CHALLENGES PERCEIVED BY LOCAL PHARMACEUTICAL MANUFACTURERS THAT HINDER ADEQUATE PRODUCTION OF ESSENTIAL MEDICINES IN TANZANIA.

By

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A dissertation Submitted in (partial) Fulfillment of the Requirements for the Degree of Master of Science, (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled **Challenges Perceived by Local Pharmaceutical Manufacturers that Hinder Production of Adequate Essential Medicines in Tanzania** in (Partial) fulfillment of the requirement for the degree of Master of Science, (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences.

…….

Dr. D Mloka

(Supervisor)

Date ……

DECLARATION

AND

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I **Sophia Josephat Mwilongo**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature…… Date ……

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DEDICATION

To my husband Dr. Alex Bitta for the love, continuous support, encouragement and inspiration that in a very a special way kept me going.

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ABSTRACT

Introduction

Limited access to essential medicines undermines the health systems' objectives of equity, efficiency and health development in many developing countries. The major factor associated with limited drug accesses is the high price of medicines. The ability of local pharmaceutical industries to manufacture essential medicines is an important contributor in facilitating access and affordability of medicines. Currently, Tanzania's local manufacturers can only supply 30% of the country's need of essential medicines despite having several pharmaceutical manufacturers.

Objective

The objective of this study was to determine the challenges that hinder local pharmaceutical manufacturers from producing adequate supplies of essential medicines in Tanzania.

Methodology

Guided In-depth interviews with Chief Executive Officers/General Managers from all the seven local pharmaceutical companies available in Tanzania were done to determine the challenges. Eleven themes were identified and categorized using content relation analysis.

Results

The challenges identified by Tanzanian manufacturers were comparable to the findings of studies conducted in other developing countries. What was unique in this study was that lack of accessory industries was among the challenges that manufacturers perceived as hindering increased capacity. In addition, in contrast to other studies requirement to adhere to Good Manufacturing Practice (GMP) regulations was not perceived to be a challenge that hindered increased production of essential medicine but rather an obligation for them to remain competitive.

Conclusion

To increase capacity of local manufacturers a multi-sectorial approach is needed to address the above identified constraints is required. A concentrated effort therefore should be put in by both parties i.e. the government and local manufacturers for Tanzania to become self-sufficient in terms of the manufacture of essential medicines.

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LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
CEO	Chief Executive Officer
DSM	Dar es Salaam
FGDs	Focused Group Discussions
FOB	Free On Board
GCLA	Government Chemistry Laboratory Agency
HIV	Human Immunodeficiency Virus
IDIs	In-depth Interviews
ITM	Institute of Traditional Medicine
KSP	Kilimanjaro School of Pharmacy
LIC's	Low Income Countries
MDGs	Millenium Development Goals
MSH	Management Sciences for Health
MSD	Medical Store Department
MIC's	Middle Income Countries
MOH&SW	Ministry of Health and Social Welfare
NEDLIT	National Essential Drug List
PSU	Pharmaceutical Service Unit
PPA	Public Procurement Act
PPP's	Public Private Partnerships
STG	Standard Treatment Guideline
TB	Tuberculosis
TNHP	Tanzania National Health Policy
TNPP	Tanzania National Population policy
TPI	Tanzania Pharmaceutical Industry
TRIP's	Trade Related Intellectual Property Rights
TFDA	Tanzania Food and Drug Authority
UNIDO	United Nations Industrial Development Organization

VAT	Value Added Tax
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER ONE

1.0. Introduction and Literature Review

Tanzania has evolved from a one-party socialist state in the 1960s to a multiparty democracy in 1992. This political evolution was accompanied by economic reforms in an attempt to combat poverty. Over 50 percent of Tanzanians live in extreme poverty, surviving on less than one U.S. dollar (USD) per day (USAID, 2003). The poverty in Tanzania is reflected through the developmental indicators which show that; life expectancy had fallen to 44 years by 2001, from 50 years in 1990, and the infant mortality rate declined by 42 percent, from 88 deaths per 1,000 live births in 1992-1996 to 51 deaths per 1,000 live births in 2006-2010 (TDHS, 2010).

Since its independence in 1961, Tanzania has recognized the importance of improving the health status of its people as a means of combating poverty. The government evolved policies and mapped out strategies of ensuring the improvement of the public health (TNHP, 2007). Improving public health was among the strategies of the health sector reform of 1994. The main purpose of this reform was to improve health services through partnership between the public sector and private institutions. As a result number of legislative reforms and amendments were instigated, among which was the amendment of the Pharmaceuticals and Poisons Act No. 9 of 1978. This act was made as a means to improve the availability, accessibility and affordability of essential medications in Tanzania (Makundi, 2005).

Access to medicine is a key factor in the effectiveness of health systems for tackling endemic diseases. Limited access to essential medicines undermines the health systems' objectives of equity, efficiency and health development.

By definition; essential medicines are those that satisfy the priority health care needs of the population, they should be selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness (WHO 2008). Also they should be available within the context of functioning health systems at all times, in adequate amounts, in

the appropriate dosage forms, with assured quality and adequate drug information, and at a price the individual and the community can afford (WHA, 2001, WHO, 2008).

The concept of access to essential medicines can be analyzed in terms of, physical availability, affordability, geographic accessibility and acceptability or satisfaction (defined as the fit between the users' and providers' attitudes and expectations about the products and services and the actual characteristics of these products and services) (MSH, 2001).

Nevertheless approximately one-third of the world's population, predominantly poor people in poor countries, did not have access to essential medicines (MOHSW, 2004). The key reason for this problem is the high price of medicines. High prices are particularly burdensome to patients in developing countries where most medicines are paid for out-of-pocket by individual patients (MOH SW, 2004). The cost to the purchase of medicines contributes significantly to the health care budget of developing countries, with drug expenditures amounting to 50%–90% of non- personnel costs (Quick etal1997).
Many international commentators and policy actors argue that the problems of pricing and accessibility of essential medicines lie predominantly at the door of market regulation failures market inefficiencies and lack of capacity of African countries to manufacture essential medicines.

To alleviate this problem global attention has turned to ensuring that medicines are made affordable in low- and middle-income countries (LICs and MICs). In these countries medicines are often highly priced in relation to income of the inhabitants. Consequently the 54th World Health Assembly, in considering the access to affordable medicines as a fundamental human right, encouraged member states to take measures that would guarantee access to medicines in the context of priority diseases and pandemics (WHA, 2001). Governments of developing countries were thus requested to promote pricing mechanism that would guarantee availability of affordable essential medicines. An "equity pricing

mechanism" that is fair, equitable and affordable even to a poor population was envisaged as a necessity in order to avoid preventable deaths and safeguard public health.

