

**ASSESSMENT OF RETAIL PRIVATE PHARMACY PRACTICE
AND REGULATIONS COMPLIANCE IN MOROGORO
MUNICIPAL COUNCIL**

By

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**Thesis Submitted to School of Public Administration and Management in Partial
Fulfilments of the Requirement for the Award of Master of Health System
Management of Mzumbe University**

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CERTIFICATION

We, the undersigned certify that we have read and hereby recommend for acceptance by the Mzumbe University a thesis titled “**Assessment of Retail Private Pharmacy Practice and Regulations Compliance: The case of Morogoro Municipal Council**”, in partial fulfilment of requirement for award of the degree of Master of Health Systems Management of Mzumbe University.

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DECLARATION

I Anthony Angelo, declare that this thesis is my personal original work and it has not been submitted and will not be accessible to any other institution/university for similar or any other academic/professional award.

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DEDICATION

This Thesis is dedicated to my beloved parents, my mother Asteria Angelo Gabunga and my father the late Angelo Anthony Gabunga my uncle Tumaini Tarisi Kagina who raised me up to where I am now, also I dedicates this thesis to my wife Rehema Kimbe, son Angelo, daughter Angel Mina and my friend Pendaeli Kisanga Shoo. I appreciate their concern about me, their encouragement and sacrifices, **May Almighty God bless them.**

LIST OF ABBREVIATIONS

ADDO	Accredited Drugs Dispensing Outlets
CFDC	Council Food and Drugs Committee
DDI	District Drug Inspector
DMO	District Medical Officer
IPF	International Pharmaceutical Federation
NBS	National Bureau of Statistics
NHP	National Health Policy
NMCP	National Malaria Control Program
OTC	Over the Counter
PCT	Pharmacy Council of Tanzania
PHC	Population and Housing Census
PPB	pharmacy and poison Board
PSK	Pharmaceutical Society of Kenya
RDI	Regional Drug Inspector
RHC	Regional health secretary
RMO	Regional Medical Officer
RUCA	Rural Urban Community Area
Rx	Prescription medicines
TFDA	Tanzania Food and Drugs Authority
WHO	World Health Organization
WMA	World Medical Association

ABSTRACT

This study was about assessment of retail private pharmacy practice and regulations compliance in Morogoro Municipal Council. Specific objectives were, to identify how retail private pharmacy practice is carried out (pharmacy owners/sellers), to identify factors hindering retail private pharmacy regulation compliance and lastly, to find out how government systems carries out retail private pharmacy practice and regulations compliance.

The case study design was used in which 16 wards were purposively selected. The study area was chosen due to the growing problem of poor retail private pharmacy practice and regulation compliance. This study covered 120 respondents aged above 15 years, data were collected through questionnaires, documentary review and interviews then analysed using Statistical Package for Social Sciences (SPSS) 22.

Infringement in provision of pharmaceutical services is common because it revealed that pharmacies were selling counterfeit drugs and performing restricted services like treatments. The reasons influencing these infringements mentioned are; satisfaction of being a nurse, mob psychology, pharmacy service is regarded as business, ignorance of pharmacy practice procedures as well as desire for profit maximization.

Challenges faced by pharmacy sellers include; customer demand selling half dose, and ignorance of customer. The government system was effective in ensuring regulations are followed by pharmacy sellers although also faced by challenges such as financial constraints, some pharmacies are owned by their co- workers, closure of pharmacies during inspections as well as personal interests of politicians.

There is a need of increase funds for inspections of retail pharmacies as well as to educate the society about health and social-economical effects of retail private pharmacy practice and regulation compliance.

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CHAPTER ONE

1.0 Introduction

This study focused on assessment of retail pharmacy practice and regulations compliance in Morogoro whereby, Morogoro Municipal Council was taken as a case study. This chapter acts as knowledge bridges where by readers have been provided with background information to be able to understand the focus of the study. The chapter has been organized into various sections; the following section covers background of the study followed by statement of the problem. The next section presents objectives of the study, research questions, significance of the study followed by the scope of the study, organization of the thesis and the last part covers limitations and delimitation of the study.

1.1 Background of the Problem

A retail private pharmacy is an example of a pharmacy which shares no connection with other chains of pharmacies. These retail pharmacies are neither owned nor are operated by the public. Also the business is not owned nor its operation listed in the stock exchange where it is exposed to the publicly traded company.

Such retail pharmacy businesses are not limited to single store operation, pharmacy under ownership of multiple store locations, and supermarket pharmacy operation (RUCA, 2000). It should be noted that these retail private pharmacy owners attempt to reach the masses which is advantageous on the side of the clients, also, they have high standards of services to customers as they struggle to overtake chain pharmacy competitors.

Pharmacy practices play volumes of roles which include compounding and dispensing of medications alongside other engagements like use of more modern services they offer to healthcare. These services incorporate practices like clinical services, reviewing medications for safety and efficacy, and providing drug information. Examples of practices carried out by these businesses entities are

community pharmacies, hospitals, clinics, extended care facilities, psychiatric hospitals, and regulatory agencies. Pharmacists can specialize in various areas of pharmacy practice included but not limited to infectious diseases, ambulatory care, nutrition support, drug information, critical care, paediatrics, etc. (Shane, 2012).

