

**THE EFFICACY OF THE LAW AND REGULATORY MECHANISMS IN
COMBATING COUNTERFEIT DRUGS IN TANZANIA**

**THE EFFICACY OF THE LAW AND REGULATORY MECHANISMS IN
COMBATING COUNTERFEIT DRUGS IN TANZANIA**

By

Phoibe Clifford Magili

**A Dissertation Submitted in Partial Fulfillment of the Requirements for Award of
the degree of Master (LLM) of Mzumbe University**

2013

CERTIFICATION

We, the undersigned, certify that we have read and hereby recommend for acceptance by the Mzumbe University, a dissertation/thesis entitled **THE EFFICACY OF THE LAW AND REGULATORY MECHANISMS IN COMBATING COUNTERFEIT DRUGS IN TANZANIA** in partial fulfillment of the requirements for award of the degree of Master of Commercial Law of Mzumbe University.

Signature

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Internal Examiner

Accepted for the Board of

.....

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DEAN/DIRECTOR,

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DECLARATION

I, Phoibe Clifford Magili I declare that this Dissertation which hereby submitted for the award of Masters of law degree (LLM)in commercial Law at Mzumbe University is my own original work and that it has not been previously submitted and will not be presented to any other university for a similar or any other degree award. Other works cited or referred to are accordingly acknowledged.

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Thank you May God blesses you all.

DEDICATION

I would like to dedicate this work for my loving husband Emmanuel Salufu for his understanding, support and encouragement during the entire period of my study.

LIST OF ABBREVIATIONS

ACTA	-	Anti Counterfeiting Trade Agreement
COSOTA	-	Copyright Society of Tanzania
EAC	-	East African Community
FCC	-	Fair Competition Commission
IP	-	Intellectual Property
IPR	-	Intellectual Property Rights
IMPACT	-	International Medicine Products Anti Counterfeiting Task
TRIPS	-	Trade in Related Aspects of Intellectual Property Rights
TFDA	-	Tanzania Food and Drugs Authority
WIPO	-	World Intellectual Property Organization
WHO	-	World Health Organization
WTO	-	World Trade Organization.

ABSTRACT

Counterfeit drugs have been a problem that has for years now been a leading problem in developed and developing countries. It is now at the point that universal abolition appears to be unachievable and a challenge not only to the world but also in Tanzania.

The laws and their regulatory mechanisms entrusted are examined and the researcher critically assesses them to see if they are effective to combat counterfeit drugs. For this purpose the researcher has selected Dar es salaam as a case study for easy accessibility of information. Interviews were conducted and questionnaires were distributed to the public, the authorities responsible and drug/medicine dealers. The researcher findings are then related to the overall effectiveness of the law and their regulatory mechanisms by studying their strengths and weaknesses in combating counterfeit drugs. The findings indicated that the law and their regulatory mechanisms are not effective in combating counterfeit drugs thus explains the growing business of counterfeit drugs in the country.

The question of how the law and their regulatory mechanisms can be more effective in future is considered. And the researcher recommends that the laws needs reviews and more amendment and in regulatory mechanism there is need to establish special institutions framework responsible to implement the law and that there should be clear regulations that provide specifically the role of each institution.

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CHAPTER ONE

INTRODUCTION TO THE RESEARCH

1.0 Introduction.

Counterfeit drugs are part of the broader phenomena of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source. There is no universal definition of counterfeit drugs, and the legal definitions vary from country to country.

WHO defines a counterfeit pharmaceuticals product as a product that is deliberately and fraudulently mislabeled with respect to identity or source. The definition applies to both branded and generic products. According to WHO definition, counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging.¹

The Tanzania Food, Drugs and Cosmetics Act² defines a drug to be counterfeit if it is manufactured under a name which belongs to another drug, it is an imitation of or is a substitute for another drug. It is also the label that bears the name of a fictitious or non-existent company, the substitute of wholly or in part by another drug and purports to be a product of a manufacturer of whom it is not truly a product.

Counterfeit medicines pose a significant danger to public health in developing as well as developed countries. Counterfeit medicines may be distributed through different channels such as government and private hospitals, pharmacies or other legitimate or illegitimate distributors. Licensed distributors, pharmacists, health care providers or

¹ Counterfeit Drugs: Guidelines for the development of measures to combat counterfeit drugs. Geneva, World Health Organization,

²No 1 of 2003.

patients may be unable to detect or differentiate between counterfeit and genuine medicines.

According to the World Health Organization (WHO), counterfeit drugs could make up as much as half of the global pharmaceutical market, with the largest share of fake products circulating in the developing world where regulation and enforcement capacity is comparatively weak. Although the basis of this estimate is unclear, the figure is especially alarming given the narrow definition of “counterfeit” used by the agency. However, it is clear that counterfeit pharmaceuticals remain one of the world’s fastest growing industry. Recent trends suggest a massive increase in counterfeit drug sales to over \$70 billion globally in 2010.³ This is an increase of more than 90 percent from 2005. Although the counterfeiting of, and trafficking in, all manner of products is on the rise globally including currency, documents, software, and electronics no other bogus product has the capacity to harm or even kill its consumer as do illicit pharmaceuticals. Additionally, most other counterfeits are not quite as lucrative.

The problem is more pronounced in countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement is weak. It is estimated that as many as 20 percent of the annual deaths from malaria worldwide may be the result of taking ineffective drugs. A recent study in *Lancet* concluded that up to 40 percent of artusenate (the best medicine to combat resistant malaria today) products contained no active ingredients.⁴

The factors facilitating the occurrence of counterfeit drugs vary from country to country. However, the most common factors are considered to be lack of legislation prohibiting counterfeiting of drugs, weak penal sanctions, weak or absent national drug regulatory

³UNODC, *The Globalization of Crime: A Transnational Organized Crime Threat Assessment*, 2010, p. 187.

⁴Robert Cockburn The global threat of counterfeit drugs: Why industry and Governments must communicate the dangers. *PLoS Medicines*, 2005,302-308.

authorities, weak enforcement of drug laws, shortage or erratic supply of drugs, lack of control of drugs for export, trade involving several intermediaries and free trade zones, sale of drugs over internet, corruption and conflict of interest

Drug faking is a threat to intellectual property rights let alone a global public health problem, because the effects can be felt from both the country of manufacturer to the recipient countries. Hence, national measures for combating fake drugs in countries might be insufficient because of the extent of the problem.

Tanzania is not an exception in the problems of fake drugs. Tanzania Drug Authority has reported the presence of counterfeit drug several times. For instance in 2009 the Eloquine (Quinine Sulphate) as malaria drug which was labeled to have been manufactured by Elys Chemical Industries Ltd of Kenya but in fact was not manufactured by the said industry Force.⁵

Combating counterfeit in Tanzania is dealt through the Merchandise Marks Act which was enacted in 1963 and came into operation in 2005. The said Act was amended in 2007 which enabled the enacting of merchandise Marks Regulation in 2008, Among the things established by the Regulation is interdepartmental Task force to implement the Act, of which combating of counterfeit drugs was vested to Tanzania Food and Drugs Authority (TFDA). The FDA is a regulatory body under the Ministry of Health and Social Welfare which is responsible for regulating the quality and safety of food, drugs, cosmetics and medical devices. It is established under the Tanzania Food, Drugs and Cosmetics Act⁶, which repealed the Pharmaceutical and Poisons Act⁷ and established the Pharmacy Board and Food Control of Quality Act.⁸ The TFDA, a semi-autonomous body, became operational on 1st July 2003. Other relevant Authorities are the Fair

⁵ www.tfda.tz. Accessed 1st March 2013

⁶ Act No. 1 of 2003

⁷ ACT No. 9 of 1978

⁸ Act No. 10 of 1978

Competition Commission (FCC) is an independent Government body established under the Fair Competition Act⁹, Tanzania Revenue Authority (TRA), Tanzania Bureau of Standards (TBS) and the Police.

1.1 Background of the Problem.

Counterfeit has been a problem since intellectual property laws were firstly widely enacted in the nineteenth century and well before that as well. The problem started and existed way back but in low level. With advancement of technology the problem began to have an impact on society as a whole and not only in products such as clothing, computer programs and films but they are also major threats in industries such as pharmaceuticals.

Increasing international trade of pharmaceuticals and sales through the Internet has further facilitated the entry of counterfeit products into the supply chain. In a report published by WHO for the period 1999 to 2002, it was concluded that the largest numbers 28 percent belongs to antibiotics. Due to lack of control and monitoring, the menace has now spread to ant HIV drugs. In 2009 -2010 several counterfeit drugs found their way to Africa labeled as being made in India.

Alarmed by the problem at national level and international level countries have tried to tackle the problem using the Intellectual Property Rights laws but due to its nature it has brought little results hence pushed World Health Organization (WHO) to take the role in highlighting the issue of counterfeit medicines and inform governments about the nature and extent of counterfeiting. However there have been debates in some countries strongly contend that counterfeiting is principally an issue of intellectual property, and expressed their concern that the WHO, by using the term ‘counterfeit’ and providing the secretariat for IMPACT (International Medicine Products Anti Counterfeiting Task) was becoming involved in the enforcement of privately owned intellectual property rights

⁹ Act No. 8 of 2003.

without the endorsement of all member states.¹⁰ Rather in 2010 at WHA (World Health Assembly) they argued that the WHO's role should be to combat substandard drugs of whatever origin as part of its mandate to protect public health.

Most African nations including Tanzania and developed countries support WHO's role as the secretariat of IMPACT. On the other hand, most South American and Asian nations are vigorous opponents of its involvement as they are the leading producing countries of these medicines thus likely to lose their market.¹¹

Since its growth counterfeit has been having its way mostly where the laws and the regulation of the problem are weak. Few countries have tried to make laws which would deter the problem and get good results. For instance, US stiff penalties on counterfeit drugs has stood as a great measure in deterring this problem. However, recently African countries have become a big market for counterfeit drugs due to poor or no effective laws and regulatory mechanism in place.

In Tanzania, the problem of counterfeit drug has grown higher especially where laws were weak and more unserious especially in 1990's where there were no at all sufficient laws to deal with the problem. In 2000's onwards laws concerned were amended and other re-enacted but there has always been a loophole that give way to the problem to keep flourish hence counterfeit drugs still flow largely to Tanzania.

1.2 Statement of the Problem

Drug counterfeiting is a particularly insidious threat in Tanzania. The most significant attempt to respond to the emerging threat of counterfeit drugs was enactment of proper laws both IPRs laws, other alternative laws and formulation of a regulatory mechanisms

¹⁰ Sagarika. (2010) TRIPS, WTO IPR: Counterfeit drugs intellectual property rights journal Vol 15 pg10

¹¹ Pecoul, B., Chirac, P., Trouiller, P., & Pinel, J. 1999, 'Access to Essential Drugs in Poor Countries: A Lost Battle; Wall Street Journal 24 Aug. 2001,

that would ensure enforcement and implementation such as establishment of authorities to oversee the objective of the law. there were also establishment of many mechanisms like counterfeit taskforce ,training officials responsible for proper regulation of counterfeit drugs and securing the country from counterfeit drugs supply chain.

The law and their regulatory mechanism were meant to control the problem of counterfeit drugs. It was intended to remove the risk and to create a free counterfeit drugs country. Yet since their enactment and establishment the law has essentially brought tangible results and hardly been enforced largely because the presence of counterfeit drugs has been reported and the impact is felt around the county.

The law has failed to create a secure drug supply chain as punishment for drug counterfeiting and liability for distributing these drugs is weak. Taking IPR-based approach for instance, basing on laws such as the Merchandise marks Act¹², the trade and Service Marks Act¹³ is not satisfactory for combating the counterfeiting of medical products. Those covering other infringements of intellectual property rights, are generic in application and not specifically or even particularly directed at medicines, they are designed to protect and enforce private rights, and the rights holder is generally responsible for pursuing potential infringers in the civil court.

There's no effective legal framework as these laws lack harmonization and proper coordination with their regulatory authorities that enforce them. The laws made and their regulatory mechanisms are weak and yet lightly enforced thus the quality, safety and efficacy of imported or locally manufactured drugs cannot be assured, the penalties given are also unsatisfactory to combat counterfeit.

This research therefore examines the efficacy of the law and regulatory mechanism in combating counterfeit drugs and the obstacles that hinder the successfully combating of

¹² Act No. 19 of 2007

¹³ Act No 326 of 2002

the problem and suggest some effective measures and solutions in dealing with the problem.

1.3 Objective of the Study.

The objective of the study is to examine the efficacy of the law and regulatory mechanism frameworks in Tanzania in the efforts made to combat and control the circulation of counterfeit drugs and to find out what gaps need to meet and to make recommendations there upon.

Specifically the researcher has the following objectives.

- To review and analyse existing laws, rules and policies responsible in controlling counterfeit drugs
- To examine the efficacy of regulatory mechanism in Tanzania in combating counterfeit drugs.
- To recommend reforms for efficient and positive results oriented legal framework.

1.4 Significance of the Study.

The study is relevant to academics and researchers as it will build on what has been written and provide new insights, knowledge and lay foundation for other coming researcher interested in this area. It is also important to the law reforms and policy makers as it will contribute to the current knowledge base on the connection between counterfeit drugs legal framework and actual problem and to also improve the competitiveness of counterfeit drugs regulation in Tanzania.

1.5 Literature Review.

The issue of counterfeit drugs is the global problem thus various authors from different countries have written on this issue in different perspectives. However the writings on this issue have been largely divided between those who support the war against counterfeit drugs and those who opposes. Since researcher's main intention is to

examine the efficacy of the law and regulatory mechanisms in combating counterfeit drugs then only the studies relevant are going to be discussed below.