Consequently a variety of strategies to lower prices of medicines for developing have been implemented over the recent years. These included having competitive and efficient drug procurement practices which encouraged more companies to produce copies of innovator products and increasing drug supply, thus driving prices down. It has also involved amending International Intellectual Property Regulations, such as Trade Related Aspects of Intellectual Property Rights (TRIPS), which in the past allowed multi-national pharmaceutical companies to block production of generics of drug innovators for a period twenty years (Mhamba R.M and Mbirigenda S 2010).

Three flexibilities were introduced within the TRIPS agreement specifically designed to promote local manufacturing of essential medicines by Least Developed Countries (LDCs) like Tanzania. To facilitate them to produce essential medicines locally without introducing pharmaceutical product patents until 2016, by granting Compulsory licensing, Bolar exception and parallel imports. Compulsory licensing is the right to grant a manufacturing license, without permission from the license holder, on various grounds of general interest including public health. Bolar exception is the right of generic producers to conduct tests and obtain approval from a health authority before the expiration of the patent, so that cheaper generic medicines are available immediately upon patent expiration. Parallel import is the rights to import brand name products when they are sold at lower prices in other countries. (Mhamba R.M and Mbirigenda S 2010).

Despite the TRIPS agreement The Tanzanian pharmaceutical industry is still in its infancy. Currently the Tanzanian pharmaceutical industry is only able manufacture 30% of the essential medicines requirements of the nation. The reasons behind this low production capacity, is unclear. The TRIPS agreement itself could be challenge although it was viewed as a golden opportunity to build up the local pharmaceutical industries in Tanzania. However,

careful scrutiny of the TRIPS agreement highlights that under the terms of the agreement, life-saving products such as pharmaceuticals are treated in the same way as any other merchandise or commodity. This prevents governments, representatives of nongovernmental and international organizations from accessing medicines and other health-care products. Furthermore, granting of patents which encourages innovation also creates monopolies that allow pharmaceutical companies to set and maintain high prices for a minimum of 20 years. This has the effect of hampering competition, delays in the production and release of low-cost generic equivalents onto the market; the main stay of lower cost medicines meeting the income needs of developing countries. In addition parallel imports block for LIC's and MIC's to make essential medicines more affordable because the branded medicines will compete with the generics that are locally manufactured.

The TRIPS agreement may not be the only factor that is contributing to the slow development of the Tanzanian pharmaceutical industries to produce essential medicines. Other factors such as lack of adequate financing may be major reasons that the Pharmaceutical industries in Tanzania can be considered to be working below production capacity. Banks often want to see a strong history of past performance before investing in a company (MSH, 2001). Since most of the companies in Tanzania lack such history, local pharmaceutical companies struggle to produce pharmaceuticals. In addition to this competition from the importation of cheap generics form Kenya and India may also be a challenge. Whatever the reasons are behind the low capacity of our local manufacturers to produce the essential medicines required by MOHSW, it is high time the reasons be elucidated as strategy to improve health care in Tanzania and achieving the millennium development goal 8 (MDG).

1.1. Statement of Problem

Medicines, like any other products, can be protected by intellectual property rights, such as patents. Such protection means that their production, importation and commercialization are subjected for a given period, to exclusive rights that allow title-holders to charge prices above marginal costs. These high prices for medicines deprive of access to the essential medicines to the poor many of which, living in the developing countries where essential medicines are needed the most.

There are currently only seven major companies available in Tanzania including; Shelys Pharmaceuticals Ltd, Mansoor Daya Chemicals Ltd, Tanzansino United Pharmaceuticals (T) Ltd, Zenufa Laboratories Ltd, A.A. Pharmaceuticals Ltd, Tanzania Pharmaceutical Industries Ltd (TPI) and Keko Pharmaceutical (1997) Ltd. (MoHSW, 2010).

Most of the pharmaceutical production done in these local industries concentrates on less sophisticated medicines such as simple antibiotics, cough and cold preparations, analgesics and antipyretics, sedatives, nutraceuticals, antihelmintics and antimalarials (MSH, 2001). More technologically sophisticated pharmaceutical products like Intravenous (IV) fluids, injectables, and more advanced antibiotics like cephalosporin are imported, as our local industries, still lack the ability to produce them (Mhamba et al, 2010).

If the current seven manufacturers were functioning at full capacity, they would be capable of catering for supply and demand of most of the essential medicines required in Tanzania. However in 1993, the domestic pharmaceutical production was only worth USD 7.2 million, It climbed to an estimated USD 11.8 million in 2000, indicating a rise in total market share for domestically produced medicines from 14 percent to 20 percent (SGC Consulting, 1995). Despite this increase, the combined market share for these local manufacturers was not more than 30%, of all essential the pharmaceuticals required in Tanzania. As a result 70% of the national drug requirement is imported (MOHSW, 2010). This high percentage of importation affects the pricing of the medicines since the Government practices a “free market economy”

which entails price deregulation system. The prices of pharmaceutical products in Tanzania are not controlled and therefore subject to price fluctuations depending on the demand.

The capability of local manufacturing industries to manufacture essential medicines is a hotly debated issue in many developing countries. Increased manufacturing capacity of local manufacturers is a key in ensuring the quality, availability and pricing of medicines within the country (Mohamed N, 2009). It is therefore imperative that the challenges that affect production are identified and addressed, to improve the health services in Tanzania.

1.2. Rationale of the Study

Encouraging and promoting local production of pharmaceuticals in developing countries is considered one of the best ways to bring the price of medicines down for these countries, and thereby increase access. The Tanzania government has put in a number of strategies for promoting domestic production of pharmaceuticals since 2005. To date local pharmaceutical manufacturers contribute to only 30% of the essential medicines. Local manufacturers probably still face a number of challenges that prevent them from ensuring adequate supply of essential medicines in Tanzania.

It was thus imperative to ascertain the challenges perceived by local pharmaceutical manufacturers that hinder increased pharmaceutical manufacturing capacity in Tanzania, and thus in turn limited access to essential medicines to the greater population.

Findings from this study may help in the formulation of strong policies to promote the increase of production of essential medicines by local pharmaceutical industries. Increased production would in turn induce competitive local production and inadvertently promote the availability and affordability of essential medicines in the market and therefore decreasing the dependency on importation as a means to implement price regulation.

It is also anticipated that findings from this study may help to promote the increase in capacity of local pharmaceuticals productivity and boost the national economic growth by increasing local employment opportunities as well as ensuring adequate if not excess supplies of essential medicine, that could be sold across borders to generate foreign income.

1.3. Research Objectives

1.3.1. Broad objective

- To determine challenges that hinder local pharmaceutical manufacturers from producing adequate supplies of essential medicines in Tanzania.