There is an appearance of the capacity of differences experienced between the market for pharmacy practices in Europe as well as in overseas with the market surveillance for those who trade in pharmaceuticals in countries with low income with less regulatory capacities. Germany is an example with 21,500 pharmacies which guarantees that medicines are effectively dispensed, and this is done by qualified and registered drugs dispensers. The law also maintains that, there is no sale of illegal, outdated and non-prescribed medicines (Montagu, 2009).

In most low and middle income countries, regulatory oversight is constrained by governments which lack the implementation staff, budgets, or efficient regulatory and judicial framework that exists in developing countries (Kumaranayake, 2000).

Pharmacy retail businesses experience non frequent regulatory inspection, and also, enforcement is weak and infringements is common (Brugha, 1999). Administration is made particularly difficult because the pharmaceutical retail market in most low income countries is highly disjointed, and the number of formal pharmacies is not big in comparison to the types of retailers' pharmacy shops, in service training are regularly given to drugs dispensing doctors and nurses, medicine sellers, drug sellers and general stores owners.

Because of this non frequent inspection, the result is widespread unregulated and sometimes illegal sales of restricted medicines, often without prescription and often by unqualified staff (Brugha, 1999). This may explain possibilities of frequent outbreaks of certain diseases globally.

Studies have been made in order to try and assess pharmacy practices by looking at a wide range of factors; these factors are not limited to drug selection, adherence to treatment protocols and dispensing without prescription. And the findings, is that the degree to which specialized drug shops adhered to treatment guidelines was varied but low overall. There is variance in concepts and based on the way in which people adhere to treatment guidelines in response to their illnesses, the guidelines are as follows by consider respectively national guidelines adherence of few African countries when provides services to the clients,

The study revealed generally to be low in Kenya (27% adherence), Ghana (20-23%), and Uganda (8-14%) (Goodman, 2012)

In Tanzania, pharmacy regulations and practices were guided by Pharmacy Council Authority of Tanzania which was later designated to Tanzania Food and Drugs Authority (TFDA) (Pharmacy Act, 2003). The regulation practices happened under guideline for registration of premises and licensing of pharmaceutical business, TFDA has therefore been authorized to approve the registration of retail pharmacies. It also considers the availability of the drugs in the public interest.

Also, this authority is mandated to authorize unregistered drugs for specific purposes where it feels fit and circumstances concur. TFDA grants licenses for Drugs importation and exportation, manufacturing and selling of medicines under specified conditions (TFDA, 2003) the registration prohibits the use of any premises for the manufacture, sale, supply or storage of pharmaceuticals, only with an approval where the premises has been registered by the TFDA for that purposes.

Generally, retailer pharmacy in Tanzania is grouped into two major types, Part I and Part II pharmacies. Part I pharmacies have to be run by a registered pharmacist and are allowed to sell both prescription only and over the counter (OTC) medicines. In 2003 there were about 344 Part I pharmacies in Tanzania, out of this number, 60 per cent were in the commercial capital of Dar es Salaam, with the rest distributed disproportionately throughout the regions, always in urban areas (Battersby, 2003).

Drugs are much more widely available from Part II pharmacies, known as “maduka ya dawa muhimu” or drug shops. These drug shops were established in the 1970s so as to address the lack of access to medicines for a larger part of the rural and peri-urban population. By the year 2003, the Pharmacy Council had records of 5666 drug shops (Battersby, 2003). Although the total number may be considerably higher, these pharmacies are required to obtain a permit from pharmacy council using TFDA each year, and to meet certain conditions related to the premises, qualifications of the drug dispensers and products stocked (Ministry of Health, 1998).

The regulatory authority dealing with drugs and its sales provides that drug shop owners do not need any specific qualifications, anyway. It maintains that all staff serving customers is required to have basic medical knowledge, and this knowledge is interpreted by regulatory staff to training pharmacy assistant or nurse who have been recently selling the drugs.

Accredited Drugs Dispensing Outlets (ADDO) offers training of dispensing drugs annually in each district as the strategy for enhancing access of medicines (ADDO, 2005). ADDO trained drugs dispensers are only allowed to dispense OTC medicines, known as “dawa muhimu” drugs, literally means cool, or could be translated as weak or mild. The classification of medicine as “dawa muhimu” is done because those drugs are relatively safe and are used for minor and self-limiting conditions, whereby their uses are believed to have a public knowledge.

The given condition is that drug shops should not sell to their customers, any prescription only drugs, including all non-topical antibiotics and injectable of any kind (TFDA, 2003). However, in Tanzania, part II retail pharmacies are victims of violation of regulations imposed on them by selling prescribed medicines and antibiotics.

Tanzania has seen establishment of several policies meant to guide and govern pharmacy practice, the Drug Policy of 2001 (Drug Policy, 2001).which emphasizes the availability of safe essential drugs to all the people at the time they need them. The central aim of the Drug Policy is to encourage the growth of local, public and private pharmaceutical industries so as to encourage the growth of local Public and private pharmaceutical industries in order to enhance self-reliance in the production of essential drugs.