Ali Faji¹⁴ in his book *A Comprehensive Guide to Toxicology in Preclinical Drug Development* has attempted to discuss the efficacy law and regulatory mechanisms in combating counterfeit drugs. He discusses some major factors which bars effort of law and regulatory mechanisms in dealing with the problem. One of the factors he is pointing out is growth in technology. He argues this factor present even more of regulatory problem now than before and that if the regulatory mechanisms are not updated it will be a waste dealing with the problem. He Further urges how law is structured sometimes affect the operation of regulatory mechanisms as they cannot take instant actions like seizing and destroying the drugs until they obtain order allowing to act as such, while at the same time the problem could be growing out of hand. Lastly he argues that as day pushes forward new weaknesses and indequences of the law are identified hence the present law doesn't adequately address the problem. The researcher agrees with the author and since study has been conducted in western countries the researcher wants to research in Tanzania and see if there are other findings constraining the efficacy.

Christopher Geiger¹⁵ in his book *Criminal Enforcement of Intellectual Property* argues that IP laws are ineffective in combating counterfeit drugs as it is difficult in calculating damages in cross border trade. It is difficult in controlling digitalized products. He contends that the danger of protection of victims rather than the infants of victims is of less relevance in an Intellectual Property realm. The researcher wants to draw attention to the importance of reforming and sharpening Intellectual Property laws against counterfeit so as to win the battle against counterfeit drugs.

¹⁴ Ali Faji. (2013) *A Comprehensive Guide to Toxicology in Preclinical Drug Development* pg 708.

¹⁵ Christopher Geiger (2012) *Criminal Enforcement of Intellectual Property* pg137.

Jay Abnese¹⁶ points out the effect of counterfeit drugs and the way it has dominated the market in many developing countries, mentioning in Nigeria 80 percent of drugs in major pharmacy stores are counterfeit and urging the ineffectiveness of the law and regulatory mechanisms to be the reason. He also poses questions like should IP Laws distinguish between different forms of counterfeit? Should general warfare counterfeit drugs be given greater consideration than economic benefit as the IP laws in that area are ineffective? .The study is speaking generally about Africa while the researcher wants to focus specifically in Tanzania and quite pose the same questions as to whether the IP laws should be more strict in this kind of counterfeit than other kinds.

Richard Abood¹⁷ contributes in this area that legislation and laws enforcement face great difficulties in eliminating the operation of rogue internet pharmacies as they are not structured well enough in way to eliminate the problem in online realm and explains that the case being so in 2010 global market for Counterfeit drugs industries has increased to be worth between US\$75-200 billion per year hence causing global threat to consumers. The researcher agrees with the author and further wants to research on ways that the laws and regulatory mechanism can be reformed so as to be able deal with the problem even online.

Naccotic control Board¹⁸ in their report of 2006 by United Nations highlights the effort made by various countries in Africa such as South Africa to improve drug control mechanisms by training law enforcement mechanisms officials on the fight against drug trafficking and providing them with skills and expertise related to drug identification .It further presents that despite the effort still many countries in Africa lacks appropriate and updated legislation qualified human resources and well structured drug control mechanism thus causing combating action of these drugs to be of limited impact.

¹⁶ Jay Abnese (2009) Combating Piracy Intellectual Property Theft and Fraud pg78

¹⁷

¹⁸ International Naccotic control Board, United Nations Report 2006.

Charles Cliff¹⁹ provides for controversial in the definition of counterfeit drugs by different countries in the world as a factor hindering efficacy of laws and regulatory mechanisms in combating counterfeit drugs. He argues that the controversial poses dilemma as to whether criminal or civil penalties to be sanctioned. The absence of certainty of the legal validity until tested in court of law and impossibility of law enforcement agencies to determine when there is a problem leads to lack of ability to control what appears on the market.

He further argues that failure to reach agreement on the definition hampers meaningful constructive policy and affects the ability of international collaboration to the effective action against producers and distributors as well as causing negative implications for how national legislation is constructed and the penalties applicable thereto. The researcher aims at exploring whether also in Tanzania colliding definitions of counterfeit drugs opens more doors for counterfeit drugs.

Robert Cockbu and Paul N Newton²⁰ are of view that along with pharmacists, health workers, and governments, needs to extend the “behind the scenes” fight against counterfeit to a public collaborative approach with a legal responsibility to report suspected counterfeits to drug regulatory authorities. In a similar way to the reporting of notifiable infectious diseases. The drug regulatory authorities, accountable to the consumers of drugs, should have a statutory duty to investigate and disseminate the information, with the interests of patients as the prime concern. Drug regulatory authorities in economically poor countries will need additional financial support.

¹⁹ Charles Cliff. Combating counterfeit, Falsified and substandard Medicines 2010.pg6

²⁰ Cockburn. The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers , Published 2005.pg36

Cockburn R ²¹ explains that most data on the epidemiology of counterfeit drugs are kept secret by the pharmaceutical industry and by governmental agencies. Drug companies employ investigators to track down and facilitate the shutting down of counterfeit industries, but this occurs very much in private. He also argues that there are no reliable accessible databases whereby health workers or the public can access current details of which products are being faked in a locality. It is obviously correct that information on anti-counterfeiting strategies and the sources of undercover intelligence should not be released, the researcher believes that the information on what drug is being counterfeited, and where, should be public knowledge but same practice has happened repeatedly in Tanzania leading consumers to suffer, thus the researcher is interested to explore further the reasons for that.

Glaxo Smith Kline case²² of the fake Halfan syrup cases highlight the importance of communication and cross-border cooperation, and the need for industry and governments to inform neighboring countries when counterfeit drugs are found, the researcher believes failure to control cross borders has geared most the inflow of counterfeit drugs thus intends to examine the effectiveness of regulatory mechanisms in controlling cross borders.

²¹ Cockburn R. Crime, fear and silence: Making public the fake pharmaceutical drug racket [presentation]. First Global Forum on Pharmaceutical Ant counterfeiting; 2002 September 22–25; Geneva, Switzerland. 2002

²² Canada v. Glaxo SmithKline Inc 2012 SCC 52.

1.6 Research Hypothesis.

The researcher is of the view that there is deficit in the regulation and controlling of counterfeit drugs in Tanzania which explains the failure in achieving the objective for combating counterfeit drugs

In addition to that the following questions will guide the researcher in answering this vital issue.

1. What is the state of the laws and the regulatory mechanism in combating counterfeit drug in Tanzania?
2. Whether the IPRs laws are equipped enough to address the problem of counterfeit drugs effectively.
3. What are the recent measures and efforts made to deter the alarming problem of counterfeit drugs?

1.7 Research Methodology

1.7.1 Research Design.

The study is going to employ case study design. A case study is fairly exhaustive method aiming at studying deeply and thoroughly. It is due to the fact that a case study provides more realistic responses than a purely statistical survey.

1.7.2 Area of Study

The study will be conducted at Dar es salaam region. Two criteria are used to select the area of the study. Firstly it is the region with relatively high counterfeit drugs trade concentration. Secondly, the researcher targets the regulatory authorities. The two criteria are mainly meant to enable the researcher capture adequate information.

1.7.3 Tools of Data Collection.

This research is a qualitative in nature; data will be collected by using the following methods namely, documentary (library research), interview and questionnaire

- **Library Research**

In Library Research, several documents will be consulted for the purpose of this study from different published and unpublished records and materials including principle and subsidiary legislations, prominent textbooks, pamphlets, law journals, periodicals and different reports. In the study the researcher will use the Libraries of Mzumbe University, University of Dar es Salaam, and the Open University of Tanzania. The researcher chose these libraries due to the fact that they are equipped with materials concerning the study and they are accessible in term of distance, cost and time for the researcher. This method will enable a researcher to know what have been done by other researchers concerning the problem.

- **Internet Search**

The researcher will have to access to the internet in order to download several materials which on one way or another relate to the study.

- **Interview**

The researcher will interview and discuss with the group of people who are directly involved in combating counterfeits. The researcher will interview ordinary citizens of Tanzania, officials from the regulatory authorities concerned. Furthermore the researcher will interview medicine distributors/seller. The interview was used to know the emotions and obtain data from the primary source directly and since the interview used open ended questions it will raise a good debate as far as required data is concern.

- **Questionnaire Method**

Questionnaire is one of the means of collecting data. The researcher provides questionnaire in order to seek information from law enforcement officials like, magistrate, lawyers and TFDA, TBS, FCC officer and individuals from different walks of life. The researcher will get data as to why despite the agencies and regulation still the flow of counterfeit drugs is high. The researcher chose that sample due to the fact that on one hand or another they are the one who deal with the issue. The reason for selecting this type of data collection instrument is to get response from the respondents even if it is hard to get time to interview them. Through questionnaires researcher can get detailed information from respondents.

1.7.4 Population Sample.

Population sample refers to the group of people who will be identified or rather selected by the researcher in data collection. The sample the researcher is using is purposive targeted only to targeted groups from whom the information will be collected.

1.7.5 Data Analysis

The data collected from interviews, observation and internet search will be analyzed through descriptions and statistical methods.

- **Descriptions Method**

Description method will be used to analyze non numerical data. Under this methods data were described so as obtain their relations and make conclusion thereto.

- **Statistical Method**

Statistical methods will be used to analyze numerical data which will be obtained from the agencies responsible. Here statistical methods such as graphs and charts will be used to analyze data.

1.8 Scheme of Presentation.

This work will be divided in five chapters:

Chapter one relate to the background of the study and its justifications. It will also focus on the objectives of the study, methodology and limitation.

Chapter two will focus on the regulations/controlling of counterfeit drugs, highlighting existing international effort for combating counterfeit drugs and conduct an examination of challenges in combating counterfeit drugs.

Chapter three will present challenges in controlling counterfeit drugs. The laws governing counterfeits drugs in Tanzania will be critically examined in the interest of descending whether they are effectively addressing the problem of counterfeit drugs. The regulatory mechanism will also be examined to see if they are empowered well to act in such capacity and cases will also be looked at to see if have wider view on the treatment of counterfeit drugs.

Chapter four will present the findings of the study critically discuss the challenges of the legal and regulatory mechanisms for combating counterfeit drugs in Tanzania and other challenges will be discussed here to justify the need for legal and regulatory reforms.

Chapter five which will cover the conclusion and recommendations will summarize the findings and draw conclusion that will be recommended for implementation

CHAPTER TWO

CONCEPTUAL AND THEORITICAL FRAMEWORK FOR EFFICACY OF THE LAW AND REGULATORY MECHANISMS OF COUNTERFEIT DRUGS

2.0 Introduction

This chapter explains the regulation of counterfeit drugs. It seeks to explain different means of drug counterfeiting and effects on brand owners and consumers. The chapter looks at international efforts level to regulate counterfeit drugs. Examination of challenges facing multinational accord over regulation of counterfeit drugs will also be conducted.

As pointed out earlier in chapter one Counterfeiting does not have universal recognized definition, but deliberate deception is the common theme. Counterfeiting typically involves one or more manufacturing, steps in producing, packing or modifying a pharmaceutical product for the purpose of deceiving either the immediate buyer or the end user.

2.1 Counterfeits in Intellectual Property

In the world of intellectual property, counterfeiting tends to have a precise meaning related to trademark Violation or patent infringement. For instance, the WTO glossary defines it as unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods. This reflects, although not entirely accurately, the definition reached in the WTO TRIPS Agreement, which refers only to 'counterfeit trademark goods. 'counterfeit trademark goods' shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and

which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation. Thus counterfeiting in the WTO and the TRIPS Agreement refers specifically to unauthorized use of a trademark. It is the responsibility of the owner of the trademark to enforce it against infringers. Hence brand owners may seek civil remedies. There are many cases where civil proceedings have been launched to prevent the sale of medicines with similar brand names under the Trademark Act, for infringement and/or on the grounds of 'passing off'. For Instance, in *Canada v. Glaxo SmithKline Inc*²³ a successful order in gaining an injunction was granted against Unitech Pharmaceuticals preventing it from selling medicines under the brand name FEXIM and with similar packaging to its own registered brand PHEXIN. Other cases arise specifically in respect of medicines because brand names may be derived from the generic name of the drug.

Drug counterfeiting can be done in number of ways for instance could be carried out by hand in squaded backstreet or could be taken on an industrial scale in pharmaceutical plant. Counterfeiting is therefore not a uniform activity. Herein below are some of the outputs and forms of counterfeiting drugs.

2.1.1 Counterfeit Product in Packaging

This is the most intuitively obvious form of counterfeiting and one that the general public most rapidly associates with fake drugs .In packaging both the packaging and its contents are entirely false and designed to deceive consumers. Pharmaceutical packaging has traditionally been fairly simple in form and content.²⁴A variation of this tactic is packaging of drugs with a deliberately incorrect country of origin. Repacking also allows the replacement of use by dates to enable expired, stolen or withdrawn stock fraudulent resold.

²³ 2012 SCC 52

²⁴ Perry G.2012 Policy Economic and Countrmeasures pg46

2.1.2 Using Genuine Package with Counterfeit Products

This is the retrieval and reuse or illegal recycling of dosage. Since security feature on the original product are often found on the packaging rather than the medium itself reusing legitimate packs with the fake contents has proved an effective way to conceal counterfeits. Examples in the case of *Fagan V Amersource Bergen Corp*²⁵ genuine labeling was used on fake medicine indicating higher dosage where the patients was given wrong dosage and the patients relapse due to these misrepresentation. Discarded pill bottles are refilled with fake pills, genuine secondary certain boxes receive false blister pack and vaccine vials are refilled with tap water.