1.3.2. Specific objectives

- To determine local pharmaceutical manufacturers perceptions on the challenges that hinder local pharmaceutical capacity from developing

- To determine the industrial manufacturing regulations/legislations that hinder local pharmaceutical capacity from developing

- To determine the industrial manufacturing policies that hinder local pharmaceutical capacity from developing

CHAPTER TWO

2.0. METHODOLOGY

2.1. Study Area

The study was conducted during December 2010 to May 2011in two regions of Tanzania i.e. Dar es Salaam and Arusha where all the seven pharmaceutical industries in Tanzania are located see figure 1. The pharmaceutical industries included; Shelly's Pharmaceuticals Ltd, Mansoor Daya Chemicals Ltd, Tanzansino United Pharmaceuticals Ltd, Zenufa Laboratories Ltd, A.A. Pharmaceuticals Ltd, Keko Pharmaceutical (1997) Ltd, and Tanzania Pharmaceutical Industries Ltd (TPI). Representatives from the Ministry of Health and Social Well fare (MOH&SW), and the Tanzania Food and Drug Authority (TFDA) were interviewed to get the governments perspective.

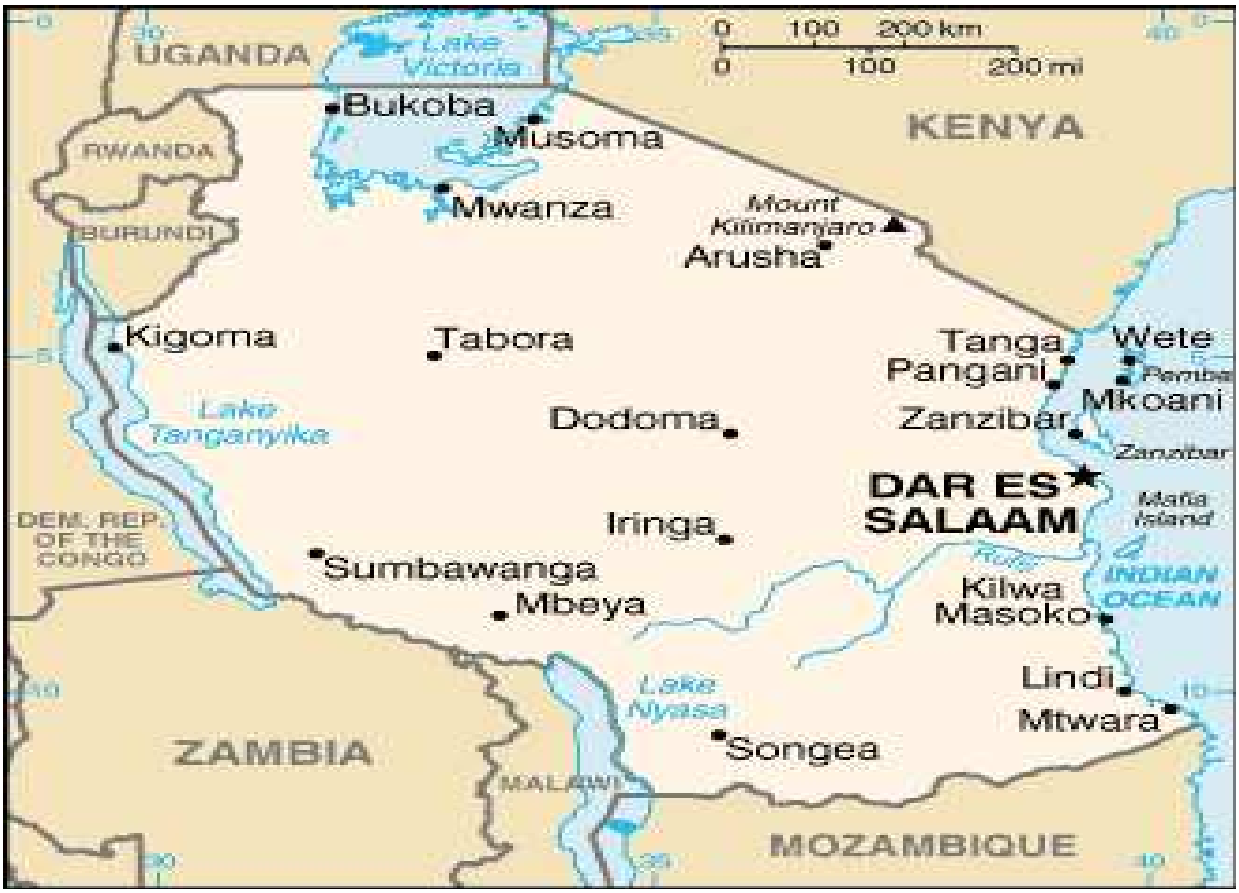

Figure 1: Map of Tanzania *Source*: CIA Fact book: Tanzania (2003).

2.2. Study Design

The study was cross-sectional which employed guided qualitative in-depth interviews.

2.3. Study Population

The study population included the Chief Executive Officers/General Managers from all seven industries available in Tanzania which included; Shelys Pharmaceuticals Ltd, Mansoor Daya Chemicals Ltd, Tanzansino United Pharmaceuticals Ltd, Zenufa Laboratories Ltd, A.A. Pharmaceuticals Ltd, Tanzania Pharmaceutical Industries Ltd (TPI) and Keko Pharmaceutical (1997) Ltd. Key informants with the knowledge on the status and access of pharmaceutical industries from respective ministries included The Ministry of Health and Social Well fare (MOHSW), and officials from government agencies as the Tanzania Food and Drug Authority (TFDA)

2. 4. Sample Size

The study included purposive sampling of all Chief Executive Officers (CEO)/General Managers in manufacturing of the seven Pharmaceutical Industries i.e. one CEO from each pharmaceutical industry available in Tanzania. These industries include: Shelys Pharmaceuticals Ltd, Mansoor Daya Chemicals Ltd, Tanzansino United Pharmaceuticals Ltd, Zenufa Laboratories Ltd, A. Pharmaceuticals Ltd, Keko Pharmaceutical (1997) Ltd and Tanzania Pharmaceutical Industries Ltd (TPI).

The study also included one government official from the Ministry of Health and Social Welfare and one official from government agency i.e. the Tanzania Food and Drug Authority (TFDA). A total of nine interviews were done.

2.5. Data Collection Technique

Data was collected through guided in-depth interviews with the Chief Executive Officers/General Managers, from the seven pharmaceutical industries, two government officials' from Ministry of Health and Social Welfare, and Tanzania Food and Drug Authority (TFDA). Data was collected over a period of six month. During the in-depth interview an

assessment guide, tape record and notes taking were used. After each interview the information obtained were transcribed and translated immediately to obtain meaningful information.

2.6 Data Management and Analysis

The data collected through the guided in-depth interviews which included interview summaries, field notes and tapes recordings were kept safe. Transcription of the data collected was done within 48hours after data collection to avoid forgetting of information obtained. Data analysis was done manually by coding and analyzing themes. Themes were identified and categorized using content relation analysis which shows relation between themes and codes. Themes were identified and ranked in order of frequency.

2.7. Recruitment and Training of Research Assistant

One research assistants with knowledge, ability and experience in qualitative research was recruited. Training covered description of the objectives of the study, orientation to the tools for data collection to understand what every question meant and how to find out more information. The recruitment process and training was done for two days.