Regarding the implementation of the Seven Star Policy (WHO, 2000) on good pharmacy education practices, it is important for these pharmacists to play the role of care giver, decision maker, communicator, manager, lifelong learner, teacher and a leader.

There is a renewed partnership (a collaborative initiative between the European Union (EU), the World Health Organization (WHO) and the African, Caribbean and Pacific Group of State) has strengthened the partnership by being a driver to many challenges that are found within the pharmaceutical sector in the United Republic of Tanzania. The discussed challenges include: low availability of essential medicines and health products in health facilities, inadequate funding, poor planning and coordination, inadequate tracking mechanisms and inadequate pharmaceutical human resources at the facility level.

Additionally, there are substandard, falsified, and counterfeit as well as unregistered medicines and health products doing rounds in our Tanzanian markets. The rational use of medicines continues to be a challenge as well, and therefore more efforts are needed to target both the public and private health workers. More importantly, these challenges adversely affect the overall quality of care and performance of service provision at the district and national levels (WHO, 2012).

A recent study from Muhimbili National Hospital towards private pharmacy regulations compliance which has been conducted by Pharmaceutical Teaching and Development Laboratory 2012 came up with suggestions that stakeholders should provide training, research development and consultancy services in the pharmaceutical sector within the country so as to alleviate the problem of poor retail private pharmacy practice and regulation compliance.

1.2 Statement of the Problem

Regulatory infringements of retail private pharmacies are common in Tanzania. There have been few practical suggestions on public policy responses other than strict regulatory enforcement, which governments are often unable or unwilling to do (Goodman, 2007).

In Tanzania, pharmaceutical personnel are envisioned to be available for dispensing of medications, especially prescription only medicines in community pharmacies. However, this has not been the case in Cederlof (1995) assertion, that most retail drugs sellers dispensing drugs irrespective of prescriptions by unqualified personnel. This argument justifies what several studies have reported that most of the dispensers are not trained pharmaceutical personnel of any kind. As a result the drugs dispensing is undertaken by untrained personnel (Basak, 2005).

Currently, in Tanzania there are about 1000 pharmacists, 1200 pharmaceutical technicians and 1500 pharmaceutical assistants registered in Tanzania (TFDA, 2008). On the other hand there are more than 9,226 registered public and private pharmaceutical outlets countrywide and 5,467 drug shops are on application process, out of the above number provided there are 3,759 trained drug dispensers (ADDO, 2005). This indicates a poor ratio between trained pharmaceutical personnel and pharmaceutical outlets that are available across the country.

The reason for poor ratio between trained drug dispensers and outlets is because of rapid increase of drug outlets and shortage of trained drug dispensing personnel in Tanzania (TFDA, 2008). It can be assumed that untrained staff run and supervise these drug outlets, a practice which may obviously contribute to poor retail private pharmacy practice and regulations compliance during service delivery. This problem is widespread in the country and many places across the country have been affected by this problem including Morogoro Municipal Council.

In addition, there is a great demand for services that are offered by retail pharmacy practitioners and their clients. The set rules and regulations by TFDA is overlooked often when offering these services, and this may be explained by the trend in which these authorities in place responds to retail pharmacy practitioners by suspending their operations until they adhere to set rules and standards.

Therefore, this study aims at establishing an understanding of different factors contributing to retail private pharmacy practice and regulations compliance so as to reduce its effects to the consumers such as adverse drug effects, drugs resistance to the customer, allergy and poor patient health which leads to economic outcomes such as drug cost resulting to the increased utilization of health services and unnecessary intervention to reduce the growing social problem which the Government is indirectly facing.

1.3 Research Objectives

1.3.1 General Objectives

The general objective of the study was to determine different factors leading to retail private pharmacy practice and regulations compliance in Morogoro Municipal Council.

1.3.2 Specific Objectives

- i. To examine how retail private pharmacy practice is carried out (pharmacy owners/sellers).
- ii. To identify factors hindering retail private pharmacy regulation compliance.
- iii. To determine how government systems carries out retail private pharmacy practice and regulations compliance

1.4 Research Questions

1.4.1 Main Research Questions

What are factors that leading to retail private pharmacy practice and regulations compliances in Morogoro Municipal Council?

1.4.2 Specific Research Questions

- i. How are the retail private pharmacies practice carried out? (owner/sellers)
- ii. What are the factors hinder retail private pharmacy regulation compliance (customers/sellers)?
- iii. How does the government system carry out retail private pharmacy practice and regulations compliance?

1.5 Scope of the Study

The study was conducted in retail pharmacy sellers, customers, pharmacists and health officers in Morogoro Municipal Council, The Study aimed to assess retail pharmacy practice and regulations compliance relating to the side effects faced by general population (Customers) such as drug resistance, allergy, morbidity and customers satisfactions due to the different reasons classified in three factors such as retail pharmacy practices and regulations compliance as well as Government Systems towards guiding those drug shops. Area for the study was based on customers, drug dispensers and Municipal pharmacists and Health officers. Data were collected through questionnaires which were administered to customers and drug dispensers (Sellers) and deep interview were conducted to the Municipal pharmacists and Health Officers found within Morogoro Municipal Council.

1.6 Significance of the Study

The Study aimed to determine factors that are associated with retail private pharmacy practice and regulations compliance.