2.1.3 Relabeling of Expired or Withdrawn Stock.

One of the key safety advances in drugs safety in the last 100 years is the system of use by dates or expiry date. This simple data point gives professional and consumers critical information on the safety of the product. The use of date for pharmaceutical must be supported by scientific evidence of shelf life, usually gained through the consuming and costly stability studies. For unscrupulous criminals, expired medicines represent a golden opportunity.²⁶ The products are original, in original packaging from legitimate but are expired, what counterfeiters do here is to change numbers and resell the product to the consumers.

2.1.4 Relabeling of Low Dose Products to indicate more Expensive/Higher Doses.

In order to tailor the dose of the drug to needs of individual, Medical practitioner and patients, many pharmaceuticals are produced in several different strength or dosage. In drugs packaging until quite recently it was common for different dosage strengths of the same drug to be resold in almost identical packaging with the only obvious packaging counterfeiters discovered that simply by changing or altering the label on a genuine low dose product to that for its high dose equivalent. They could produce fantastic profit

²⁵ 2006. Suppra 2nd 198

²⁶ Perry G loc.cit

with minimal effort.²⁷This is seen again in *Fagan V Amersource Bergen Corp*²⁸ where lower dosage was labeled indicating higher dosage with the intent to mislead and obtaining more profit.

2.1.5 Dilution

In this case the counterfeiters refill empty packaging or they dilute product in its original packaging. The relabeling or uplabelling of drugs discussed above is actually just a more sophisticated form of dilution. In that the actual dosage strength is lower than the labeled dosage. Although in the case of uplabelling the injected material itself is not tempered with. Dilution of medicines pays counterfeiters much and its simplest way to achieve this is to physically dilute the relatively expensive medicine product with a change alternative. Sold dosage form may be diluted at a point of manufacture.²⁹ For example in 2002 diluted counterfeit of the children's malaria syrup Halfan was discovered, which had been diluted to 40-percent strength. The syrup is a lifesaver for serious cases in Africa. The diluted drug was discovered on sale in a pharmacy in Kumasi, Ghana's second-largest city. At 40 percent the desired effect could not be reached particularly for children easily led to losing their lives.

2.1.6 Using of Counterfeit Documentation

Counterfeit of drugs and packaging allows fake products to enter the supply chain. But in order to sell large quantity of product and to insert it into legitimate channels counterfeit use counterfeit documentation such as import licenses, regulatory clearance and quality document which of another original manufacturer so that they look genuine in the eyes of the law.

²⁷ Mark D. Pharmaceutical Ant Counterfeiting. Combating the danger from fake Drugs pg40

²⁸ Fagan Loc cit

²⁹ Perry G loc cit

2.1.7 Diversion

Diversion is the movement of branded goods across international markets, contrary to the wishes and legal rights of the brand owner, Diversion product are genuine but the essential market destination is not the one intended by the manufacturer. Counterfeiters divert pharmaceuticals which were part of aid and sell them at higher expensive price. This is also evidenced in *Fgs Constructions Inc v Michael Carlow*³⁰ where medicine that were to be shipped to Africa to be sold at a lower price were returned back to US secretly and sold at very high cost.

2.2 Effects of Drug Counterfeiting

Counterfeit drugs can lead to several consequences. These can be either of economical nature or concern the health and well-being of patients³¹. The former is effecting all stakeholders from pharmaceutical industry to the patients whereas the second effects the national health systems and of course mostly and most prominently the patients.

Pharmaceutical companies lose money due to counterfeits when their products are forged. This holds true profit for the developed states where most of the innovative products originate as well as for some of the less developed. At national levels and health wise the effect of counterfeit drugs is much more severe in developing countries than it is to developed countries due to financial constraints.³²

The consequences for patient health are seldom severe in developed countries and cases are known where counterfeit medicines led to the death of patients, For instance the issue of Heparin case in US in 2007 that possibly led to the death of 81 patients.³³ Due to

³⁰ 1995 ,95-1164

³¹ Hughes N. Fighting Fakes: How Can Drug Makers Stem the Tide of Counterfeit Medicines? Wall Street Journal Europe 2 August 2006.

³² Cockburn. The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers , Published 2005 March 14

³³ This incidents happened in 2007 where at least 81 people died after consuming herperin medicine,US Food and Drugs Authority was alerted of the problem after the death of three people,in entire 3 previous years Herperin had been used and casing no problem to people until Jan 2007-May 2008 where it led to deaths,blood pressure and excessive sweating,a Chinese US base d pharmecutical Company was discovered to be manufacturing using processed herpin which had almost no scrutiny regulatory control.

the high amount of counterfeits in the supply chain and due to the problems to detect the effects of counterfeit drugs, many cases may not be known though. Corporation affected by produced drugs counterfeit denotes loss of profits and sale strategies which can reach immense demolition in the first instance. This is due to perfect communication and product and logistic counterfeited drugs enter market at the same time as original.

Besides having impact on brand owners drug counterfeiting has big impacts on consumers as well. All other counterfeit have impacts on consumer's life as they deceives consumers and removing the trust of the real brand owners. But there is a big difference between what is used on the outside and what is put in the inside. The impacts of counterfeit drug to consumer are far worse than others because it endangers people's health and put their lives between death and life. That is no wonder why US choose life imprisonment sentence as punishment for drug counterfeiter and China putting a death sentence for those dealing with counterfeit drugs.³⁴This explains why WHO not an Intellectual Property entity still take charge of the situation. It is because the impact of counterfeit drug is far much worse than other types thus leading to permanent disabilities and death.

For many goods, such as clothing or accessories, the effect of counterfeiting is principally financial and economic. Employment and income may be diverted from brand-name manufacturers to counterfeiters and consumers may benefit from lower prices or lose from poor-quality imitations. Essentially, income is redistributed between brand owners, counterfeiters and consumers.

The extent to which the economic losses fall on the brand owner is undisputed. In the case of food, medicines, cosmetics and some other goods, counterfeiting can also pose a serious threat to human health because products are likely to be either substandard or

³⁴, Susan Thaul. How FDA Approves Drugs and Regulates Their Safety and Effectiveness CRS Report .June 2012 Pg 51

contain positively dangerous components or ingredients. This kind of counterfeiting is thus qualitatively different form, for example, a fake Rolex watch. Counterfeit medicines pose a considerable threat to health. Although detailed knowledge of their prevalence and impact on human health is limited, they can fail to cure, promote antimicrobial resistance and ultimately kill. The threat from these medicines is probably growing, particularly in poorer countries with weak regulatory mechanisms and poorly monitored distribution networks.³⁵

2.3 Regulation of Counterfeit Drugs

Recognizing the nature of the problem the laws and regulations of counterfeit drug are very important tools in order to put counterfeit drug to an end. However the end result has not always been so encouraging. The expectations placed on law and regulatory authorities have brought negative result almost worldwide. The researcher is of the view considering the stiffness of the problem that there is a need of sharp laws and effective regulatory authorities to regulate counterfeit drugs. The central issue is how to effectively regulate. Some scholars have argued that this is due to poor economy and regulation of distribution chains and other suggest international accord to fight the problem hence will be easier to manage the end points.

2.4 International Initiatives in Combating Counterfeit Drugs

Counterfeiting has been described by many studies as the world's second oldest profession because for as long as people have been coining and faking money, other have been trying to fake drugs, hence as long as pharmaceutical manufacturing remains lucrative and dynamic industry with large price differentials, there will be drug counterfeiter working to exploit the high demand, no matter what the human toll may be.³⁶ While little can be done to remove the profit motive, the world can work towards limiting the effects on global health by reducing the opportunity of counterfeiters to infiltrate national drug supplies and by punishing transgressors sincerely.

³⁵ Perry G. Policy Economics and Countermeasures (ILM Publication 2012) pg 40

³⁶ Wertheiner AC (2005) Defining the problem and finding the solution, expert opinion pg 5

Globally controlling counterfeit requires the emergence of adequate regulatory and quickly control regime as largest share of fake products circulating where regulation and enforcement capacity is comparatively weak .This first requires that the international community become aware of the threat posed by counterfeit drugs and motivate various public and provide stakeholders to work together toward a multilayered ant counterfeiting strategy.

Intellectual Property Rights (IPRs) laws deals with the problem worldwide using TRIPS WTO agreement. The Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS Agreement) sets the standards for intellectual property protection in the world today. It came into force on 1 January 1995 and is binding on all members of the World Trade Organization (WTO). The TRIPS Agreement sets minimum standards in the international rules governing patents on medicines. Article 46 of the Agreement states that IP-infringing goods should be "disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed.It further states that "the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce. In other words, though there is no such thing as a single international patent law, TRIPS represents a harmonization of patent laws The agreement deals with counterfeit drugs thorough protection of patents by greatly strengthening and extensively harmonizing under the TRIPs Agreement.³⁷ However, as compared with other IP, patent rights are expensive to enforce. A final, enforceable judgment may not be obtained until years after a lawsuit is filed. Patent holders must prove in civil litigation that an alleged accused is making or selling a product that is described in the patent. This requires a detailed review of the patent document and correspondence with the relevant patent office. Frequently, technical experts are retained to opine on technical terminology and

³⁷ Antoinette Konski IP Strategies to Combat Distribution of Counterfeit Drugs pg3

the meaning of phrases or terms during that phase of such lawsuits. Only after that initial review is an allegedly infringing technology compared to the property right defined during the initial phase of the proceeding. So a patent can prevent others only from manufacturing, using, selling or importing products that are exact or close copies of patented technology. Rarely, however, are counterfeit medicines such close copies of the original. They seldom contain the same or the same amounts of a genuine patented formulation. Leading up to the TRIPS Agreement, the debate over increased protection for intellectual property largely centered on the pharmaceutical industry as the pharmaceutical industry is closely tied to the emotionally charged issues of public health and survival in developing countries, The demand for pharmaceuticals is price-inelastic over a wide price range Patent regimes differ most starkly across countries in the pharmaceutical sector, and pharmaceuticals are frequently targeted for explicit exclusion from patent and trade secret protection in developing countries.

The definition of counterfeit which also includes patent infringement has posed threat to many countries that it would form a basis of taking broader measures over patent infringement. In public health a broad definition of counterfeit medical product has raised few concerns that the mixture of IP definition will result in shifting the focus from quality safety and efficacy to IP infringement, in public health perspective such mixture together with broader measures by customs administrator will result in seizures at border and that this has to do more with IP violation and little with relevance to quality, safety and efficacy.

Public health concerns over IP protection of counterfeit drugs are based in cases were generics medicines were seized for being counterfeit after establishment of IPRs plus borders measures. This can be found in the case of shipments of Indian generic drugs destined for Venezuela being seized at Dutch ports on charges of counterfeit and patent infringement in Dec 2008, drugs seized were deemed to be of violation of intellectual

Property Rights ³⁸.Further the concern is that definition on counterfeit based on IP violation is wrong as it aims at protecting the IP holder and can result to national legislation aimed to protect IP holder and block access to medicine, while according to public health the term drug counterfeit is meant to ensure good, quality safe and effective medicine and has nothing to do with Patent protection.

Also there have been other critics of the TRIPS Agreement argue that its implementation will lead to higher prices. Although the expectation was that the effects would be most strongly felt by countries but the result has been the opposite and counterfeit drugs problem has become more especially in developing countries due to demand of cheaper medicine.³⁹

2.5 Other Efforts in Combating Counterfeit Drugs

WHO international conference in combating counterfeit drugs held a conference in February 2006 to promote collaboration and harmonization between international stakeholders. The result of this conference was the Declaration of Rome in which international community recognized drugs counterfeiting to be a serious criminal offence and a threat to global health and pledged to work together to address it through a new WHO Taskforce known as International Medical Products Ant-Counterfeiting Taskforce.⁴⁰

International organizations, developed and developing countries joined hand with WHO to create IMPACT to tackle the fake drug trade. WHO IMPACT fulfills its functions through five cohesive working groups which are the legislation group, the regulatory implementation group, the enforcement group, the communication group and technology group. The legislation group is aimed at developing and disseminating legislative

³⁸Carlos M.2010.Research handbook on Interpretation and enforcement of Intellectual undr WTO Rules pg 38

³⁹Brian D.Counterfeit drugs and National Security. Stimson Centre Report.Feb 2011 pg 8

⁴⁰World Health Organisation.2010.International Medical Products Ant Counterfeiting Task force WHO.Geneva. pg 33

principles to the government to promote the adoption of effective legislation for example the IMPACT General Meeting in Hisbon, calls for complementation and strength in legislation to protect public and personal health from being further damaged by counterfeit drugs. The regulatory group carries out responsibility in insuring effective legislation executes activities through guidelines and regulatory rules and collaboration among different stakeholders in the battle against counterfeit drugs .The group developed a counterfeit oriented revision of the WHO guidelines on good distribution practices focusing on securing drug distribution chain and strengthening measures to combat counterfeit drugs distribution.

The enforcement group plays an integral part in improving the coordination and communication among enforcement official in different countries and promotes a rapid exchange of information. Interpol and IMPACT trained a total of 350 law enforcement officers in 2008 have carried out a number of joint operations in Asia and Africa⁴¹.

The communication group within IMPACT develops campaigns and other education sessions targeted at patients, health professionals, Pharmaceutical supply chains, the media law enforcement agencies, government and other nongovernmental associations. The communication focuses in two main objectives which are raising awareness of the risk and promoting policy resolution produced by IMPACT.

Some countries such as China and India that are leading suspect of manufacturing counterfeit strongly contend that counterfeiting is principally an issue of intellectual property, and expressed their concern that the WHO, by using the term ‘counterfeit’ and providing the secretariat for IMPACT, was becoming involved in the enforcement of privately owned intellectual property rights without the endorsement of all member

⁴¹ World Health Organisation.2010.International Medical Products Ant Counterfeiting Task force WHO. Geneva.pg 21

states in the WHA. Rather they argued that the WHO's role should be to combat substandard drugs of whatever origin as part of its mandate to protect public health.⁴²

2.6 Challenges Faced in Combating Counterfeit Drugs Worldwide.

Worldwide combating counterfeit drugs has not been a smooth path as there are number of barriers that hinder the whole exercise to run amicably .Such challenges are discussed herein below.