2.8 Pre- testing

The tool for data collection was Pre-tested in one of the selected industry that was Shelly's Pharmaceuticals Ltd. Pre-testing was necessary to assess the applicability of the tool if they provided the depth, range and quality of information required and the likely response rate.

Necessary deletions and additions were effected on the final tool and to obtain the required information. Data collected during pilot test using Shelly's Pharmaceutical Industries Ltd. was included in the final report since there were little changes in the final tool.

2.9 Ethical Considerations

Ethical clearance was sought and obtained from the research and publication committee of Muhimbili University of Health and Allied Sciences (MUHAS) prior to the study. Permission to collect data collection was sought from the administrators of each pharmaceutical industry and respective ministry as well as government agency involved in the study. Informed consent was sought and obtained from the participants. Participants were informed about the objectives of the study and that their participation was voluntary. Participants were informed that they were free to decline and that it would not interfere or affect their production activities. Participants were assured that the information provided will be treated with utmost confidentiality.

CHAPTER THREE

3.0. RESULTS

3.1 Demographic Profile of the Study Area

The study was conducted in two regions, that is Dar es Salaam and Arusha where all of the seven pharmaceutical industries available in Tanzania are located.

Table 1: Locations of Pharmaceutical Industries and the Ministries.

No	Name of Industry	Location	Region
1	Shelly's Pharmaceuticals Ltd	Mwenge along New Bagamoyo Road	Dar Es Salaam (DSM)
2	Mansoor Daya Chemicals Ltd,	Keko Industrial Area	DSM
3	Tanzansino United Pharmaceuticals Ltd,	Plot no 321 Block T, Light Industries Chang'ombe	DSM
4	Zenufa Laboratories Ltd,	Kipawa Industrial Area	DSM
5	A.A. Pharmaceuticals Ltd	Mbezi Beach along New Bagamoyo Road	DSM
6	Keko Pharmaceutical (1997) Ltd,	Keko Mwanga	DSM
7	Tanzania Pharmaceutical Industries Ltd (TPI)	Plot no 34, Themi Industrial Area	ARUSHA
8	Ministry of Hearth and Social Welfare	Samora Avenue	DSM
9	Tanzania Food and Drug Authority	Mabibo – External	DSM

3.2: Nature of ownership of the pharmaceutical industries

The study findings indicated that the majority of pharmaceutical industries in Tanzania are private industries and three industries are in joint venture between the government and local entrepreneurs i.e. KEKO, TPI and TANZANSINO. Two of the four private industries are joint venture with foreign companies' i.e. Shelly's and ZENUFA see Table 2 below**.**

The study also revealed that most pharmaceutical industries concentrated on producing non sterile generic pharmaceutical products i.e. tablets, capsules, creams and ointments and liquids. TPI was the only industry that produces antiretroviral (ARV's.) see Table.2 below. None of the local industries produce sophisticated pharmaceutical products like Intravenous infusions (IV), injectable and other sterile products such as eye and ear drops, despite endemic diseases such as malaria; cholera can be treated using IV infusions and strong antimicrobials.

Table 2: Nature of ownership of the pharmaceutical industries

Name of Industry	**Nature of ownership**	**Products lines produced**
Shelly's Pharmaceuticals Ltd	100% private (ASPEN 60% and Sumaria Industries 40%	Liquids Creams/ointments Capsules,Tablets
Mansoor Daya Chemicals Ltd,	From 1962, 100% private (Local entrepreneurs)	OTC only
Tanzansino United Pharmaceuticals Ltd,	From 1997, Joint venture CHINA (HOLLEY INDUSTRY) 55%and TANZANA (JKT SUMA) 45% minority shareholders	Tablets only
Zenufa Laboratories Ltd,	From 2007, 100% private (Local entrepreneurs 60% and Belgium Government 30%)	Tablets, Capsules Dry Liquids i.e suspensions
A.A. Pharmaceuticals Ltd	100% private. (Local entrepreneurs)	Creams/ointments Antiseptics
Keko Pharmaceutical (1997) Ltd,	Public until 1997. Joint venture 60% local entrepreneurs majority holding and 40% Government minority shareholder	Tablets Capsules Liquids Creams/ointments
Tanzania Pharmaceutical Industries Ltd (TPI)	Public 1980-1997. Current Joint venture 60% and 40% Government	Oral i.e. ARVs' and general Liquids

3.3 Challenges perceived by local pharmaceutical manufacturers that hinder production of essential medicines in Tanzania.

The qualitative information collected from the local pharmaceutical manufacturers on the challenges perceived that hinder production of adequate essential medicines**,** were identified into eleven themes which are presented below:-

3.3.1 High Operating Costs due to Inadequate and Unreliable Utilities

Manufacturers mentioned high operating costs due to unreliable public utilities a major challenge. High costs of energy and water had made it difficult for local pharmaceuticals industries to maintain their full manufacturing potentials. Manufacturers claimed to be forced to take extra tactical measures such as producing one pharmaceutical product at a time when power is available from the national grid, rather than producing multiple products if there was no power rationing. They reported lack of stable power creates deterioration of reagents and wastage of chemicals that were used in the laboratory for quality control of the pharmaceutical products. The respondents also complained on expenses which they were forced to incur for buying and running generators. The following contention summarizes the information from one of our respondent.

"When there is no electricity we are forced to switch on our standby generators which will also run our air conditions which are very expensive because using a generator for one day here in productions and air conditions it costs more than 6,000,000/Tsh per day."(Interviewee from industry)

Manufacturers also reported that the lack of reliable water supply was among the challenges that face the local pharmaceutical industries in Tanzania. Most of the local pharmaceuticals industries were located in Dar es Salaam where water rationing is common. Shortage of water causes industries unnecessary expenses to the pharmaceutical manufacturers as they are forced to drill wells buy and maintain water pumping machines and water purification systems to ensure the supply of clean water for production of medicines.

The claims of the local manufacturers were supported by the respondents from the MOSHW and TFDA, who agreed that lack of reliable public utilities were a challenge to both manufacturers and the Government. They stated that the government was taking necessary measures to rescue the situation by finding different sources of energy and water.

3.3.2. Poor Infrastructure.

Manufacturers stated that a poor roads and communications service was one of the challenges that faced local pharmaceutical industries in Tanzania. Most Tanzanian roads are poorly maintained leading to high operating costs especially in the distribution of medicine during rainy seasons. The rainy season is associated with interference of the supply chain of manufactured medicines as well as the irregular supply of raw materials needed to manufacture medications leading to insufficient production of essential medicines. Respondent from the MOHSW agreed with the manufacturers that poor infrastructure was a challenge to the manufacturers. It was also reported that an additional challenge was that, the Ministry of Land and Natural Resources has not dedicated specified areas for the establishment of pharmaceutical industries. These areas should be assured with good infrastructure and public service utilities; this will ensure the development and sustainability of local industries.

