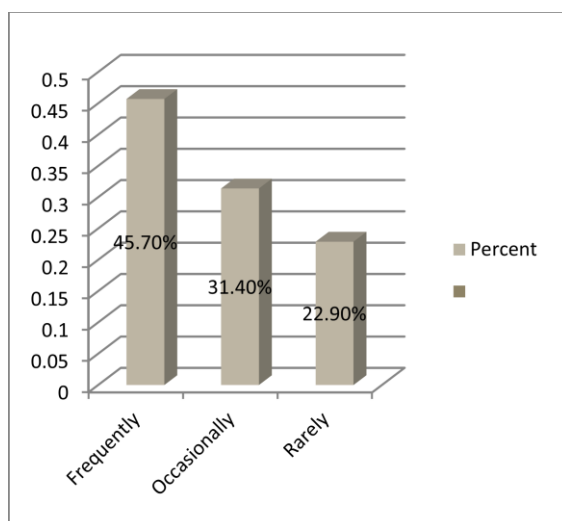


Figure 8: Extent of ICT Application within the Medicals Supply Chain

These findings agree with agree with Basheer (2008) to the extent that there is a big challenge especially in the development and manufacture of generic medical products. Since the true measure of quality is in the consumers view, it can be postulated that the companies whose products are preferred have better workmanship and thus produce better quality. Further, technology use (or lack of it) is a contributing factor to the flourishing trade in substandard medical products because if it were adequately deployed, it would be the surest way to assure consistence. Although majority gave authorities thumbs up in technology use, the issues raised on public participation in the fight against substandard medical products e.g. lack of the common place mobile phone in the picture are critical and will need to be considered.

CONCLUSION

In conclusion, the study found the regulation, supply chain, handling and storage and workmanship to be contributors to substandard medical products. The regulatory system is lacked clear policies focused on the problem of substandard medical products and has largely adopted a unilateral approach to tackling the problem. The supply chain communication and coordination was confirmed to be seriously broken with different players handling the problem the best way they know how. Serious averseness to liaison with manufactures and the regulatory authorities was revealed. With respect to handling and storage lack of an expeditious clearance system medical products at ports and absence of specialized handling equipment during transportation are some of the critical matters revealed by the study, especially considering that 70% plus of finished products are imports. Demand was also proved to be a critical factor fueling the supply of substandard products even far more than costliness. In relation to workmanship and technology use, the study confirmed that there is lack of uniformity in product quality by different manufactures. This could be attributed to differences in expertise and levels of technology deployment.

Recommendations

Regulatory infrastructure should be improved, e.g. set a specific unit within the medicals regulatory arm to streamline, develop and implement policies in liaison with other industry stakeholders to will ensure effective quality surveillance encompassing the importation, local production and holding and distribution of these products. There is need to bring all stakeholders on board to bolster efforts towards eliminating the substandard products with a mutual partnership approach including regular education and training

programmes at various levels e.g. manufacturers, importer/exporter, local wholesalers, retailers and the public. Authorities should employ or liaise with epidemiologists to trend disease patterns and match them with drug requirements and then focus surveillance efforts for substandard based on expected demand. Further, more innovation should be encouraged to adopt a more preventive than reactive approach. The common place mobile phone should be brought to the center of tactics to rid the market of substandard products.

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