2.6.1 Insufficient or Missing Regulations

Without the proper regulation of all aspects concerning manufacture, distribution and sale of drugs, the health market of a country cannot be secured with regard to counterfeit medicines. The problem of insufficient or missing regulations is wide spread. WHO estimates that 30% of all countries are missing drug control regulations or cannot enforce them whereas only 20% have well developed drug regulation systems. The remaining 50% show varying degrees of effectiveness and regulation.⁴³The issue is evidenced in Asia, Africa and other developing countries for example in South Asia 38 persons were killed of administered drugs which were below standard.89 people were killed in Hait 1995 after consuming drugs containing toxic substance, same evidenced in Nigeria where uncountable number of ant malaria and ant-cholera were evidenced to be in distribution in all pharmacies in Nigeria in 2000.⁴⁴

It is clear that even Western countries have to do more to prevent counterfeiting. Because of the overwhelming volume of global trade witnessed over the past decade, weak public health protections and enforcement in one country generate border enforcement challenges for even the most well-regulated public health system.

⁴² Charles Cliff. Combating counterfeit, Falsified and substandard Medicines, Defining the way forward. Nov 2010 pg 4

⁴³ World Health Organisation General information on counterfeit medicine(www.who.int/medicine/services_counterfet/overview)Accessed March 2013.

⁴⁴ UNODC: http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_Report_2009..

2.6.2 Insufficient law Enforcement and Insufficient Penalties

Insufficient law enforcement and insufficient penalties as well as missing regulations and weak authorities leads to the prospering of undesired counterfeit activities, insufficient law enforcement and insufficient penalties has led to this effect. Counterfeiters are not persecuted through corruption, because of insufficient resources, penalties are too low for deterrence, and this leads to the continuance of the problem. In South Africa for instance the penalty is 3years imprisonment and Rand 5000⁴⁵ which is approximately 900,000/Tshs, In Ghana⁴⁶ same has been complained that the profit counterfeiters make is too high while the penalties are too low to deter the problem and in Tanzania is 5million/= Tshs penalty and 2years imprisonment. These low penalties pose a real challenge in fighting against counterfeit drugs.

2.6.3 Insufficient or Missing Authorities

The regulations mentioned above have to be enforced on the market. To achieve this it is vital to have a working and effective authority in place asserting the necessary controls on new drugs before they are allowed to enter the market, on the local manufacture and the importation of drugs as well as on the distribution chain for pharmaceutical goods. Some countries around the world lack such an institution hence leading to a flourishing illegal market for counterfeit drugs.

Furthermore, the relevant authority also lacks a backup by suitable analytical laboratories to be able to detect counterfeits.

2.6.4 Lack of a Universal Definition of Counterfeit Drug

Lack of Global definition of counterfeit drugs, counterfeit drugs is not clearly defined world or recognized as crime everywhere. Different countries define counterfeit differently depending on how they perceive, this has caused confusion and debate among nationals hence the target in fighting counterfeit drugs is also different. For instance in IPRs the definition of counterfeit includes the violation or infringement of all

⁴⁵ <http://www.lafafsi.com/articles>.accessed May 2013

⁴⁶ Joyceline Sambira. Counterfeit Drugs Raise Africa's Temperature. May 2013 pg3

forms of IP thus includes patent in which counterfeit medicines fall but there is also another side which protest that and argue that counterfeit drugs cannot be measured by IP or Patent infringement as at their stand counterfeit is only if it lacks safety, quality and efficacy, as seen in the incidents in December 2008 where drugs heading to Venezuela from India were seized in Dutch for charges of being counterfeit and patent Infringement and concerns were raised that such approach will block access to medicines⁴⁷.

2.6.5 Conflicts of Interest among Countries.

There is a debate against ant counterfeit war, a protest from counterfeit producing countries against international ant counterfeiting initiatives. The protest countries avers that the war against counterfeit is first not the duty of WHO to be done as it is an IPRs agenda .But moreover these countries sees the overall efforts will close the door for generic drugs which are most used in developing countries which they purports to be fit for human use. These kinds of debates slow down the all exercise of fighting counterfeit drugs and provide an avenue for counterfeit to expand their trade. For instance Kenya's Anti-Counterfeit Act 2008 and Anti-Counterfeit Goods Bill of Uganda in 2008 has been subjects to lots of protest from drugs producing countries such as India that these laws will close the doors for more affordable drugs for developing countries and the laws were subject to amendment was also seen in famous Kenyan case of *Patricia Asero Ochieng and others V Attorney General*⁴⁸ where counterfeit law was ordered to be amended.

2.6.6 Existence of Extraterritorial Zones

Extraterritorial zones are substantially out of control of regulatory oversight and control and it is possible to manipulate goods and documentations that accompany them. Trade routes also tend to be less controlled than the rest of the territory of a country. Being less

⁴⁷ Carlos op cit pg 36

⁴⁸ 2009 KPN 407

regulated open special opportunities for the illegal market such as counterfeit drugs to have their way in other countries without being recognized.

2.6.7 The Internet

The Internet offers many opportunities to criminals willing to exploit them. It is possible to disguise the real identity, to easily reach a large amount of potential customers with mass spam emailing and presenting as a legal Internet pharmacy and to act globally. Patients, foremost in developed countries, seek an easy, prescription free way too cheap, maybe stigmatized or even illegal medicines. This combination leads to a high degree of counterfeits in the illegal Internet market⁴⁹. A pioneer of the Canadian Internet pharmacy business, Andrew Strempler, 38 years old, was sentenced in U.S. federal court in Miami to four years in prison for conspiracy to commit mail fraud in connection with the sale of foreign and counterfeit medicines to U.S.⁵⁰ customers. Law-enforcement officers and drug-company security officials say a routine challenge in pursuing Internet pharmacy crimes is that networks often span many nations and jurisdictions, and operators of Internet pharmacies in many cases don't break local law because they sell their wares overseas.

2.6.8 Lack of International Harmonization

The issue of counterfeit drugs has its roots in international level as the illegal trade involves transportation of drugs from countries to countries, however there is a lack of international harmonization that would help dealing with the problem from its roots, countries to join forces to fight this enemy still the force is divided between those who fully supports it and those who protest, hence pose a challenge in combating the problem.

⁴⁹ Albert. I. 2012 counterfeit medicine Policy, Economic and countermeasures pg 41

⁵⁰ Christopher Weaver. Former Internet Pharmacist sentence in Fake drugs case, US Today Newspaper Jan 9 2013

2.6.9. High Price and Demand of Medicine in the Developing Countries

High prices affect the prevalence for counterfeit drugs on two ways. First patients will tend to look for cheaper drugs and will rather be open for less trustworthy sources of the drugs they need. High drug price is of course a major incentive for counterfeiters. The same holds true for goods where the demand is higher than the supply, besides the fact that the price of the goods in question will also rise. Unmet demand is also a problem of especially rural areas in developing countries where official, legal channels cannot satisfy the customer needs in regards of pharmaceuticals

2.6.10 Extremely Fragmented Distribution Channels

These channels involve an unnecessary large numbers of transactions which increases the opportunity for counterfeiters to infiltrate the normal distribution system. Trade in pharmaceutical rarely takes place between the manufacturing country and the importing country. For example the counterfeit glycerin that killed more than 100 patients in Panama in 2006 was sold from factory in China to a trading company in Spain to Panama.⁵¹Such channel gives a way for counterfeit medicine to find their way easily in different countries.

⁵¹ www.nytimes.com/2007/05/06/world/06_poison.html. Accessed April 2013

CHAPTER THREE

AN OVERVIEW OF LEGAL, REGULATORY AND INSTITUTIONAL FRAMEWORK FOR COMBATING COUNTERFEIT DRUGS IN TANZANIA

3.0 Introduction

Chapter three critically examines the law governing regulation of counterfeit drugs in Tanzania. The aim is to see if there are sufficient to address the problem of counterfeit drugs and point out challenges. The laws related to regulation of counterfeit drugs since independence are examined and their amendments thereto. Details of challenges in regulating counterfeit drugs are presented under this chapter. Regulatory and institutional frameworks for regulating counterfeit drugs are examined. This is to see whether the authorities entrusted with dealing with this matter are competent in regulating and monitoring the overall objective of combating counterfeit drugs.

For this purpose therefore the researcher has formulated a specific question to answer the vital issue. Following the research objective the questions are formulated to guide to guide the study as herein below.

What is the state of legal and regulatory framework for combating counterfeit drugs in Tanzania

The aim of this question is to verify whether there is deficit in fighting counterfeit drugs.

3.1 Major Laws and Regulations in Combating Counterfeit Drugs

In Tanzania the major laws in combating counterfeit drugs basically fall into one category of IPRs laws which is the Merchandise Marks Act⁵² and Tanzania Food, Drugs and Cosmetics Act⁵³. After attainment of independence in 1961 Tanzania thought of

⁵² Act No 19 of 2007

⁵³ Act No 1 of 2003

taking an earlier step in war against counterfeit whereas in 1963 the Merchandise Marks Act⁵⁴ was enacted so as to fight all sorts of counterfeit in the country.

3.1.1 The Merchandise Marks Act

The Merchandise Marks Act was enacted in 16th May 1963 by the parliament of Tanganyika as Act No 20 of 1963. The enactment of this Act provided statutory assurance in war against counterfeit in general in the country. However such an expectation remained on paper because since its enactment the Act did not come into operation for some reasons known as delay in publication, since its enactment it took 42 year to come into operation. Thus during the time after independence The battle to fight counterfeit went in vain until 2005 when the Merchandise Marks Act⁵⁵ was brought into operation.

3.1.2 The Pharmaceutical and Poisons Act

Along there was Pharmaceutical and Poisons Act⁵⁶ which was enacted on 9th May 1978 as Act No 9 of 1978, It repealed the Pharmacy and Poisons Ordinance and provisions relating to drugs. The Act composed rules on controlling of the problem of counterfeit drugs. Section.51.⁵⁷ Prohibited false and misleading medicines which are calculated to mislead as to the nature, substance or quality of the product medicine appliance .The Act also provided a punishment of fine not exceeding ten thousand shillings for a person convicted with counterfeit drugs.

However in 2007 the Merchandise Marks Act⁵⁸ was amended and more strength was added to this legislation after taking into consideration the public critics as to the performance that law. The amendment gave new life to the law as now new provisions relating to powers of inspector, penalty and fine, seizure and proceedings as well as

⁵⁴ Act 20 of 1963

⁵⁵ Act No 1 of 2003

⁵⁶ Act No 9 of 1978

⁵⁷ ibid

⁵⁸ Act No 19 of 2007

enactment of a Regulation for better implementation of the Act were incorporated to sharpen its efficacy. Also in 2003 Tanzania Food, Drugs and Cosmetics Act⁵⁹ enacted to repeal the Pharmaceutical and Poisons Act of 1978.

3.2 Current Laws Controlling Counterfeit Drugs

Currently there are two main laws that deals with controlling the issue of counterfeit drugs, one is the Merchandise Marks Act⁶⁰ which is made to address all kinds of counterfeit products in the country including counterfeit drugs but also Tanzania Food Drugs and Cosmetics Act⁶¹ which is in charge for controlling the quality, safety and effectiveness of drugs and prohibiting counterfeit drugs. These laws are examined as herein below.

3.2.1 The Merchandise Marks Act

The current Merchandise Marks Act is a product of the Merchandise Marks Act of 1963 and the amendment thereto in 2007. This Law governs all sorts of counterfeit goods in Tanzania. This Act is to be read together with the Merchandise Marks Regulation⁶² enacted in 2008 which provide for practical strategies and mechanisms for implementation of the main legislation. The main aim of this law is to fight counterfeits and to provide protection to intellectual property rights owners.

The Act Merchandise Marks Act under S.49 empowers the minister to make Regulations for the better implementation of the Merchandise Marks Act⁶³ Through that power the Minister enacted the Merchandise Marks Regulations 2008 and were published in the Government Gazette of 20 June 2008. Unlike the main legislation which does not define counterfeit goods, the Merchandise Marks Regulation in

⁵⁹ opcit

⁶⁰ Act 19 of 2007

⁶¹ Act No 1 of 2003

⁶² GN 89 of 2008

⁶³ Act No. 19 of 2007

Regulation 2 defines counterfeit goods as “goods available as a result of counterfeiting and piracy and includes any means used for the purposes of counterfeiting or piracy.”⁶⁴

The Act under Section 2C establishes the offices of chief inspector and other inspectors with various powers to implement the law. The Chief inspector’s powers include powers to investigate, powers to initiate proceedings before the courts against the suspects; powers to conduct searches and seize suspected counterfeits, powers to destroy counterfeit products, powers to receive complaints from brand owners and conduct summary proceedings.⁶⁵

Furthermore, Regulation 8 establishes an Interdepartmental Task Force⁶⁶ to oversee the implementation of the Act. The Members of the Task Force are appointed by the Minister from the Attorney General Chambers, Tanzania Revenue Authority, Tanzania Police Force, Tanzania Bureau of Standards and representative from the Food and Drugs Authority. For the first time the Task force provides a good cooperation between various organs of the government in an effort to fight a common enemy, counterfeiting.

Another important thing made by the Regulations is the establishment of Zonal offices⁶⁷ in various places around the country to combat counterfeiting. Since Tanzania is a big country, the zonal simplify the efforts against counterfeiting around the whole country. The zonal offices are ran by responsible officers who have the authority to monitor border posts and seize, detain and or dispose of counterfeit products before they are exported or imported into the country.