- It will help in improving health service delivery to the clients which in turn will help to reduce the side effects of drugs such as drug resistance drugs allergy and diseases morbidity
- It will help retail pharmacy sellers to be aware of the existing service delivery guidelines which will help them to improve service delivery.
- It will also help policy makers to review available policies concerning retail private pharmacy practice and regulation compliances so as to identify the existing gap and make necessary amendments.
- It will also help a researcher as it is his partial fulfilment for the award of master of health systems management of Mzumbe University
- The study will reduce cost of treatment to the government indirectly because side effects of poor retail pharmacy practices like drugs resistance and allergy to the customer (general population)

1.7 Organization of the Thesis

Chapter one comprises of six parts, it starts with background information of the study followed by statement of the problem, objective of the study, significant of the study, scope of the study, organization of the thesis and limitations and delimitations.

Second chapter is literature review, it chronologically entails theoretical review of the study which includes meaning and concepts of the study, retail pharmacy practice, retail pharmacy regulations compliances, quality assurance, medicine information and patients' satisfactions the second part is empirical literature review which includes pharmacy regulation practice in India, pharmacy regulation practice in South Africa. Also, Pharmacy regulation practice in Kenya and the last part is conceptual framework.

Chapter three is methodology used in the study, it starts with introductory part followed by research design, study area, study population, sample size and sampling technique. The chain followed by data collection techniques, ethical consideration and the last parts are validity and reliability of the study.

Chapter four is data presentation starting with introduction followed by research findings.

Chapter five is discussion of findings; first part is introduction, followed by findings and discussion from first group of respondent that is sellers of drugs shops, followed by findings and discussion from second group of respondents that is general population (customers) then third part involves finding and discussion from pharmacist and health officers.

Chapter six is concerned with summary, conclusion and recommendation of the findings, it start with education to sellers and owners, review of available guidelines, participatory approach, avoidance of biasness in registrations and lastly is increasing funds in supervisions.

1.8 Limitations and Delimitation

The research met its merit; the objectives presented were achieved, however, certain issues that would have hindered the success of this thesis arose. These issues are discussed below;

The researcher was met with financial challenges, example, the proposed budget was never met. Initial budget never included emerging issues like the fluctuated costs of transport and research digital audio recorder. The researcher, however, managed to carry out the research by making certain adjustments which on the other hand affected the efficiency.

Some respondents were not reliable; they did not fill and submit the questionnaires as they had earlier promised. The researcher had to take longer time in trying to understand them, because, their pharmacy retail shops had crucial information that

the researcher so much sought, thus, dalliance in the collection, interpretation and analysis of data as to the proposed date.

Certain retail pharmacy owners had unreliable businesses, for instance, their shops were closed often making the researcher believe there was something fishy, also, access to oral interview was never made possible, this was because they feared the unseen repercussions, possibly that authorities would look for them for doing such businesses. The researcher had to expand their knowledge of his intention, which it was purely academic, though, not all bought his idea and such lengthy negotiations hindered time that was set for data collection and analysis.

Finally, there was a challenge in meeting some pharmacists and health officers, they would in most cases fail to honour their promises, for such cases, the researcher was forced to remain patient and make more appointments which did not turn to be honoured as well. However, the patience of the researcher overcame everything the response did not happen on time but the data were obtained.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

This chapter discusses the literature review of the study. It is offering the theoretical reviews where definitions of key concepts are provided and review of theory embedded the study. The second section presents the empirical reviews, and the last section discusses the conceptual framework that was adopted for this study.

2.1 Theoretical Literature Review

2.1.3 Retail Private Pharmacy

A retail private pharmacy is an example of pharmacy which shares no any connection with other chains of pharmacies and they are neither owned nor operated by the public traded company. Private pharmacies are pharmacist owned, privately held businesses in varying practice settings. They include single store operations, pharmacist owned multiple store places licensed, compounding and long term care (LTC), specialty, and supermarket pharmacy operation (IPT, 2011).

2.1.4 Retail Private Pharmacy Practice

Pharmacy practice refers to the discipline of pharmacy involving developing of the professional roles of pharmacists. Pharmacists do engage themselves in such practices so as to effectively respond to the needs of the masses using their services for their various immediate maladies. The services are notorious for provision of optimal, evidence grounded care.

Basically, this practice demands viable support, of which primarily relies on provision of an established national framework which considers a followed quality and standards and guidelines outlined below.

Pharmacy regulation practices are the act of regulating or the state of being regulated. It is a principle, rule or Law which is designed to control or govern

conduct (RUPRT, 2000). Such regulations stipulate that these pharmacists should be held responsible for taking reasonable steps that ensures dispersion of medicine follows prescription orders, the order should be regarded with consistence and safety with whoever is mentioned in the very prescription.

Certain procedures must be ensued by pharmacists in their areas of jurisdiction, these procedures are not but limited to application of independent judgement to provide for safety for persons as well as to conform to the requirements of the prescribers, also, should such formalities fail, then the prescriber must be consulted and communication made fast-(RUCA, 2000).