3.3.3 Shortage of Human Resources;

Manufacturers claimed that lack of experts and skilled human resources was another challenge in local pharmaceutical industries in Tanzania. They agreed that technical expertise is absolutely critical in terms of sufficient numbers of human and appropriate skills in different fields. The manufacturers identified shortage of skilled scientists such as chemists, process engineers, biomedical engineers, and bioinformatics specialists, -computer scientists, industrial pharmacists, biochemists and laboratory technicians.

Two manufacturers reported that most of the experts and skilled industrial pharmacists for productions in pharmaceuticals industries in Tanzania are expatriates who demand high salaries. Manufacture also stated that they had to start by providing training for the local

employees at different institutions within and outside the country for them to acquire the required industrial skills for the production. This was an additional cost for the local manufacturer. All manufacturers claimed that the pharmacy Institutions in Tanzania was producing too few pharmacists with little industrial skills and experience in pharmaceutical production.

The respondent from the Ministry of Health and Social Welfare stated that there already Government efforts in place to reduce the shortage of pharmaceuticals human resources through increasing the enrollment at MUHAS School of Pharmacy and the establishing schools of Pharmacy at Bugando University and St John University – Dodoma and pharmacy CPE and diploma courses at St.Luke Foundation in Moshi.

3.3.4 Inadequate Government Support

Manufacturers claimed that inadequate government support was a challenge in the development and growing local pharmaceutical industries in Tanzania. The respondents complained to run their industries without government support to facilitate reduction of some of the taxes and duties of imported packaging and raw materials for medicines productions. The manufacturers also claimed that the government had not taken any initiative to encourage investment in the pharmaceutical industry.

3.3.5 Inadequate Financing

Manufacturers revealed that, most of the pharmaceutical industries were operating on banks loans which were not sufficient to run the industry as banks charged high interest rates. Thus most industries were operating using insufficient capital which minimizes production, development of the industry and reduces their competitiveness with other industries. Two manufacturers reported to be operating using their own capital but it was revealed in the study that they were in fact collaborating with foreign companies to make things move. For example Shelly's Pharmaceutical was owned by the local the Sumaria group which owned 40% of shares, while 60% was owned by ASPEN of South Africa.

3.3.6 Low Prices of Imported Products

The majority of Pharmaceutical Manufacturers reported that importations of essentials medicines from other countries such as China India and European countries was the major challenge that hinders development of local pharmaceuticals industries. They reported that some of the imported medicines are also produced by our local pharmaceuticals industries. These imported medicines which are produced by giant companies are treated similar to local products and therefore are cheaper in prices compared to those produced locally which are often more expensive due to high production costs. As a result the locally produced medicines remained to be expensive in local market and this created unfair competition

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3.3.7 Consumer Perception toward Imported Products

All manufacturers interviewed stated that a consumer perception about locally produced generic products were another challenge. They said many Tanzanians believe that the most quality medicines are imported. Therefore products which were produced by our local pharmaceuticals industries faced stiff competitions in terms of market share from those imported medicines.

The following contention summarizes the information from one of our respondent.

"Competition is good, but if you are not competing apples against apples you find a big problem because others will choose another choice."(Interviewee from industry)

3.3.8 Lack of Accessory Industries.

Manufacturers revealed that the manufacturing and distribution of pharmaceutical products were more complex and regulated than the activities in most other industries. They said the situation makes difficult for them to develop manufacturing base for pharmaceuticals (primary manufacturing) which concerns with production of active ingredients. Manufacturers stated that primary manufacturing was complicated and expensive process and therefore they rely on importation of raw materials from other countries such as India, China and Europe where they are very expensive. The finding also revealed that there were few accessory chemical

industries in Tanzania that could support the local manufacturers to produce quality raw materials for pharmaceuticals production. As a result all current local manufacturers in Tanzania perform secondary manufacturing processes which were less complicated. As can been seen from the product array produced by our local manufacturers See table 2 (page 14).

3.3.9 Port Delays:

Manufacturers complained on the delays of raw materials from Dar es Salaam port in terms of clearing procedures which hinder the production of essentials medicines. Most of the respondents claimed that it takes one to three months to collect raw materials which were needed in the production of medicines. The respondents reported that these delays were partially responsible for them failing to supply their tenders to Medical Store Departments (MSD) as well as other in the markets in required time. They stated that the limited time given by MSD to local producers would not accommodate any delays from the port on importations of raw materials. The manufacturers also revealed that the pharmaceuticals industries were paying tax, clearing fees, storage charges and container demurrage charges.
The following contention summarizes the information from one of our respondent.

"importations of raw materials there is serious delays in our ports authorities for collecting our goods and it costs us a lot of money, one and two numerous delays which again costs a lot of money because if materials are delayed you might find that on site you have five of six materials to make a product the six material is stacking in the port or there issue like carrying documentations which means has a lot of services."(Interviewee from industry)

3.10 Industrial manufacturing regulations/legislations that hinder local pharmaceutical capacity from developing

Manufacturers mentioned regulations that hinder the local pharmaceuticals industries in Tanzania. One manufacturer claimed that there was a contradiction in the definition, between

Tanzania Food and Medicines Authority (TFDA) and Government Chemistry Laboratory Agency (GCLA) as to what should be considered as a pharmaceutical ingredients and an industrial chemical. This lack of clear definition has tax implications that may adversely affect the support and promotion of local pharmaceuticals industries in Tanzania. The respondent stated that they were paying 0.5% free on board (FOB) for (Pharmaceutical Ingredients that fall under the category of industrial chemicals) to GCLA and were getting 2% FOB exemption from TFDA for those fall under the category of Active Pharmaceutical Ingredients (API) during the importation of chemicals for the production of the essential medicines for the Tanzanians. This situation may lead some of their pharmaceutical products to be very expensive in the local market rather than imported finished products and cause a strong competition to the local pharmaceuticals industries. With regard to complying to Good Manufacturing Practice (GMP), the majority of the manufacturers were happy to comply to GMP although so far only two of the local manufacturers, namely TPI and Shelly's have complied to GMP. The majority of respondents said that GMP requirements were necessary to be observed because medicines are used by people therefore a serious control in medicines productions will be the only way to ensure public health safety. Majority of local pharmaceuticals industries manufacturers were ready to meet the GMP compliance the problem was lack of sufficient capital to run their industries and lack of support from the Government for them to develop.

The following contention summarizes the information from one of our respondent.

"One chooses what business she/he wants to deal with, if you go to the pharmaceuticals manufacturing and marketing you know that it is a regulated business so you will not enter if you have a problem with registrations. We are geared and we know what the requirements are" (Interviewee from industry).