The Regulations have also prescribed the fees and fines payable for counterfeiting offences as well as prescribing various forms that may be used to commence an application either before the Chief Inspector or Custom officials. Any person convicted of an offence under the Act may be sentenced to pay a fine or serve a prison term of 1

⁶⁴ Op cit

⁶⁵ Act No 19 of 2007

⁶⁶ GN 89 of 2008

⁶⁷ ibid

year or both. The maximum fines has been capped at Tsh 5,000,000/= which is roughly US\$5000.

The Regulations also in Regulation 18(4) provides for the possibility of obtaining *ex parte* search orders (*Anton Piller Orders*). The search order can be obtained from any District Court by the Chief Inspector or any IP right holder. The order will authorize the said inspectors to enter and search any premises that *are* suspected to contain counterfeit good.⁶⁸

However The Merchandise Marks Act⁶⁹ has a broad scope and it is not focused on the counterfeit drugs alone or promotion and protection of public health; this leads to the arguable implication that the counterfeiting of a T-shirt is as serious a crime as the counterfeiting of a life-saving medicine.

3.2.2 The Tanzania Food, Drugs and Cosmetics Act

Beside the Merchandise Marks Act there is also an alternative law which is Tanzania Food, Drugs and Cosmetics Act⁷⁰ which also plays a very vital role in combating counterfeit drugs. The main purpose of enactment of this Act is to provide guide to importation, distribution, and sale of drugs and ensuring genuine supply of drugs as well as fighting counterfeit medicine. The Act also apply in other area such as food and cosmetics.

Unlike the Merchandise Marks Act this Act has clear focus in combating counterfeit drugs. Section 76⁷¹ defines counterfeit drugs and what amount to counterfeit drugs an interpretation which is not provided in Merchandise Marks Act.⁷²

⁶⁸ *ibid*

⁶⁹ Act No 19 of 2007

⁷⁰ Act No 1 of 2003

⁷¹ *ibid*

⁷² Act No 19 of 2007

Tanzania Food, Drugs and Cosmetics Act in Section.76 (3)⁷³ provides that a drug shall be deemed to be counterfeit if it is manufactured under a name which belongs to another drug, or it is an imitation of, or is a substitute for, another drug, medical device or herbal drug resembles another drug or medical device likely to deceive or bears upon its label or container the name of another drug, medical device or herbal drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug, medical device or herbal drug; or the label or container bears the name Of an individual or company Purporting to be a manufacturer of the drug, medical device or herbal drug; which individual or company is fictitious or does not or it has been substituted wholly or in part by another drug substances it purports to be it is a Product of manufacturer of whom it is not truly product.Section.76 (2)⁷⁴ provides for punishment of drug counterfeiting that;

Any person who deals in or manufactures counterfeit drugs, herbal drugs, medical devices, commits an offence and upon conviction is liable to fine of not less than five million shillings or to imprisonment for term of not less than two years or to both such fine and imprisonment.

The punishment of not less than five million or two years is definitely not satisfactory compare to the danger counterfeit drugs pose to consumers and owners of brand as well. Although not related to the matter notably the punishment provided by the same Act for doing unauthorized clinical trial is much higher compared to the punishment of counterfeit drugs while both matters involve risks that can cause death but on counterfeit drugs it goes further into violating IP right, quoted herein below is Section 71⁷⁵ providing for punishment of un authorized clinical trial

⁷³ Op cit

⁷⁴ Act No 1 Of 2003

⁷⁵ Act No 1 Of 2003

Any person, who contravenes the provisions of this part, commits an offence and upon conviction is liable to a fine of not less than ten million shillings or to imprisonment for a term of not less than five years or to both such fine and imprisonment.

For any meaningful success access counterfeit drugs it requires meaningful punishment to deter the problem but the law have no sharp teeth to combat counterfeit drugs as such penalties leaves the offenders little untouched thus providing good environment for counterfeits.

3.3 The Institutional Framework for Regulating Counterfeit Drugs

The institutional support for combating counterfeit drugs in Tanzania is entrusted basically on Tanzania Food and Drug Authority (TFDA), and then there are other institution such as Fair Competition Commission (FCC), Tanzania Bureau Standard (TBS) and Tanzania Revenue Authority (TRA) as the regulatory institutions in the detection, control and prosecution of offenders dealing in counterfeit and substandard products. The institutions are discussed below as follows.

3.3.1 The Tanzania Food and Drugs Authority

Tanzania Food and Drugs Authority (TFDA), is a regulatory body responsible for controlling the quality, safety and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices. It is established under Tanzania Food, Drugs and Cosmetics Act⁷⁶, after repealing the Pharmaceutical and Poisons Act⁷⁷ and became operational on 1st July 2003. Section 76 of the Tanzania Food, Drugs and Cosmetics Act⁷⁸ gives mandate to the authority to ensure the stoppage of counterfeit drugs and also provide for monitoring strategies and mechanism of ensuring effective fight against counterfeit. TFDA was

⁷⁶ Act No 1 of 2003

⁷⁷ Act 9 of 1978

⁷⁸ Op cit

established mainly to have an effective and efficient regulatory authority responsible to control, combat and stop the flow of counterfeit drugs in Tanzania.

3.3.2 The Fair Competition Commission (FCC)

The Fair Competition Commission (FCC) is an independent government body established under the Fair Competition Act in 2003,⁷⁹ to promote and protect effective competition in trade and commerce and to protect consumers from unfair and misleading market conduct. The FCC is the lead institution that deals with sorts of counterfeit goods in the country by empowered by the Merchandise Marks Act. FCC is working with other relevant authorities to ensure that curbs against the importation of counterfeits are effectively implemented.

3.3.3 The Tanzania Bureau of Standard (TBS)

Tanzania Bureau of Standards (TBS) was established under the Ministry of Industry and Trade by an Act of Parliament, the Standards Act⁸⁰ as the National Standards Institute and became operational in April 1976, it was subsequently renamed Tanzania Bureau of Standards through an amendment to the Act by Act No.1 of 1977. The Standards Act No. 3 was later repealed and replaced by the Standards Act No. 2 of 2009, which gave the Bureau more powers in carrying out its mandate.

The Bureau was established as part of the efforts by the government to strengthen the supporting institutional infrastructure for the industry and commerce sectors of the economy. Specifically, TBS was mandated to undertake measures for quality control of products of all descriptions and to promote standardization in industry and commerce.

One the role vested on the Bureau is to provide for the inspection, sampling and testing of locally manufactured and imported commodities with a view to determine whether

⁷⁹ Act No. 8 of 2003

⁸⁰ Act No.3 of 1975

the commodities comply with the provisions of the Standards Act or any other law dealing with standards relevant to those commodities and that is how it is comes to be part of Taskforce responsible in the country to fight counterfeit drugs.

3.3.4 The Tanzania Revenue Authority (TRA)

Tanzania Revenue Authority (TRA) was established under the Tanzania Revenue Authority Act Cap 399 (Revised Edition of 2006). The Authority is a semi-autonomous agency of the Government responsible for the administration of the Central Government taxes as well as several non-tax revenues. The major functions of the Tanzania Revenue Authority are, to assess, collect and account for all Central Government Revenue; Administer effectively and efficiently all the revenue laws of the Central Government. Advice the Government on all matters related to fiscal policy; Promote voluntary tax compliance. Improve the quality of services to the taxpayers, Counteract fraud and other forms of tax evasion and to produce trade statistics and publications. Most people don't consider the task of TRA to be unrelated to counterfeits. However, TRA play a critical role because it has to inspect all imports when doing its function as a revenue collector. During this period provides information to other law enforcers such as FCC or TFDA or TBS or the Police Force on recognizing or suspecting counterfeit goods hence work more closely with other regulatory institutions in the fight against counterfeiting and substandard products in Tanzania.

3.4. The Institutional Performance in Combating Counterfeit Drugs.

Tanzania has four institutions that are very relevant in controlling counterfeit drugs, such institutions as mentioned earlier in this chapter are TFDA, TRA, FCC and TBS, the performance of each institution play a very significant role in deterring counterfeit drugs, their performances are examined herein below.

3.4.1 The Tanzania Food and Drugs Authority.

TFDA is a focal point for all drugs activities in Tanzania, including importation, manufacturing, distribution and sale. In order to strengthen and smoothen facilitation services TFDA has established 5 office zones to ensure control of the counterfeit drug by regulating the importation and exportation of drugs in the zones and conduct surveillance of products in the market. Presently office zones include Northern Zone, Lake Zone, Southern Highlands Zone, Eastern and Central Zone.⁸¹

TFDA is responsible for registration of medicine/drugs,⁸² the agency has formed and using the procedure to register each medicine that enters into the country. This is done through a database that has been established to keep in record every medicine that goes into the market and this allows easy detection of the counterfeit drugs.

TFDA conducts inspection and Surveillance by inspecting manufacturers, wholesalers and retailers and clinical trials sites and at port of entry to ensure that standard requirements of the drugs, herbal drugs are complied to. Inspections of manufacturers industry for ensuring that the drugs are reaching the standard, inspecting drugs in ports and markets. TFDA has established a mechanism to visit drug manufacturer industries and markets to make sure that what is produced and the condition it produces in order to ensure that no counterfeit is produced.

Laboratory Analysis for Quality, Safety and Effectiveness is also another role TFDA does is to conduct laboratory analysis, these analysis are carried out to ascertain the quality, safety and effectiveness drugs, manufactured or imported into Tanzania.

TFDA also provide public education by educating and informing stakeholders on all issues related to institution's functions such as control of the quality, safety and rational use of drugs, food, herbal drugs, cosmetics and medical devices. This section gives details on what is Public education all about.

⁸¹ <http://www.tfda.or.tz/>

⁸² *ibid*

TFDA has made effort to conduct big operation around the country in search for counterfeit drugs and ensuring adherence of the law. These operations have made very great impact on combating counterfeit as many counterfeit drugs are seized and destroyed during this period. Such operation is for instance Operation Mamba (IMPACT) – targeting counterfeit medicines in Tanzania and Uganda which took place between 29 September and 5 October 2008. The operations formed part of the WHO’s International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Operation Mamba demonstrates the way in which multiple law enforcement agencies can be mobilized to achieve a common goal. Police, drugs and Revenue Authorities joined their respective forces in Uganda and Tanzania, with the aim of inspecting and confiscating counterfeit medicines.⁸³ However the operation has not been able to be conducted every year as wished due to financial constraints.

Recognizing without trained personnel the war against counterfeit would be in vain the TFDA developed training for the officers in charge of the situation. Staffs are trained to identify counterfeit drugs to inspect in ports and market places so as to make the exercise easier, 329 inspectors trained.

Establishment of Guidelines for control of exportation and importation of drugs. In view of unique nature of pharmaceuticals, Tanzania Food, Drugs and Cosmetics Act⁸⁴ under Section 17 provides for control of importation and exportation of pharmaceuticals or any substance used for the manufacture of pharmaceuticals. The law requires that any person dealing with importation of pharmaceuticals must be registered by the Tanzania Food and Drugs Authority and the imported products must also be registered or approved. In order to protect the entire Tanzanian population, pharmaceutical manufacturers, importers, wholesalers, and distributors are required to adhere to set requirements as

⁸³ <http://www.interpol.int/public/news/2008/mamba20081029.asp>

⁸⁴ Act No 1 of 2003

stipulated in these guidelines. These guidelines are therefore aimed at providing guidance to importers, wholesalers and distributors of pharmaceuticals on such requirements in order to ensure that only safe, efficacious and acceptable quality pharmaceuticals are imported or exported.⁸⁵

Development of inspection guidelines.⁸⁶ This handbook is part of the attempt to harmonise the inspection techniques and to draw attention to the details that the Tanzania Food and Drugs Authority feels are important. In this respect, drug inspectors have an important role in protecting consumers. Succinctly, the inspector main job is law enforcement. This handbook is intended to serve, as quick reference material for drug inspectors to use in the course of their inspection work.

TFDA has approved ports of entry that are allowed to import and export drugs. The following are the approved/designated ports of entry for all pharmaceutical products and raw materials imported into the country Dar-es-salaam International Airport, Dar es salaam sea Port, Kilimanjaro International Airport, Horohoro ,Holili, Namanga, Sirari, Mwanza Port, Mwanza airport, Tanga Port and Tunduma⁸⁷ .Approving of this ports enable it to provide officer or the inspector at each port to ensure that counterfeit products are not finding their way in. As per Regulation 7 of Exportation and Importation of Pharmaceuticals Guidelines⁸⁸ any person caught smuggling drugs through other ports, including the infamous “out of the way routes” shall be guilty of an offence and will, accordingly be taken to court.

The performance and effort of TFDA in fighting against counterfeit drugs in the country since its establishment is undisputed. However the question is whether the level of its effort attained is satisfactory to effectively combat counterfeit drugs in Tanzania. Despite all the success the current level of regulating counterfeit drugs is not yet

⁸⁵TFDA Guidelines for control of importation and exportation of drugs 2005

⁸⁶ TFDA (2005) Inspector Hand book 2nd Edition.

⁸⁷ <http://www.tfda.or.tz/>

⁸⁸ TFDA Guidelines for Control of Importation and exportation of drugs 2005

adequate as more than 40%⁸⁹ of the drugs in the market are counterfeit either by expiry, ingredient and so forth. This study has found out there are still some weakness in regulating and monitoring all counterfeit activities in the country.

There are only eleven official ports approved to import and export pharmaceutical data shows that there other unofficial/unregulated ports almost 49 which are also used to import and export drugs of which gives a big chance from counterfeit drugs to be imported.⁹⁰TFDA lacks adequate work forces to cover all mini unnoticed ports of entries where drug dealers can use as avenue to import fake products, because the inspection guards are only in the official ports while unofficial ports are left freely unregulated. In this area TFDA has proved quite ineffective has it has failed to control these unnoticed ports and no strategies so far has been developed on how they will go about dealing with these unofficial ports of entry that are the big door for counterfeit drugs.