2. 1.4.1 Sound Management Structure

In Tanzania, TFDA acknowledges the need for an established practice that takes into consideration efficiency in sales and distributions of drugs for privately owned retail shops. They claim that there should be well organized structures that seek to imitate the requirements of various patient groups, also, their organizational needs and range of level of activities within the pharmaceutical service, (TFDA, 2008). For this practice to achieve its effectiveness there should be an established professional and managerial accountability which is well harmonized.

2.1.4.2 Quality Assurance

Quality assurance must be an integral part of pharmaceutical practice. This is to say, there must be a compliance of statutory requirements and size that is sufficient in order to allow for provision of range of activities entailed in pharmaceutical services (NHP, 2004). Additionally, quality assurance should work at its best in order to have a place that is secured and conveniently situated for both the staff as well as the patient.

2.1.4.3 Safe Systems of Work

According to TFDA, errors that may arise in any component of pharmaceutical services must be contained at all costs. Such a requirement is a key in the interpretation and dispensing of prescriptions and the distribution of medicines (TFDA, 2008).

The system should consider the need for ensuring safety for both the staff from hazardous cases as well as disposal of all waste. Also, there should be systematic supply and management of drug for efficiency in terms of economy, whereby, there should be established prescription monitoring service which will ensure regular monitoring of prescription of services, including administration of medicine and ensured compliance with accepted practice and safe systems of work (TFDA, 2008).

Also, it is important that patients are counseled, in this case, their caregivers are subjected to such therapies for them to be well equipped so as to handle and promote safe use of medicines on the patients, and this means, including of activities that involves drug dispensers to offer counseling to patients before administering drugs on them. Such counseling should also be administered both to transferred and treated outpatients (TFDA, 2008).

2.1.4.4 Medicine Information

Medical information must be provided to both retail drug dispensers and customers in order to promote the safe, effective and economic use of medicines, this should be done through creation of a platform which ensures awareness is guaranteed to both the profession and to the public, that is to say, schools, community clinics, and patient support groups and many more.

Also, recommendation has it that there should be a proper coordination of any drugs adverse reactions to medicines such as established reporting system to facilitate the detection of previously unknown adverse effects and reactions that may occur in the treatment course.

2.1.4.5 Patient (Customer) satisfaction

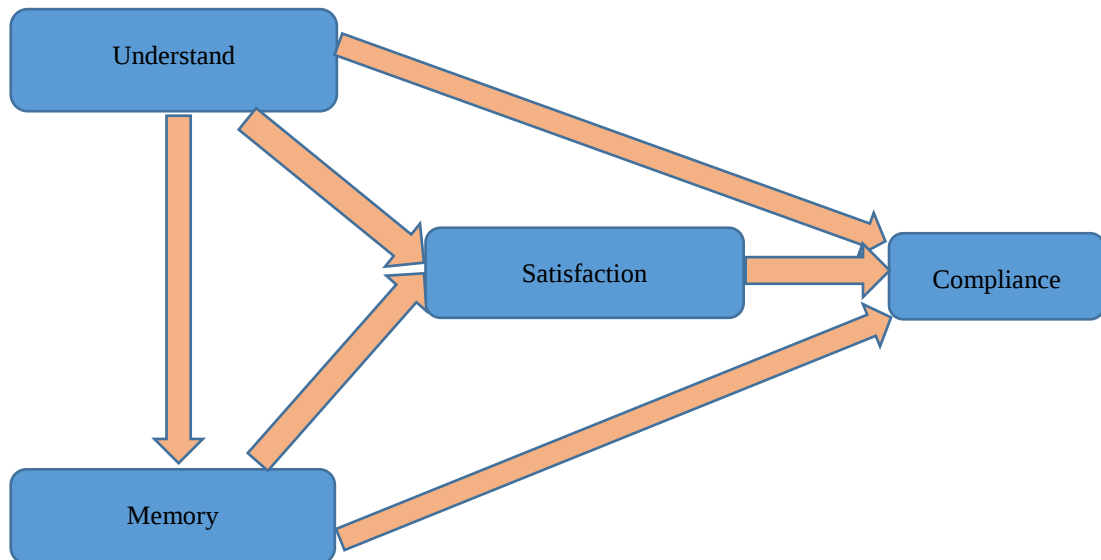
Patient is a customer in drugs shops or anybody who receives attention of the retail pharmacist and other services in the drugs dispensing outlets. Patient forms key participant in this nature of study since they are the main customers for which the retail pharmacy business is intended.

Satisfaction is an enjoyable feeling that you get when you obtain something you desired, or when you have done successive something you preferred to do (Cambridge English dictionary). Satisfaction is explained in this area of research to mean the response from the patients who as well act as customers in various pharmacy retail outlets.

Patient (Customer) satisfaction can be defined as a meeting of expectation of patient from a medical services and consultations (Mishra, 2014). When individual attends to the drug shops for any kind of service, he/she has an image of various aspect of the services delivery as per the cost involved. For those looking for medication, the main expectation is to get required services and stays healthily.