3.11 Industrial manufacturing policies that hinder local pharmaceutical capacity from developing.

The manufacturers, MOSHW and the TFDA claimed that the National Medicine Policy was in place since 1991. This policy aims at ensuring rational use of medicines, promoting and supporting productions of medicines to produce essentials medicines so as to make Tanzania self-reliant as well as recognizing the use of traditional medicines. Most of the respondents suggested that this policy did not boost the development of local pharmaceuticals industries in Tanzania. What are required are friendlier policies for the reductions of taxes on the importation of raw materials import. They claimed that the current policy was only documented but was not used to solve the challenges that were hindering pharmaceuticals industries from developing.

CHAPTER FOUR

4.0. DISCUSSION

The challenges as perceived by the local manufacturers, affecting the growth and development of local pharmaceutical industries to increase their capacity and become self-reliant and independent from importations can basically be divided into two categories Governmental issues and Local manufacturers' issues.

4.1 Governmental issues

From the study it was seen that many of the challenges as perceived by the local manufacturers were associated with government issues including, the government's lack of commitment in implementing production friendlier policies, lack of provision of supportive infrastructure and unreliable utilities such as water and electricity non provision of skilled human resources such as industrial pharmacists, lack of accessory industries, insufficient government support and Port delays.

Manufacturers and respondents from the MOHSW stated that poor roads and communications services appear to be one of the challenges that were facing local pharmaceuticals industries in Tanzania. These finding are similar to those of Mhamba R 2010, which found that, access to medicines and pharmaceutical manufacturing was affected by the poor quality of physical and social infrastructure. The lack of good roads, sufficient harbors, airports etc, is national problems that are not unique to the pharmaceutical industry alone.

On the other hand the issue of public unreliable utilities such as water and electricity are issues that can be tackled almost immediately. It is true that irregular supplies of water and electricity, adversely affect the manufacturing cost of essential medicines in Tanzania, as local manufacturers have to seek for alternative electricity and water sources that are costly.

The issue of high operating cost due to reliable utilities is not unique for Tanzania. In a

Study done in Uganda, it was found that the high cost of energy made it difficult for local companies to realize their full manufacturing potential. They were often forced to take tactical

measures such as producing only at times when power is available from the national grid. The power interruptions also create wastage of reagents and other chemicals that are used in the quality control labs when the tests have been interrupted (Mohamed N, November, 2009). Furthermore access to clean water is critical to achieving GMP, which ensures quality of essential medicines as well of their competitiveness in the global market.

Lack of sufficient number of experts and appropriate skilled human resources in the different field is probably a genuine reason that may contributes in delaying the capacity development of our local pharmaceutical industries as reported by the manufacturers and also this finding is comparable to a study by Mhamba R.M and Shukurani Mbirigenda in 2010. The manufacturers complained that they incurred cost for providing training for the local employees at different institutions within and outside the country for them to acquire the required industrial skills for the production. This was despite, the efforts made by the government to establish several training institution related to pharmacy e.g. St.Luke Foundation in Moshi, Bugando University and, St John University – Dodoma and increasing the enrollment at Muhimbili University of health and allied Sciences. Nonetheless all of these institutions are more bent on producing community and hospital pharmacists rather than industrial pharmacists. This matter is reflected by the fact that to date that there is only one university in Tanzania offering a Master degree industrial pharmacy and only two places namely St. Luke foundation in Moshi the R&D Laboratory under Action Medeor at MUHAS School of pharmacy that are offering diploma and CPE in industrial pharmacy respectively. What is even more unfortunate is that the majority of the students attending industrial pharmacy courses at these places come from Kenya, Uganda and other neighboring countries. This is probably due to fact that the governments of our neighboring countries have prioritized local pharmaceutical production. It is clear from the above findings that Tanzania may have the expertise in industrial pharmacy but is not harnessing them internally to facilitate the growth of its local pharmaceutical industry. As a result in future Tanzania may remain far behind in terms of competitiveness in the pharmaceutical manufacturing industry as compared to other countries in East Africa Community (EAC).

Inadequate government support was also reported as a challenge in the development and growth of the local pharmaceutical industry. The respondents claimed that they ran their industries without government support, especially with regards to reduction in taxes and duties on imported packaging and raw materials required to produce essential medicines. The manufacturers also claimed that the government had not taken any real initiative to encourage investment in the pharmaceutical industry. These finding are comparable to two previous independent studies done by Aghaibiam 2006 and Bate 2005 respectively. The lack of government support may be genuine challenge for our local manufacturers, especially when one considers that 3 out of 7 pharmaceutical industries in Tanzania namely KEKO, TPI and TANZANSINO are being financially assisted by the government. However these industries have not shown any significant signs of developing their manufacturing capacity of essential medicines despite this assistance. On the other hand however, the government has made some steps in supporting and promoting our local pharmaceutical industries including establishment of the TFDA and MSD. TFDA was established to ensure the local pharmaceutical industries are able to comply to GMP and thus assure the production of quality generic essential medicines. The government has been supportive by providing GMP training through TFDA and been leant by providing local manufacturers a grace period of 10 years to attain GMP requirements, in recognition that this is a costly and time consuming process. Thirteen years have now passed since TFDA required our local manufacturers to comply with GMP standards, so far only two industries have complied (TFDA report 2010). Nevertheless all local manufacturers are still being allowed to produce, sell and advertise their pharmaceutical products despite non compliance with GMP. In addition to this in 2003 the government through an amendment of TFDA's registration regulation for human medicines food and cosmetics, provided special consideration for locally produced generic products in the registration process even if the local manufacturers had not attained GMP standards. To top it all the TFDA guidelines on importation of Active Pharmaceutical Ingredient were modified so that the local manufacturers were given exemption of 2% on FBO and MSD which operates on tendering system was directed to ensure that local manufacturers products were given 15% domestic preference equalization factor during tender bidding so as to increase the chances for

local manufactured products of winning the bids. All these measures clearly suggesting that the government is actively supporting the local manufacturers to grow.

Financial stability is a prerequisite factor in the development of any type of a business including the pharmaceutical industry. The manufacturers reported that they were operating on banks loans which were not sufficient to run the industry and that the banks charged high interest rates. Lack of access to commercial credit through the local banks is deterrent of the growth of local pharmaceutical industries. High bank interest rates (over 15%) tend to marginalize local investors by reducing their capability to borrow as was shown in the study done by Mhamba R.M and Shukurani Mbirigenda 2010.

Lack of accessory industries to support the pharmaceutical industry was perceived as a challenge by some of the local manufacturers. The lack of accessory industries to support the pharmaceutical industry is a challenge that has not featured in other studies done. However the presence of accessory industries is a very crucial element in furthering the development of pharmaceutical industries. The majority of our local manufacturers perform what are known as secondary manufacturing processes i.e. the mixing of active with non-active ingredients. These processes are less complicated and are less expensive. They do this to avoid the high cost involved in setting up primary manufacturing industries that are concerned with the production of the active, non-active ingredients, as well as the final formulation of the pharmaceuticals. Even though our local manufacturers mainly perform secondary manufacturing these process are still expensive as they rely on the importation of raw materials including active ingredients from abroad. Local manufacturers are forced to import raw materials because of the lack of accessory chemical industries in Tanzania that can support the local manufacturers to produce quality raw materials for their pharmaceuticals production.