Confirmed by the Tanzania Food and Drugs Authority (TFDA) Inspection and Control Manager, Mr. Emmanuel Alphonse Says

“The problem in Tanzania’s Lake Zone is serious because counterfeit drugs are smuggled from neighboring countries through ‘panya roots’. Worse still, members of the public are not aware of the problem and its dangers.”⁹¹

Despite the presence of training for drug officials and Inspectors there is still Lack of appropriate knowledge, skills and experience in drug inspection coupled poor enforcement strategies on how to detect, confiscate, or investigate suspects of counterfeit medicine, This is due to the fact that there are only few trained personnel with that needed capacity to investigate inspect and recognize all forms of counterfeit drugs. Thus when counterfeit comes in many faces the inspector fails to identify for instance when expired date are changed with the high level of technology our inspector only ends up in checking whether there are the rights ingredients but detection of frauds in changing

⁸⁹ Opcit

⁹⁰ TFDA(2013 March 15)Interview with TFDA Director Central Zone)2013,interview.

⁹¹ The Citizen 22nd July 2012

expired dates have proved a failure. Beside of having few trained personnel the authority have very few staff to cover all Tanzania. Thus shortage of staffs in this Authority stands as a pullback factor to the effective enforcement of the law.

The official Zones are not established all over the country and where established official zone has to cover more than three regions something which does not guarantee the exercise to be effective because also there are few personnel. For instance Southern Highlands Zones covers Mbeya Ruvuma, Rukwa and Iringa with only one office located in Mbeya with few staffs hardly reaching 20. Also regions such as Tabora and Lindi are not covered hence these places are easily taken advantage of.

3.4.2 The Tanzania Bureau of Standards.

Despite the presence of the Standards Law, many critics consider the TBS toothless and a failure in waging war against counterfeit products.⁹² TBS has no legal teeth to prosecute those trading in both counterfeit and sub-standard goods. Given the subtle power of those trading in both counterfeit and sub-standard goods, the TBS has remained so despite long stated intentions to amend the law to give TBS teeth. In the war of fighting the influx of substandard goods, imports covered by compulsory standards are approved by TBS before entry. To date TBS inspectors are stationed at ports of Dar es Salaam and Tanga, Horohoro, Holili, and Sirari. Also market surveillances are carried out countrywide. Like other regulatory authorities, TBS does not have enough professional staff and the budget has. Some respondents wonder what role TBS plays, given that counterfeit products are now predominant not only in the black market, but in the open market too. Lack of coordination with other organs is one of the that obstacles undermining the TBS. Apparently, the role of TBS is not to fight counterfeit as such but simply to standardize products intended for the Tanzanian market as long as they are approved by TBS and regardless of any conflicts relating to IP rights.

⁹² Mkono & Co. Turning the tables on counterfeiters, World Contact handbook 2008

3.4.3 The Fair Competition Commission.

The FCC is also responsible for the regulation and implementation of the Merchandise Marks Act. The FCC has tried its best to wage war against counterfeiting activities since its creation. Critics⁹³ say that the coming into operation of the Merchandise Marks Act and its recent amendments are the most divisive legal reforms in the long history of the counterfeiting problem in Tanzania. For some, this is a sign of positive developments towards stamping out counterfeiting. However more reforms are required, especially in the counterfeit drugs, to have a useful coordination between the various organs in the fight against drug counterfeiting. However in 2010 FCC and other East African stakeholders met on strategies of how to combat counterfeit drugs, where several issues were highlighted such as formulation of EAC Counterfeit policy and a Bill at the same time which were to supersede the national legislation and also the meeting meant to address weak regulatory systems, stimulate interagency cooperation and involve copyright holders in order to improve criminal enforcement of IP in the region. The workshop also sought to impart a proper understanding by the judiciary of the gravity of offenses involving counterfeit medicines so as to issue appropriate deterrent sentences⁹⁴. though the meeting brought results but not that expected level the problem has really been growing since hence indicates failure to act.

3.4.4 The Tanzania Revenue Authority.

The TRA customs department does have legal powers to detain suspected counterfeit and substandard goods pending proof from other state organs being provided to it. Unfortunately, the TRA does not have the capacity (experts and equipment) to detect

⁹³ August N. Mrema Mkono & Co., Tanzania Recent Legislative Changes in Trademarklaw in Tanzania 2008 pg1

⁹⁴ FCC Newsletter January 2011

and control counterfeit and substandard goods coming into the Tanzanian market. This is a patent weakness that the Tanzanian government (in the EAC) needs to address if fighting counterfeits and substandard goods is to be successful

All these institutions are supposed to be placed under one roof as a task force to enforce core regulations in fight against counterfeit. But practically speaking that is not the case as other institutions as TBS and TRA have to work with their own institutions and the matter of counterfeit is not really the central issue to them, hence cooperation between these institutions is not really there thus the joint force of combating counterfeit drugs as one task force is not a promise.

The researcher is of the view that all this is due to the deficits in regulating counterfeit drugs in the country, this challenge to the government call for immediate attention.

3.5 Conclusion.

When the Merchandise Marks Act⁹⁵ and Tanzania, food, drugs and cosmetics Act⁹⁶ came in place and establishment of regulatory agencies there was a high expectation for change and impact in the country, but none has managed yet to bringing of such results as the level of counterfeit drugs is still higher than the genuine ones. The study has found some silent features in the laws such as light penalties which give more room to counterfeiters to bring in their products. There are many unregulated drug areas such as non regulation of unofficial ports which are actually best ports of entry for counterfeiters.

⁹⁵ Act No 19 of 2007

⁹⁶ Act No 1 of 2003

CHAPTER FOUR

FINDINGS AND ANALYSIS

4.0 Introduction

Chapter four presents the findings and analysis by discussing the efficacy of the law and regulatory mechanism in fighting counterfeit drugs .The discussion will be grounded on the assessment of strength and weaknesses of existing legal framework. With the objective of determining whether there is a need for imminent regulatory reform.

4.1 Challenges of the Law in Regulating Counterfeit Drugs Tanzania

As observed in earlier chapters there are some challenges that are found in the law. The study reveals salient features that pose a challenge in attainment of a goal against counterfeit. The Merchandise Marks Act is the Principal legislation enacted in 1963 and amended in 2007 to deal with all sorts of counterfeits goods. It was necessary to have such a law in order to deal with all chaotic drug distribution and to protect both consumers and brand owners. By enacting this law it was intended to put in place effective enforcement as well as to ensure proper adherence.

However it is of interest to note that the law exists but there is hardly any sign of counterfeit drugs to disappear and the counterfeits amounts to 40% of the drugs in Tanzania⁹⁷ . Indeed most respondent commented that they do not feel the impact of law in place and many studies have pointed out the problem still exists due to inefficacy of the law. Basically speaking the study has revealed that the laws responsible for combating counterfeit drugs have a number of defects which tend to affects also its implementation.

The Merchandise Marks fails to distinguish counterfeit drugs from other forms of counterfeit. The definition given under its Regulation does not establish the difference

⁹⁷ WHO (2006) WHO Toll for Assessment of Medicines Regulatory System Pg 9

between counterfeit drugs and other forms thus not giving a special kind of attention to a product that can affect human health and the one that affects ones interest. Despite the improvement in amending and strengthening IPRs law in counterfeit very little has been accomplished that is concrete in the area of counterfeit drugs as compare to other forms.

These laws pose challenges in attainment of the goal to combat counterfeit drugs. The laws lack proper penalties' for those convicted with the offence. The Merchandise Marks Act provide very low penalty for those found guilty of an offence of counterfeit drugs. In Merchandise Marks Regulation Rule 3 provides for imprisonment of 1 year or a fine not more than 5mil shillings.⁹⁸First emphasizing on the fine rather than direct punishment is a problem as the offenders can pay such amount or less and walk away to continue doing the same. On the Interview with a Central zone Managing director of TFDA, complained about the fine of 5mil or less as in court legal practitioners presenting offenders argue up to the lowest amount and walk away freely nearly paying zero amount compared to the offence committed. This kind of penalty cannot be effective to deter the problem of counterfeit drugs or punish the offenders hence not effective.

Regulation 50 and Regulation 18(14)⁹⁹ much considers the brand owners rather than the consumer/public who is actually much affected by the problem, the law gives more room to owner to commit suspects offenders and to obtain exparte search order (Anton Pillars Orders) where the offence has been committed. Frankly the brand owners are not at all time interested to commit themselves into establishing cases that little affects them and it can be a super task to find a owner as the issue of counterfeit drugs involves many jurisdictions. While at the same time highly affects consumers hence if the brand owners do not see the importance the problem stays unsolved.

⁹⁸ GN No 89 of 2008

⁹⁹ GN No 89 of 2008

Along with the Merchandise Marks Act¹⁰⁰ there is Tanzania Food, Drug and Cosmetics Act¹⁰¹ which has more specifically pointed out the problem of counterfeit drugs. However like Merchandise Act the penalties provided under this law are also too low. Section 76¹⁰² provides that any person who deals in or manufactures counterfeit drugs commits an offence and upon conviction he or she is liable to fine of not less than 5mil or imprisonment for two years or both. The punishment is too low compare to the threat it poses and it will be unrealistic to deter the problem of counterfeit drugs. For instance China and India have gone to the extent of imposing life imprisonment to whoever is dealing with counterfeit drugs, In December2009 six Chinese¹⁰³ who exported fake ant malaria drugs to Nigeria under a made in India label were sentenced to death in China.US passed also the Counterfeit Drug Penalty Enhancement Act in 2011¹⁰⁴, which further increases penalties for counterfeit drugs trafficking to reflect public mood. The maximum penalty of 20 years' imprisonment and fines up to US\$4 million were even extended to first-time offenders. Repeat offenders could be fined up to US\$8 million. Institutions could be fined US\$10 million for a first time offence and US\$20 million for repeat offences. Zero tolerance towards counterfeit drugs set by the US is a good learning example for Tanzania whose minimum sentence is 5years and maximum penalty not provided. August N.M. and Mkono & Co Advocates in their paper Recent Legislative Changes in the trademark law in Tanzania¹⁰⁵ presented that given the money which can be reaped by counterfeiters, the consensus is that the penalties prescribed by the law are too small and will not offer a good deterrence against counterfeiting. Nevertheless, the task force can advise the Chief inspector on the method of calculating the suitable fines for each particular case, and impose a fine appropriate with the harm or potential harm and also to deter such offence.

¹⁰⁰ Act No 19 of 2007

¹⁰¹ Act No1 of 2003

¹⁰² ibid

¹⁰³ East African Journal of Public Health Volume 5 Number 3 December 2008

¹⁰⁴ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257912.htm>. Accessed 12th April 2012

¹⁰⁵ Mrema op cit

The study reveals multiple legislations. There is no harmonization of counterfeit laws or counterfeit drug laws in one piece of legislation. Currently the issue of counterfeit drug and the sectors regulators thereto are dealt with separate pieces of legislation incorporating rules in that particular sector. These laws should be deliberately harmonized into one piece of legislation, Moreover the main institutions under each are established under different laws. For instance the penalty for offence of counterfeit in the Merchandise Marks Act¹⁰⁶ is capped at 5mil shillings and in Tanzania Food, drugs and Cosmetics Act¹⁰⁷ should not be less than 5mil,it will be meaningful for those authorities to regulate the issue of counterfeit under one piece of legislation. For examples in Kenya¹⁰⁸ and South Africa¹⁰⁹ have moved way far in the fight against fake goods by formulating specific laws. The Kenyan law gives a broad definition on counterfeits while the current law in Tanzania, Merchandise Marks Act has not defined sub-standards and counterfeit drugs. Absence of a single legislation do pose a challenge especially when the regulatory mechanisms differs this put more confusion during the enforcement time hence makes these laws weak and hard to tackle the problem.

4.2 Legal Confusion Between Counterfeit Drugs and Generics Drugs

A generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. Generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics .but one problem generics drugs in Intellectual property they are infringing patent rights as they are identical to other brands. According to Intellectual property law all goods that infringe or violate IP rights are considered counterfeit but in Public health not all goods that infringe patent rights are counterfeit as

¹⁰⁶ Act No 19 of 2007

¹⁰⁷ Act No 1 of 2003

¹⁰⁸ Kenya Anti-Counterfeit Act of 2008

¹⁰⁹ South Africa. Counterfeit Goods Act 199 No. 37 of 1997

long as they contain safety quality and efficacy. This confusion is seen in the famous Kenyan case of *Patricia Asero Ochieng and others V Attorney*¹¹⁰ which serves as a precedent for all East Africa, in this case Section 2 of Anti-Counterfeit of Kenya was urged to threaten access to lifesaving generic medicines by confusing “generic” with substandard and fake medicines. The section defines counterfeiting as “taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods, (such as) the manufacture, production, packaging, re-packaging, labeling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods.

On April 20, 2012, Kenya’s High Court ruled that the Act violates the right to life, human dignity, and health, as outlined in the Constitution of Kenya, and that intellectual property rights should not override these fundamental rights. The court further ordered Kenya’s Parliament to review the Act and to remove ambiguities that could result in arbitrary seizures of generic medicines under the pretext of counterfeits. The case, which was filed by three people living with HIV, argued that the Act could destabilize a legitimate supply of low-cost generic medicines, including antiretroviral treatments. In her ruling, Judge Mumbi Ngugi said that "the Act is vague and could undermine access to affordable generic medicines since it failed to clearly distinguish between counterfeit and generic medicines.