Satisfaction is determined by the content of discussion between drugs dispensers and patients that is patients (customers) need to know as much evidence as possible (ley, 1989) aspect of patient satisfaction may associate with compliance with the advices given during the consultation thus compliance to the consultation is the results of understanding, memory and satisfaction (ley, 1988)

Figure1.1 ley's Model of patient's compliance



Source: Ley's Model of patient's compliance

Several endorsements have been made in order to improve communication between drug dispensers and Patients (customers), therefore to improve this, may help to improve compliance (Ley, 1989). Suggested that one way of improving compliance is to improve communication in terms of consultations of an oral communication, the following influences are important on improving compliance;

- Primary effect in the sense that Patients have a tendency to remember the first thing they are told believing that is helpful to them. It is thus expected that if retail private pharmacy sellers are taught about private pharmacy practice and regulation compliance, they will abide to the stated regulations.
- To Stress the importance of compliance so that to use the advices given properly. If retail private pharmacy sellers and owners are continuously reminded of the recommended pharmacy practices and regulation compliance, it is believed that they will be able to follow all guidelines accordingly.
- To simplify the information not to have ambiguous answers. Information on retail private pharmacy practice and regulation compliance must be simple to be understood by stakeholders. This will help pharmacy sellers and owners to easily

be aware of the pharmacy practices and regulation compliance which in turn will enable them to follow the rules properly.

- To apply repetition on matters related to retail private pharmacy practice and regulation compliance can help to update awareness among retail private pharmacy sellers and owners hence this will improve retail private pharmacy practice and regulation compliance.
- To follow up the consultation with additional interviews so as to establish whether private pharmacy practice and regulation compliance is followed in accordance to the stated rules. This will also help to improve the situation when things are done wrongly or as expected to be done.

2.1.5 Retail Private Pharmacy Regulation Compliance

This refers to how private pharmacy act in accordance with the established rules and regulations that guide drug shops. Such regulations cover the following;

2.1.5.1 Registration of Retail Pharmacy or Drug Shops

According to TFDA, it is a requirement for any business premise dealing with sales and dispensing of drugs under section 18 Act 2003 to acquire a licence for doing business. (TFDA, 2008).

This should be well addressed in line with manufacturing, sale, supply or storage of pharmaceutical business, which means, there shouldn't be registration of any such dealings as the use of any places for the manufacture, sale, supply or storage under condition that the place has been registered under TFDA Act 2003.

Moreover, section 20 of the same Act requires stake holders in such business to get licence from the relevant authorities before doing the business. And the mentioned practices do not guarantee the means of controlling such premises but as other means of assistance in imposing relevant legislation. This includes adherence to good hygienic and pharmacy practices of these premises as required by laws and regulations.

Another requirement outlined under section 18 of the TFDA Act 2003 prohibits the use of any manufacturer which lacks registration by the very authority. Similarly, TFDA Act 2003 section 20 stipulates that obtaining of business licence is compulsory in order for one to engage him/herself in drug business activities.

The TFDA authority is allowed to suspend and cancel the registration certificate and license of any pharmacy found to operate against the given law. Such guidelines are put so as to see that there is an improvement of basic needs including distance which should be minimal between the retail private business pharmacies. The action is made so as to achieve a fairly distribution to the other outlets as well as accessibility of drugs in different areas.

Also, these guidelines have been established to incorporate the retail size of these private pharmacies. The guidelines are meant to ensure efficiencies majorly in two main parts; the main guidelines and six annexes. The main guidelines give a procedure for application for registration of retail private pharmacy.

These discussed guidelines also outlines procedures on the location, places design and layout, required service providers, storage facilities, sanitation and hygiene, and also stock control and handling, records and documentation, recalls, reject and withdrawal, cessation of business, validity of premises registration and pharmaceutical business permit, payment of fees, language, notification for change of any or changes of registered premises, refusal or revocation of registration certificate and permit, appeals and required reference materials.

These mentioned annexes include application forms, registration certificate of pharmacies, business permit, medical representative permit, inspection checklists and particulars or contents for records books. Sellers should note that, the requirements mentioned in these guidelines are in accordance with minimum requirements. In that sense sellers are encouraged to abide to these requirements.

The said applicants must read carefully and understand these guidelines before engaging in construction of the intended pharmacies. The following are requirements to be followed by an applicant; a copy of the Guidelines for the construction of the intended premises, Application for premises registration and permits to operate the business of pharmaceuticals.

2.1.5.2 Location of Drug Shops

TFDA (2008) states that drug shops and premises should be located far from areas where activities emit intolerable materials and exhaust contaminants and also things like open sewage and offensive trade (TFDA, 2008). It also well advocates for location of pharmacies far away from petrol stations where fuel fumes are inevitable, such measures do guarantee safety and quality of medicines and dispensation process in the pharmacy.

Other issues that demand attention of quality assurance are mitigation measures against possible fire outbreaks, therefore, prevention facilities is a must, and if possible, such shops should be within secured premises in the shopping malls, supermarkets among other places considered safe from possible fire outbreak. These mentioned places are reliable for they are equipped with prevention facilities. (TFDA, 2008).

Also, TFDA (2008) offers that the pharmacies shall be designed in a way that, it shall have no direct link to building with bar, restaurant, medical laboratories, dispensary, clinics or in direct link to residential houses where the business is housed.

And that these mentioned premises should have a postal address and physical address of the premises to include plot and house number, street or settlement, district and region where the business is to be carried out, clearly shown in the application form for easy communication and reach during supervision and inspection. Also crucial is the sign board that should be put in order for customers and inspectors as well as the displayed logo at the main entrance.