Some manufacturers reported that delays of raw materials from Dar es Salaam port due to bureaucratic clearing procedures hinder the production of essentials medicines. They claimed that it took between 1-3 months to clear raw materials from the ports. As a result they lost

income due inability to manufacture their products and failure to deliver their products customers. Moreover, the inability to clear raw materials at the ports results in that the raw materials are kept in appropriate conditions for a long time, which in turn ultimately may affect the quality of the finished product. This challenge however, is not unique to the pharmaceutical industry. Port delays are phenomenon that affects all industries in Tanzania. As port delays are a national problem the government should intervene to facilitate reduced bureaucracy when clearing pharmaceutical ingredients as a means to boost the local industries.

The lack of implementation of government policy has been found to be the problem not only in Tanzania but also in other neighboring countries. The manufacturers, respondents from the Ministry of Health and Social Welfare and TFDA reported that the national medicine policy was in place since 1991. This policy aims at ensuring rational use of medicines, promoting and supporting productions of medicines to produce essentials medicines for the country to become self-reliant. This is line with the findings of study done in Uganda which showed that the government's policy to promote local manufacturing of pharmaceutical products lacked a proper legislative framework for its implementation (Mohamed N, November 2009

4.2 Local Manufacturers Issues

Low price of imported medicinal products from abroad was also perceived by most of the manufacturers to be a challenge to their development. This perceived challenge may be partially true when you only refer to the study findings of Taylor et.al 2009 and Mohamed N 2009; that found that medicines produced by smaller companies were more expensive than those produced by transnational companies because they cannot benefit from economies of scale (whereby a producer's average cost per unit falls as scale is increased) and that local industries face unfair competition particularly with regard to when comparing the price from imported pharmaceutical products from countries such as India and China respectively. This may however not be the case for the products produced in Tanzania, if one refers to study done by Mackintosh and Mujinja in 2008. Their study which compared average rural selling

prices of medicines by country of origin in rural areas of Tanzania, found that there was no significant difference in the average price of medicines for medicines made in India compared to the same medicines made by African and European manufacturers; even though Indian firms are internationally regarded as low cost suppliers of essential medicines. What is evident from the above findings is that local pharmaceutical manufacturers in Tanzania need to understand that there is little impact on the price differences between their products and those that are imported. What they need to focus on is the real issues behind why customers prefer imported products over the local ones. One factor that may be affecting sales of local products could the issue of the quality of local products as compared to the imported ones. Compliance to GMP is the best approach to ensure product quality. Most manufacturers in this study have not complied with GMP and did not consider it a challenge. This is surprising as GMP compliance is an exercise that is time consuming and expensive. The facts that most manufacturers do not take GMP compliance seriously, this may be the result of the fact that their low quality products adversely affect their sales (Taylor et.al, Sept 2009). A study done by Risha P. in 2003 found that a number of Tanzanian drug formulations for paracetamol, acetylsalicylic acid, diclofenac sodium, metronidazole, sulfadoxine/pyrimethamine and chloroquine failed in stability testing and drug release studies.

4.3 Study Limitations

The study was not able to get the views of production managers and other expertise that are involved in the manufacturing as a result of limited time of the study. Their views may have highlighted both the non-technical and technical barriers that hinder increased capacity of the local pharmaceutical manufacturers.

The study was also not able to determine the local consumer's views on the quality of locally manufactured pharmaceuticals as a result of limited time of the study. Their views may have provided evidence of the stated challenge by the manufacturers.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study has identified a number of challenges that are hindering the development of the Tanzanian local pharmaceutical manufacturers to increase their capacity to manufacture essential medicines. It is clearly evident from the results of this study that our local manufacturers are a long way from attaining maximal production capacity of essential medicines. This can be clearly visualized from the limited array of products that they produce as seen in table 2. However it is possible from them to increase their capacity if both the government and the local manufacturers themselves put in, collective efforts to rectify the barriers that concern them individually.

On the part of the Government it will only be able to address all its challenges if it will involve all the stakeholders of pharmaceutical manufacturing. Linking the Ministry of Ministry of Health and social Welfare (MOHSW) and the Ministry of Industries and Trade with other major stakeholders of pharmaceutical manufacturing such the Ministries of Lands, Education, Infrastructure, Agriculture etc, will ensure the development and implementation of policies and regulations which will facilitate growth and development of our local pharmaceutical industries. Collaboration between government ministries and agencies will ensure implementation of policies, a constant supply of inputs, such as energy, clean water, skilled expertise, good infrastructure for industrial development and advanced technology.

In addition compliance of all local manufacturers to GMP standards will ensure the production of quality products and thus make them locally and internationally competitive assuring their sales and growth.

5.2 Recommendations:

1. The study recommends the Government formulate a clear plan of action to ensure skilled staffs are available for pharmaceutical manufacturing, by facilitating that the Schools of Pharmacy in the country enroll more students and revise their curricula accordingly to incorporate industrial pharmacy modules. The government should promote industrial pharmacy and industrial pharmacy courses by reviewing the current undergraduate Pharmacy curriculum to provide more training and exposure industrial pharmacy, or by considering prolonging the current Bachelor of pharmacy program to five years. The fifth year could be year of specialization in either industrial pharmacy of clinical pharmacy. The graduates of this program would be awarded a Doctor of pharmacy (Pharm D) degree or Masters of Science Degree in Industrial Pharmacy. This will guarantee production of competent pharmacist in different fields and automatically increase the number of skilled industrial pharmacists and alleviate the human resource gaps in the pharmaceutical industries

2. The study recommends the government reformulate its KILIMO KWANZA policy to promote the cultivation of medicinal plants, and other plants that can be used to make raw materials for pharmaceutical manufacturing. This will also facilitate the establishment of accessory industries to process these raw materials into active and non active pharmaceutical ingredients.. Currently the government has put much emphasis on KILIMO KWANZA to alleviate poverty and hunger by promoting agriculture for production of food. Instead of only concentrating on alleviating poverty associated with hunger it should direct some of the resources for KILIMO KWANZA to booster the development of accessory chemical industries that could supply the local pharmaceutical industries. For example the commercial cultivation of ***Acacia senegal* (L.) Willd,** an indigenous tree that can be used to extract gum Arabic. Gum Arabic is used extensively in pharmaceutical preparations, inks, pottery pigments, water-colors,

wax polishes, and for dressing fabrics by giving them luster. Pharmaceutically it is used mainly in the manufacture of emulsions and in making of pills and troches (as an excipient). Commercialization of this tree will facilitate the production of gum a useful product of the pharmaceutical, cosmetic, plastic and food industries. It will at the same time boost the development of accessory chemical industries required to process the raw gum. These accessory industries will create jobs and foreign revenue from the export of these products to pharmaceutical and other industries outside Tanzania. The jobs and revenue generated will contribute to poverty reduction through industrialization and assist Tanzania to achieve its MDG goals. The Government should thus collaborate with the institute of traditional Medicine (ITM) and pharmaceutical manufacturers to identify what are the plants that can be commercialized as strategy to promote the growth of our local industries in the production of essential medicines.