This legal confusion has been a barrier into attaining the overall goal of combating counterfeit, one because they give room for counterfeit to flow in as 70% of drugs enter in Africa are considered counterfeit and these are the drugs that comes from generic producing countries like India that normally do not contain right dosage and ingredients. For instance in 2012 ,1/3 of Ant malaria imported in Tanzania and Uganda were counterfeit and the medicines were brought from India as normally but India denied that

¹¹⁰ 2009 KPN 407

no fake medicines have been sent from India to the continent of Africa," a spokesman for the ministry of external affairs in Delhi said¹¹¹, while Ugandan Anti-Counterfeit Goods Bill and Kenya's Anti-Counterfeit Act 2008 led India into taking steps to reverse anti-counterfeiting measures on a fear that new and proposed anti-counterfeit laws could potentially deprive Africa of the so called generic medicines and begun fighting back to counter the confusion surrounding counterfeit drugs in the region and won in Kenya in *Patricia Asero Ochieng and others V Attorney*¹¹² where Kenya's High Court ruled that the Act violates the right to life, human dignity, and health, as outlined in the Constitution of Kenya, and that intellectual property rights should not override these fundamental health rights. The study reveals that the issue of generic medicine is used an excuse to import drugs that violate IP rights and not even contain what they allege to contain in a medicine hence stands to weaken the law and make the goal to combat counterfeit drug unachievable.

4.3 Response on Effectiveness of the Law

Item one of the Questionnaire sought to find out the effectiveness of the law in combating counterfeit drugs .Majority of the respondents showed dissatisfaction to the effectiveness of the law. Over 80% of the respondents were of the view that the law is not effective at all and adequate to combat counterfeit drugs. Only 6.5% of all respondents feel that the law is effective. Basically the respondents have blamed the law for not being effective and not having strong weapon enough to deal with the problem. Table 4.1 below shows the response rate of from each category of respondent.

¹¹¹ [Jason Burke](#) in Delhi theguardian.com, Wednesday 2 January 2013

¹¹² 2009 KPN 407

Table 4.1. Response Rate on Effectiveness of the Law

Response	Regulatory Authorities/Staffs	Drug distributor/sellers	Ordinary people
Effective	05 4.7%	06 8.4%	15 6.6%
Not effective	100 95.2%	50 70.4%	179 79.9%
Not sure	0 0%	15 21.1%	30 13.3%
Total	105 100%	71 100%	224 100%

As shown in the table above .179(79.9%) of the ordinary people out of 224, 50(70.4%) of drug dealers/distributor out of 71, and 100(95.2%) of Regulatory Institutions /staffs out of 105 were of the view that the Act is not effective and adequate enough to fight counterfeit drugs. On the other side 15(6.6%) of ordinary people, 06(8.4%) of Drug sellers and 05(4.7%) Regulatory Institutions staffs were of the view that the law is effective.

4.4 Responses on Increasing of the Punishment

On the other side as shown in table 4.2 below it was indicated that 170(75%) of the ordinary people,40(56%) of the Drug distributor/dealer and 80(76%) of the Regulatory Institutions/staffs said that there is a need for increasing the punishment for offence of counterfeit drugs while 30(13%) of the ordinary people,10 (14%) of the drug distributors/sellers and 10 (9%) of the Regulatory Institutions/staffs said the punishment is effective.

Table 4.2 Response Rate on Increasing the Punishment

Response	Regulatory Institutions/staffs	Drug Distributors/dealers	Ordinary people
Punishment should be increased	80 (76%)	40 (56%)	170 (75%)
Punishment should not be increased	10 (9%)	10 (14%)	30 (13%)
Total	105 100%	171 100%	224 100%

Basically drug counterfeiters have been using these obvious deficiencies in law to import, manufacture and supply fake, expired drugs. Every year studies/shows there more counterfeit drugs destroyed but less offenders convicted.

4.5 Challenges of the Regulatory Authorities in Combating Counterfeit Drugs

The researcher assessed the effectiveness of regulatory mechanisms by examining the strength and the weakness of the regulatory authorities that oversee the implementation and enforcement of the law. Experience suggests effective regulatory framework is likely to bring positive results on controlling counterfeit drugs while for poor regulatory framework likely to constrain effective regulation hence leads to poor results. The findings are provided herein below.

The study has revealed that there is poor enforcement of the law especially in the area of offenders, from the laws pointed above the punishment provided for offenders is 2years imprisonment or 5mil fine, noting that they are very cheap punishment earlier still the enforcement of which is not proper. This is evidenced in the case of Tanzania Pharmaceutical Industry (TPI) This is a distributor of drugs based on Arusha was discovered circulating counterfeit drugs, the drugs which have gone unnoticed even after

passing through MSD Medical Store Department and distributed in public hospitals. The counterfeit drugs found lacked some key ingredients and have developed fungus. TPIL that is the genuine distributor reported the matter to TFDA and the accused were dismissed from their positions and were not convicted to serve any of the punishment. The law mentioned above provides for fine and imprisonment in case a person found guilty for dealing with counterfeit drugs but the release of the accused in the incidence of TPI indicates poor enforcement of the law

The study reveals that there is an unharmonised regulatory system with other bordering countries, there are many porous borders between Tanzania and other neighboring countries, the regulatory authorities in place lacks harmonization with bordering countries concerning what is imported by drug distributor of countries like Uganda and Malawi, hence security cannot be guaranteed considering presence of unofficial entry ports zones

Failure to control existence of unregulated zones and unofficial ports which are main routes of counterfeiters. There are some regions which have no special office zones to make close control of the drugs distributed in, and also there more than 30 non official zone,¹¹³ of which these regulatory authorities fails to send their officer to ensure adherence of the law, thus because of that zero supervision counterfeiters easily import their drugs without being caught until they are already in the market and already consumed by the people.

The finding also shows that drug regulatory authorities lack competence, qualified laboratories as well as sufficient and financial resources to enable enforcement. The level of drugs counterfeiting is very high due to technology hence without proper and qualified laboratories it is never possible to detect the counterfeit drugs hence stands as a weakness in enforcement. The Presence of Counterfeit Metakelfin tablets in March

¹¹³ TFDA(2013 March 15)Interview with TFDA Director central zone)2013

2009, Counterfeit anti-malarial¹¹⁴ and Counterfeit Chloroquine¹¹⁵ in 2001 Expired Chloroquine Injection from an unregistered manufacturer, evidences the incompetence for all the medicines have to pass through these laboratory first in order to be approved, being of lower standard and found in market pose a serious questions to these laboratories as to whether they are sufficient tool to help regulate the whole issue of counterfeit drugs. Drug regulatory authorities also lack the power to enforce measures which prevent counterfeiting. For example the capacity of TFDA officials is not sufficient to control all manufacturers and drug dealers; there is limited number of drug inspector compare to the size of the country and number of ports of entry.

The study has found that detection of counterfeit drugs packaging and labeling is difficult for regulatory authorities, detection without a genuine sample is far more difficult. Sophisticated counterfeit packaging and labeling requires specialist equipment. With high quality equipment for the production of counterfeit goods, packaging and labeling, the counterfeits become harder and harder to detect especially for patients and prescribers. Often only highly developed methods like detailed chemical analysis or x-ray refraction will reveal the counterfeit. This can consequently lead to a higher prevalence of fake drugs, especially in the legal supply chain. Taking the case of TPI again failure of MSD to detect the counterfeit ARVs until found in market proves inefficacy, 1570 drugs were in circulation and already consumed by the patients before being discovered.¹¹⁶

¹¹⁴ www.tfda.com, *Metakelfin tablets* were found on the market.of Pyrimethamine 25mg, one of the active ingredients while Sulphame thoxypyrazine was available at 0.4% (acceptance limits 90-110%) Several batches were confiscated from the private pharmacies Suspended importation, distribution and use of Metakelfin in Tanzania.

¹¹⁵ <http://www.tfda.or.tz/>

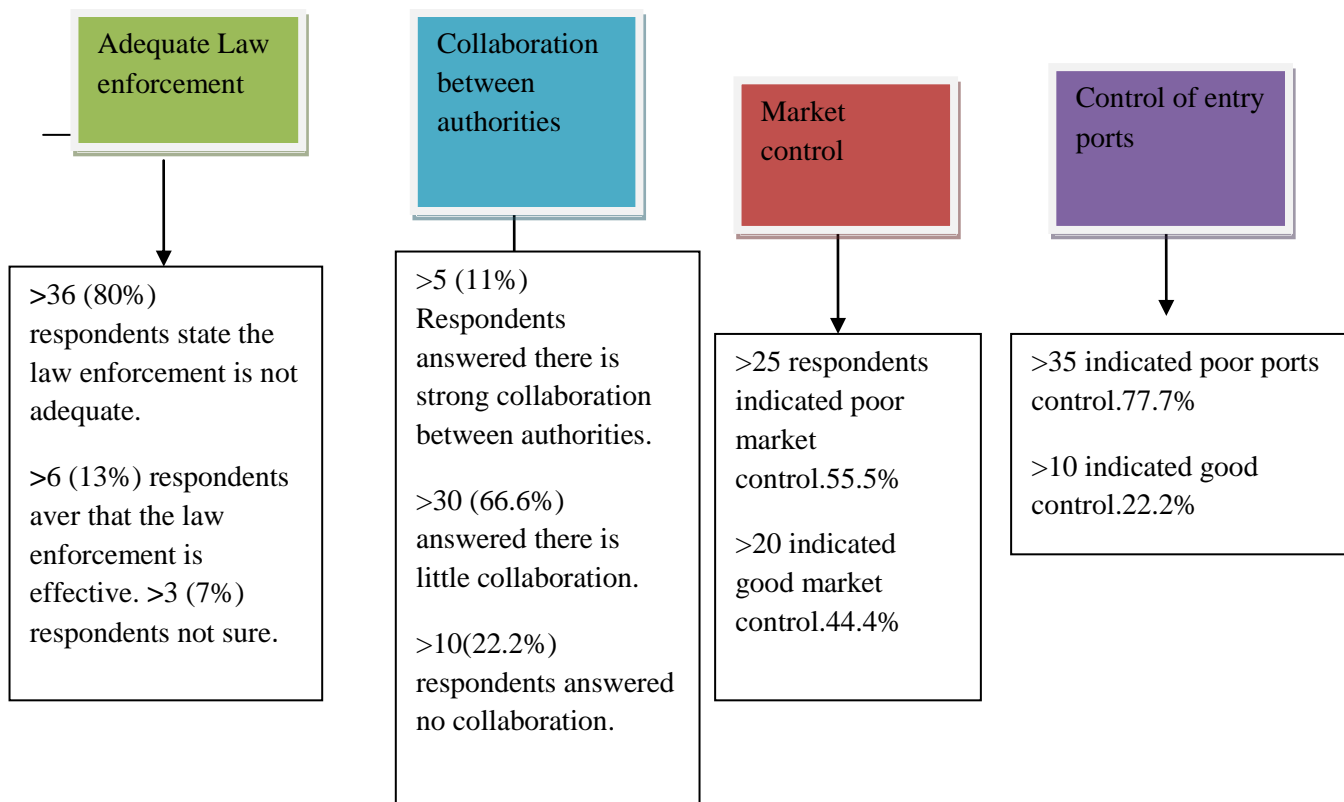
¹¹⁶ <http://www.dailynews.co.tz/index.php/local-news/11058-tfda-says-tpi-made-fake-arvs>.Accessed April

Without the proper regulation of all aspects concerning the manufacture, the distribution and the sale of drugs the health market of a country cannot be secured with regard to counterfeit medicines. . Manufacturers and importers of APIs and or finished drugs should need a license for production.

4.6 Public Response on Efficacy of Regulatory Agencies

During data collection the questionnaire were given to addressing various issues around law enforcement, anti-counterfeit actions, collaboration with other departments, controlling of entry ports, and market control. The findings are summarized here in below.

Table 4.3. Response Rate on Effectiveness of the Regulatory Agencies



The response and the results presented in table 4.2 above shows that the majority of respondents are dissatisfied or have unfavorable perceptions of the regulatory authorities' performance in implementing and regulating counterfeit drugs activities. The responses above suggest that collaboration among the authorities responsible in regulating the problem of counterfeit drugs is not effective. Confederation of Tanzanian Industries Report on Effect of counterfeit and substandard goods on Tanzania economy¹¹⁷ also shows that Tanzania has several regulatory agencies, each working more or less independently on its mandate. That the agencies have been doing a good job so far in their respective duties and responsibilities but not well cooperating in regulating counterfeits. Since counterfeiting is an organized, largely criminal activity sometimes put in the same yardstick as drug trafficking, the agencies need to work more closely together. Sharing information on suspected counterfeit and substandard goods would provide lead for the relevant authority to take action promptly. The war on counterfeits and substandard goods cannot be won without all these agencies coming together to map out a strategy for confronting this organized crime and ways of sharing information and reporting, including methods of protecting the informers.