Registration of premises shall be approved if the new premise is at least 300 metres away from the existing pharmacy. However, the authority shall have power to review this requirement from time to time in accordance with the community requirements and the population of a given locality. It is equally important for these sellers to adhere to the principles and rules that require them to be retail pharmaceutical dealers with a registered pharmacy (TFDA, 2008).

2.1.5.3 Appearance of Pharmacy Premises

TFDA (2008) stipulates that the design and layout of the pharmacy must permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimize the risk of errors, cross infection and anything else which would have an adverse effect on the quality of products (TFDA, 2003).

It is important that there should be assurance entailing that all if not major parts of the premises are maintained in an orderly and observe a condition that is neatness. The name of the responsible pharmacist must be displayed obviously over the main entrance of a pharmacy. The name and surname of the pharmacist(s) on duty must be displayed conspicuously in or outside the pharmacy for purposes of identification of such person(s) by the public.

TFDA (2008). maintains that, it is necessary for pharmacists and pharmacist support personnel on duty to have on, a name tag or budge that indicates his/her name, surname and the registered designation including responsible pharmacist, and specialist among other relevant persons. This should be addressed in order for the public to have the specialists' identification. This may be combined into a single badge or two separate badges. The pharmacy must have a single point of entry and a single point of exit in compliance (OHSA, 1993).

The opening and operation of another business in a pharmacy must be such that: the other business has obtained approval from their statutory council or registration Authority (if applicable) and submits same with the application. The other business does not pose any conflicting interest either ethically or professionally to the practice of pharmacy such as added security risk to the keeping and supply of medicines, added risk to the patients compromises the quality, efficacy and safety of the medicine.

The very premises of the other business must be clearly identified and demarcated from the Pharmacy premises, the demarcation must be permanent, solid and closed off at all times, which Demarcation may be, brick and mortar, aluminum, steel, glass, dry wall or Wood partition (OHSA, 1993).

2.1.5.4 Safety of Pharmacy Premises

There should be a favorable condition for working, and this should be made possible by arrangement and protection of people working in the premises which is in compliance with the relevant legislation relating to the safety of the workplace.

Also, there must be fire extinguisher in any licensed pharmacy, and these fire extinguishers must be regularly checked in order to toe the procedural line. Electrical equipment must be safe and maintained regularly, proper provision must be made for an adequate number of electrical sockets. Care must be taken to avoid trailing wires across floors, work surfaces or sinks (TFDA, 2008).

2.1.5.5 Condition of Pharmacy Premises

According to FIP (2009), pharmacy premises must be in a good condition, such conditions include keeping clean and in good order the walls, floors, windows, ceiling, woodwork and all other parts of the premises .Also, these places must be repaired so as to prevent any practicable risks of infestation countertops, shelves and walls must be finished in a smooth, washable and impermeable material which is easy to maintain in a hygienic condition (FIP. 2009).

2.1.6 Construction of Pharmacy Premises

The authority regulating sales and regulations of drugs demands that construction of the premises must ensure that the entry of insects, animals (especially rodents) or birds is prevented and that the premises can be easily cleaned and disinfected (TFDA, 2008).

2.1.6.1 Environment in Pharmacy Premises

It is important to note that storage of thermo labile medicines must be in accordance with the storage instructions of the manufacturer, which means refrigerators used for the storage of thermo labile medicine, must be calibrated regularly. Products must be protected from the adverse effects of light, freezing or other temperature extremes and dampness, levels of heat, light, noise, and ventilation among others, must exert no adverse effects on pharmaceutical stock as well as personnel.

All parts of the premises must have suitable and effective means of heating or cooling, lighting and ventilation. Suppose windows can be opened, they must be locked securely when the pharmacy is closed. Also, background music or other broadcasts in the pharmacy must not be played at such a volume so as to cause distraction (NHP, 2004).

2.1.6.2 Hygiene in Pharmacy Premises

A hygiene practice is compulsory in the medical premises, there must be an area where equipment and other tools can be washed and these areas must have a source of hot and cold tap water. A suitable, clean wash hand basin made of a smooth, washable and impermeable material which is easy to maintain in a hygienic condition and has a source of hot and cold tap water and a closed drainage system must also be made available.

WHO (2010) maintains that toilet facilities must be kept clean and in good order. Hand-washing facilities must be provided in the toilet area or the lobby together with a conspicuous notice requesting users to wash their hands. These toilet facilities must

include readily available hot water, soap and clean towels or other satisfactory means of drying the hands. Toilet areas must not be used for storage, or as a source of water for dispensing (WHO, 2010).

2.1.6.3 Storage Areas in Pharmacy Premises

Storage within pharmacy areas must have sufficient shelving constructed from a smooth, washable and resistant material, these materials must be easy to maintain in a hygienic condition for the keeping of medicines above floor level. Also, storage areas for pharmaceuticals must be self-contained and secure. Storage areas must be large enough to allow for orderly arrangement of stock and proper Stock rotation (WHO, 2010).