3. The study recommends that TFDA enforces its regulation to ensure local manufacturers become GMP compliant, to ensure the quality of locally manufactured medicines plus so as to make sure they remain globally competitive. Thus for local manufacturers to be competitive they will need to strive to comply with the minimum standards of GMP. Enforcement of the TFDA ACT of 2003 which requires GMP compliance of local manufacturers will ensure that the medicines on the market are consistently of good quality. This may positively affect local consumer perception towards locally manufactured generic products considered currently a challenge to the development of our local industries

4. The study recommends the government considers a multi-sectorial approach to develop a newer policy for promoting pharmaceutical manufacturing and an implementation framework that will cater across several government ministries and agencies to facilitate its implementation. Collaborative efforts between the Ministries of lands, Finance, Education, Energy, water and environment, Agriculture and Infrastructure to reformulate and implement this policy. Bringing together all stakeholders of pharmaceutical manufacturing will facilitate that the government can effectively pull resources to provide skilled human resource in industrial pharmacy, improved infrastructure and sufficient land for the expansion of pharmaceutical industry, reliable public utilities, financing and attractive for tax packages. However there needs to be a clear framework on how to implement this modified policy in order to promote development of our local pharmaceutical industries.

APPENDICES

6.1. APPENDIX 1 ASSESMENT GUIDE

Code No----------

A: FOR CHIIEF EXECUTIVE OFFICERS

CHALLENGES PERCEIVED BY LOCAL PHARMACEUTICAL MANUFACTURERS THAT HINDER PRODUCTION OF, ESSENTIAL MEDICINES IN TANZANIA

Name of the interviewer----------

PART A Administrative Information

1.1 Name of Industry----------

1.2 Year started---------- and Location----------

1.3 Title of the interviewee----------

1.4 What was the source of capital?

a). Bank Loan b). Government support c). Saving

1.5 What is the type of industry?

a). Private only b). Government owned c). Both

1.6 How many product lines are produced? Give the list of products in each product line.

PART B: Policy Issues

2.1. What are the challenges are you facing in the production of essential medicines? And how do these affect the production of essential medicine in Tanzania?

Probe on –

-Imported products -Capital -Existing policies -Market issues -Legislations/Regulations

2.2. What is the geographical distribution of your Market?

Probe on

-Internal market -external market

2.3. Can you tell us about the existing competition from other local producers?

2.4. What is the status of laws on drug manufacturing, registration, and patent protection, labeling and prescribing standards?

Probe on-

-impact of the laws in production of essential medicine in Tanzania

2.5. Does Good Manufacturing Practices and enforcement of standards affect your industry? How?

Probe if his industry meets GMP

2.6. What tax incentives and ownership requirement exist? How do they affect production of essential medicines in Tanzania?

Probe on-

-Limits on foreign ownership

-Requirement of local ownership

-Restrictions on foreign investors

2.7. How does the availability and cost of utilities affect production of essential medicines?

Probe on- -Power -Water -Waste disposal

2. 8. Are technical and production staffs available?

2.9. Are there import duties on pharmaceutical ingredients packaging materials and equipment?

2.10. Give your opinion on how to increase the production of essential medicines in Tanzania to meet the needs.

6.2. APPENDIX II ASSESMENT GUIDE

B: FOR GOVERNMENT OFFICIALS

Code----------

CHALLENGES PERCEIVED BY LOCAL PHARMACEUTICAL MANUFACTURERS THAT HINDER PRODUCTION OF, ESSENTIAL MEDICINES IN TANZANIA.

Name of the interviewer----------

PART A Administrative Information

Name of ministry----------

Title of the interviewee----------

PART B POLICY ISSUES

2.1. What are the laws/regulations regarding production of essential medicine in Tanzania?

2.2. What are the policies in place?

Probe on-

-Since when are they in place

-Practicability

-Do they hinder production?

-Any suggestions regarding the laws and policies

2.3. Why do you think local industries in the country do not produce to meet the needs of essential medicine in the country?

Probe on-

-Capital

-Government tax on imported ingredients

-Lack of skilled personnel

-Poor government support

2.4. What efforts have made to encourage more production of essential medicines in Tanzania?

2.5. Suggestions

6.3: APPENDIX III

STUDY PARTICIPANTS INFORMED CONSENT FORM

Title:

ASSESSMENT OF CHALLENGES PERCEIVED BY LOCAL PHARMACEUTICAL MANUFACTURERS THAT HINDER PRODUCTION OF ESSENTIAL MEDICINES IN TANZANIA.

NAME OF INVESTIGATOR: Mwilongo Sophia J.

SPONSOR: MINISTRY OF HEALTH AND SOCIAL WELFARE (MOH &SW)

ADDRESS: MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
P.O BOX 65001,
DAR-ES SALAAM.

Identification number:_____

Introduction:

Hello! This consent form contains information about the research named above. In order to be sure that you are informed about being in this research, we are asking you to read or have read to you this consent form. You will also be asked to sign it or make a mark in front of the witness. You will be given a copy of this form. This consent form might contain some words that are unfamiliar to you. Please ask us to explain anything you might not understand.

Reason for the research:

You are being asked to take part in this research that aims to assess the barriers perceived by local pharmaceutical manufacturers that hinder local pharmaceutical industries to produce adequate essential medicines in Tanzania.

General information and your part in research:

If you agree to be in this research you will be required to answer a series of questions in the interview guide. The interview will be conducted at the manufacturing site where you will be working or visiting at the production site. Therefore there will be no additional costs for traveling.

Risks:

We do not expect any harm to happen to you because of joining this study

Benefits:

The information you give will contribute on improving the production of essential medicines locally in our country and therefore reduce dependency on importation

Right to withdraw and alternatives:

Taking part in this study is completely your choice. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdrawal from the study will not involve penalty.

Confidentiality:

All the information obtained from this study will be used for the research purpose only, and will not be shared to any one without participant consent.

Who to contact:

If you have any questions about your rights as a participant, you may call Sophia J Mwilongo (0756-069163), Principal Investigator, Dr. D. Mloka who is the supervisor of this study, MUHAS PO BOX 65001, Dar es Salaam.

Your right as participant:

This research has been reviewed and approved by the IRB of Muhimbili University of Health and Allied Sciences. An IRB is a committee that reviews research studies in order to help protect participants. If you have any questions about your rights as the participant you may contact Prof. M. Aboud, Chairman of the College Research and Publications Committee, P.O Box 65001, Dar-es-salaam, Tel: 2150302-6.

Signature:

Do you agree?

Participant agrees..... Participant does not agree.....

I, _____I have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of research assistant _____

Date of signed consent _____

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