Moreover the findings shows that there is no adequate enforcement of the law ,this suggest that there is need to sharpen law enforcement mechanism and that the regulatory authorities mandated to implement the law needs to be awoken to give the law a task it deserves. For example the issue of Counterfeit Metakelfinin 1999 and Ampicillin in 2000, where either the evidence was misplaced and suspects released or the dealers in counterfeit drugs were not taken to court in time.¹¹⁸

55.5% of responses on efficacy of regulatory authorities indicates poor market control, that means nearly half of response on this item indicate good market control, This is one area at least the regulatory authorities have managed to deal with the problem, there are

¹¹⁷ Information of Tanzanian Industry(CTI) Effects of counterfeit and Substandard goods on Tanzania Economy.2008 Pg 32

¹¹⁸ <http://www.tfda.or.tz/>

number of cases where many counterfeit drugs circulating in the market have been seized and destroyed, for example In June 2001, expired Chloroquine Injection (from an unregistered Indian company) was relabeled as Quinine Dihydrochloride Injection 600mg/2ml from a company in Cyprus were seized and destroyed . The culprit was prosecuted but case abetted due to death of the culprit. In January 2005, fake Gentrison Cream (a product of Shin Poong, South Korea) was reported.¹¹⁹In this case, the active ingredient was replaced with hand and body lotion. The general public was alerted through Press Release and batches were recalled from the market. The culprit was prosecuted

Moreover the finding on item of controlling ports of entry indicates poor ports control as 77% of the responses answered there is poor ports control, On interview with the Managing Director of TFDA Central Zone and also one FFC officer both said that the issue of controlling ports of entry is a big challenge that they have not found a solution to it yet and that the man power or officers responsible to stay guard in ports are also few in number hence not able to cover all ports that the counterfeiters uses to import counterfeit drugs.

From the findings presented above it is clear that the regulatory authorities are not working to the expected level and not effective in regulating the problem of counterfeit, this shows that much is required from these authorities to effectively implement and regulate the problem of counterfeit drug however regulatory authorities are still considered as very important agencies and tool in the whole exercise of combating counterfeit drugs.

¹¹⁹ <http://www.tfda.or.tz>

4.7 Other Challenges in Regulating Counterfeit Drugs

Lack of regulation by exporting countries and within free trade zones. Pharmaceuticals made for export in manufacturing countries are not regulated to the same standard as those produced for their domestic use. Moreover drug control is sometimes lax in free trade zones that pharmaceutical are exported through and where repackaging and relabeling takes place, the kind of trade arrangement can provide better opportunities for counterfeiters to introduce illicit material into distribution chain.

Licensed drug suppliers are also in involved in distributing counterfeits drugs. For instance TFDA halted distribution of all drugs manufactured by the Arusha-based Tanzania Pharmaceutical Industry (TPI) and suspended three top officials after discovering they were involved in circulating counterfeit anti-retroviral drugs¹²⁰.

Lack of awareness, Ignorance of the risk of counterfeit medicines among health professionals and consumers hinders detection and reporting even when patients experience treatments failure or adverse reaction. High price of drugs, when prices of legitimate medicines are high and price different between the identical products exist, there is a great incentive for people to see bargain in unregulated markets and for counterfeiter to supply cheap counterfeit drugs, and this is due to weak economic climate.

The level of corruption deserves mentioning in this regard since its influence may undermine enforcement through many different channels, illicit production facilitate many counterfeit drug to be undetected if authorities choose to ignore them. Distribution channels are breached where fake goods are mixed with genuine articles of various stages of distribution, or complaint may never be heard out thus even strictest law could therefore be without influence in a party's decision to counterfeit conducts.

¹²⁰ Tanzania's Daily News reported Thursday (October 11th)

4.8 Conclusion

Despite the impact that the law and regulatory mechanisms have brought in combating counterfeit drugs, the impact is still not yet vigorous. There are still weaknesses and challenges which stand as a door for counterfeiters hence need to be improved. It is important for the law to be reviewed and amended so as to fill the lacuna in the mentioned challenges.

CHAPTER FIVE

SUMMARY CONCLUSION AND RECOMENDATION

5.0 Introduction

This chapter combines the findings of the entire dissertation and draws some final conclusion. Recommendations are also given under this chapter.

5.1 Summary Findings

Generally chapter two is on the regulation of counterfeit drugs; it seeks to explain different means drug counterfeiting, its effects on brand owners and consumers. Under this chapter the effort made at international level to regulate investment were examined. Although the efforts are subject to debate but their contribution have helped in the formation of international umbrella and chain against counterfeit drugs.

In chapter three overview of legal and regulatory and institutional framework for combating counterfeit drugs in Tanzania was examined. The study leant that the laws governing counterfeit drugs and the regulatory authorities have not managed to demonstrate the expected results. The laws are not adequate as there are silent features that pose challenges in regulating counterfeit drugs effectively.

In chapter four findings and analysis was made based on discussion on the assessment of the strength and weaknesses of existing legal framework to see the need for review of legal and regulatory framework. Shortcomings found in the law pose challenges that need amendment.

5.2 Conclusion

From the review above this study has leant that the over flowing of counterfeit drugs is due to deficit in legal and regulatory framework, knowing that a good legal and regulatory framework is essential for combating counterfeit drugs and enforcement is critical there is a need of establishment of appropriate legal and institutional framework

as it provides the parameters within which enforcement can be pursued, The study reveals a need for clear policy on combating counterfeit drugs and enforcement that contains concrete elements that can provide purpose needed to improve the outcome.

Effective coordination between relevant bodies appears to be the key to strengthening, planning and enforcement and this is one area where the regulatory authorities have shown weakness by working less coordinated, the study reveals there is a need to ensure coordination in order to strengthen enforcement Coordination.

Moreover the study reveals other problems on the issue of definition of counterfeit drugs, considering that counterfeit drugs is a global problem .The definitional issue should be of practical importance at national and international level as well, But the failure to reach agreement on these definitions hampers meaningful and constructive policy debate and inhibits the degree of international collaboration necessary to take effective action against the producers and distributors of these medicines. It also has important implications for how national legislation is constructed and the penalties applicable for different kinds of offence.

Despite some success revealed in combating counterfeit drugs there are still weakness in term of legal and regulatory structure in regulating counterfeit drugs. The legal and regulatory framework still faces challenges in creating an improved free counterfeit drug environment. The general public is of the view that the problem had not adequately been addressed in Tanzania.

5.3 Recommendations

To conclude the major findings of this dissertation relate to the efficacy of the law and regulatory mechanisms in combating counterfeit drugs, as found out the structure pose challenges that need to be addressed. Therefore this study recommendation is directed towards developing of sound regulatory framework which would be efficient and supporting institutions that enforce the relevant law and regulation.

5.3.1 Increasing Penalties for Medicines Counterfeiting

Drawing from the findings the penalties are too light to deter the problem .It is suggested that there be an update of drug legislation to put tough sanctions and penalties to deter counterfeiters.

To make it deterrent the magnitude of the punishment need to be scaled up significantly and have relevant, up-to-date laws, as well as rigorous penalties consistent with the trafficking in illicit narcotics to ensure that traffickers can be prosecuted and or sufficiently deterred.

5.3.2 Enhancing Enforcement of Drug control Laws

As drawn from the findings there is need for the laws to have a well defined drug laws that must be compulsorily implemented by every government administration that comes to power and by every arm of the legislation such as the judiciary that handle cases of violators, Governments should ensure that drug control laws are enforced, clearly specifying the agency or agencies entrusted to enforce those relevant to counterfeiting. Every effort should be made to identify the sources of counterfeit drugs and to assess their levels in the national drug distribution channels. All reports of counterfeit drugs should be investigated. Workers in the national distribution channels are often favorably placed for early recognition of counterfeit drugs in the marketplace. These workers should be encouraged to be on the alert for counterfeits and to report any suspicion the authorities should in turn be able to react rapidly and appropriately to these reports, without detriment to the reporter.

5.3.3 Regulatory Strategies to be Strengthened

Regulatory authorities should ensure survey regularly distribution channels with a view to detecting the presence of any counterfeiting of their products; drug manufacturers whose products have been counterfeited should be encouraged to share this information willingly with the authorities responsible and law enforcement agents so that it may be

used as evidence in court proceedings, in which they could be witnesses. The laws need, reviews into its structure in order to bring a clear understanding of who is responsible for regulating, There is need for legislation to give power the organization responsible for regulating the law and conduct proper assessment. An effective mechanism will help combating counterfeit drugs. Legislation should be regularly scrutinized and amended as required. It should regulate the manufacture, importation, distribution, supply and sale of drugs, thereby ensuring the following

5.3.4 Empowerment of Judicially

It is also recommended that judicially should be empowered. The government should regard the counterfeiting of drugs as a serious offence and the judiciary should be empowered to impose harsh sentences in keeping with the nature of the contravention. Many calls have been made for the imposition of very severe penalties. Also drug counterfeiting cases should be given priority and handled speedily in the court system, and the courts should be empowered to order the confiscation, forfeiture and destruction of any detected counterfeit drugs.

5.3.5 Provision of Training Relevant to the Problem

Drawing from the findings it is recommended adequate training should be provided for the personnel for competent law enforcement authorities who are active in the field of combating falsified and/or counterfeit medicines and to involve experts from the relevant stakeholders, thus covering the private and public sector.

5.3.6 Empowerment of Regulatory Authorities

It further recommended that the government should empower regulatory authorities by provision of adequate workforce, equipments and materials for enforcement activities as well as provide finance for building of quality assurance laboratories that is well equipped in every state of the country, as these will reduce the workload of staff and increase efficiency. Development of appropriate procedures for the rapid assessment of

suspected counterfeits and the rapid identification and quantification of their active ingredients. Small officials should, at least, be able to carry out simple screening methods on drugs and so be able to quantify the active ingredients present. The agencies should either be appropriately located within the Ministry of Health or be under its purview or jurisdiction. The powers and duties of the national DRA should also be appropriately defined by law.

5.3.7 Increase Political Will and the Strong Commitment

Political will and the strong commitment of the government are essential if there is to be a concerted effort to improve drug control and decrease the incidence of counterfeit and to foster international cooperation in the control of pharmaceuticals and entering into bilateral and multilateral agreements with other governments and with international organizations such as WHO and the International Criminal Police Organization/Interpol.

5.3.8 To Encourage Specific Awareness Programs

To encourage specific awareness-raising programs and campaigns pointing out the health threat posed by falsified and/or counterfeit medicines, the general public should be encouraged to become involved in the fight against drug counterfeiting. Education and information campaigns directed to the public should be established. Consumers should be encouraged to report to the regulatory authorities or the police any suspect products and/or illegal or unauthorized drug manufacturers and distributors they may encounter. to report to their prescribers or physicians, any lack of improvement in their health status in spite of their compliance with prescribed treatment regimens; and all adverse reactions experienced during treatment (unexpected adverse reactions might indicate that the drug used was a counterfeit).

5.3.9 Increasing National and International Cooperation

It is further suggested that there be cooperation between countries, especially trading partners, is very useful for combating counterfeiting, in particular to establish and maintain suitable channels of communication among authorities, and to promote training and specialization of personnel. Such cooperation should include the timely and appropriate exchange of information on imported and/or exported drugs, on manufacturers and wholesale distributors, and on the harmonization of measures to prevent the spread of counterfeit drugs. There should be cooperation, including exchange of intelligence and in accordance with national and international legislation operational information, between all authorities involved, such as health authorities and agencies, customs authorities and police authorities, and to establish partnerships with private stakeholders, notably marketing authorization holders and right holders, and, as regards online sales of medicines, e-commerce operators and online payment providers. Countries should explore the possibility of using their diplomatic channels for the exchange of information on counterfeit drugs in international commerce. Countries are encouraged to harmonize their drug control legislation with relevant international agreements. Also necessary that authorities improve borders control both official and non official and develop appropriate international collaboration and exchange of information.

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QUESTIONNAIRE

The following questionnaires have been prepared by PHOIBE MAGILI as partial fulfillment of the requirement for award of degree of master of laws (Commercial law)at Mzumbe University. All the responses obtained will be strictly confidential and will be used only for the specified purposes.

Your cooperation in completing this study by responding to the questions herein below will be highly appreciated.

A.LEGISLATIVE ASPECTS

Questions

1. Do you consider the law related to counterfeit drugs effective in Tanzania?

- a. Effective ()
- b. Not effective ()
- c. Not sure ()

2. Do you consider there is a need for more effective and specific legislations to combat counterfeit drugs in Tanzania?

Yes () No ()

3. Is the punishment provided by law related to counterfeit drugs effective?

Yes () No ()

4. Should there be more severe punishment for offences related to counterfeit drugs?

Yes () No ()

5. What are other areas in legislations related to counterfeit drugs that you think needs to be changed?

(a).....

(b).....

(c).....

B.REGULATORY ASPECTS

1. How do you perceive the performance regulatory mechanisms in controlling counterfeit drugs?

2. Is there adequate enforcement of the law relating to counterfeit drugs?

Yes () No ()

3. Is there effective Market control against counterfeit drugs?

Yes () No ()

If your answer is no in the question above please explain why

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

3. Do you consider the control of entry ports against counterfeit drugs effective in Tanzania?

Yes.....

.....
.....

No.....

.....
.....

4. Is there an operational coordination mechanism in regulating counterfeit drugs between regulatory authorities?

Yes.....
.....
.....

No.....
.....
.....

5. What are your suggestions on how the problem of counterfeit drugs could be curbed?

- (a).....
- (b).....
- (c).....

INTERVIEW GUIDE QUESTIONS FOR KEY INFORMERS

TFDA, TBS, TRA AND FCC.

I am conducting a study on Efficacy of the Law and Regulatory Mechanism in Combating Counterfeit Drugs in Tanzania (a case of Dar es salaam) .will be asking questions regarding regulation of counterfeit drugs. I guarantee you that the discussion is completely confidential. Thank you in advance for your responses.

General particulars of the Respondent

Sex of the respondent: Male.....Female.....

Job position.....

QUESTIONS

1. How do you perceive the problem of counterfeit drugs?
2. What are the reasons for the preponderance of counterfeit drugs?
3. What have you been doing as institutions to check influx of counterfeit drugs?
4. Are the laws of counterfeit drugs adequacy in regulating counterfeit drugs?
5. How cordial are the relationship of authorities regulating counterfeit drugs?
6. What are the methods employed by the task forces in carrying out their duties and the major problems affecting performance.
7. What are your suggestions on how the problem of counterfeit drugs could be curbed?