2.1.6.4 Waste Disposal

The TFDA (2012) contributes that a suitable and adequate means of waste disposal must be available and in use. Moreover, such waste materials must not be allowed to accumulate and must be collected in suitable covered (as applicable) containers. These containers are best placed for removal of and collection of waste disposals. Written sanitation procedures must be available detailing schedules, methods, materials and equipment available. Another important aspect that is maintained by TFDA (2012) is that responsibility must be assigned in writing.

The condition has it that under no conditions waste substances must be disposed down surface water drains, example is storm water drains. In all circumstances, drugs dispensers must apply his/her pharmaceutical knowledge and skill, together with any necessary expert advice from a Local Authority or Provincial department of health, to separate and dispose of materials, and biomedical waste safely and in accordance with regulations (TFDA, 2012).

Maintaining of hygiene with respect to sewage disposal, TFDA (2012). Concludes that there must be adequate, suitable dispensing equipment in the dispensary. And these items in the dispensary must be cleaned, in good repair and of suitable material. Below is a list that provides a standard.

In order to maintain the hygiene, it important that, first of all, each of the equipment must be specific for each service which may be provided in the pharmacy, a suitable means of counting tablets and capsules. Second, the equipment must be cleaned regularly so that cross contamination between products is avoided. And finally, there must be an accurate dispensing balance with proof of annual maintenance (if compounding is performed in the pharmacy).

2.1.6.5 Types of Drug Shops

Tanzania has a country has different types of pharmacies, these pharmacies are based on the types of premises that are well designed (TFDA, 2008). These types of pharmacies are retail pharmacy premises which have a minimum of two rooms with clear separation and linked to each other for displaying and dispensing and store room. Also, these premises must have one main secured entrance, the minimum total size area of the premises shall at least measure 20m².

More importantly, the rooms should have not less than 2.5m internal height. And these very rooms should be equipped as indicated in the inspection checklist where adequate shelves or pallets as the case may are well put for proper display and storage of medicines respectively.

Additionally, other pharmacies to say, whole sale shall have not less than three rooms with clear separation and linked to each other for display, receiving and dispatch, record keeping and storage. The rule stipulates that it is important that these premises do have one main secured entrance. And more so, the premises shall have a minimum total size or area of at least 40m².

The rooms within the pharmacy premise should have not less than 2.5m internal height. And finally, these rooms should be equipped as indicated in the inspection checklist with adequate shelves and pallets for proper display and storage of medicines respectively.

Retail and whole sale premise is considered as another type of pharmacy. The pharmacies assume the role of both retail and whole sale business, in which case, such premises must have at least three rooms namely; display, receiving and dispatch room; sales, recordkeeping and dispensing room; and the storage room, the minimum total size or area of the premises shall at least measure 40m².

According to TFDA (2008), these rooms should have not less than 2.5 m internal height and should also be equipped in respect to the inspection checklist. The rooms should be equipped as indicated in the inspection checklist with adequate shelves and pallets for proper display and storage of medicines respectively. Finally, a clear demarcation of wholesale receiving/dispatch area from the retail part shall be provided to allow orderly receipt/dispatch of pharmaceuticals in bulk (TFDA, 2008). Warehouse is the last type of pharmacy premises, the regulation states that warehouses shall be designed and constructed to ensure good storage conditions, sufficient lighting and ventilation. It is noted that any warehouse shall have enough capacity to allow storage of various categories of pharmaceutical products. The warehouse floor shall be durable to withstand heavy movement and loads; the premises shall be provided with well-fitted shelves or pallets.

Also, the guiding rule has it that premises shall be equipped with temperature and humidity control facilities, monitors and fire extinguishers.

And lastly, residential home shall not be used as a store room whereas the storeroom shall only be used for storage purposes and no sells shall be conducted within the storerooms.

2.1.7 Government Systems on Retail Pharmacy Practice and Regulations Compliance

The Tanzanian government has put in place the system whereby the retail private pharmacy practice and regulation compliance demands, inspections, inspection checklist for new pharmaceutical premises, a letter of commitment, an inspection report and all other necessary documents from the drug inspectors, internal Technical Committee of Inspection and Licensing of pharmaceutical and Cosmetics Businesses for approval (TFDA, 2008).

2.1.7.1 Cessation of Business

To all licensed drugs dispensers, the regulation has the mandatory for closure of the business premises or suspension since it is within its jurisdiction to determine any permit that has been suspended and or cancelled in accordance with the provision of the Tanzania Food, Drugs and Cosmetics Act, 2003.

And in case the permit is revoked, there shall not be renewed except with the consent of the authority if satisfied with the reasons given by the prior permit holder. Suppose there is satisfaction from the authority, it may issue or declare a business closed down and deleted from the register, if for any reason such premises will be found operating contrary to the prescribed requirements and standards stipulated in the Act.

The operation of the business shall be closed down and deleted from the register whereas the notice that is given by the health supervisor expires without the retail shop owner being able to secure the supervision of another supervisor, because of conditions that are set out in work contract agreement between the retail shop owner and the authority.

And also, where the supervisor has given notice to the retail shop owner, therefore, the supervisor shall continue to inspect the very premise while the retail shop owner continues paying for the very premises monthly expenses until the end of the notice or any changes within the notice.

Moreover, such notice given either by the retail shop owner or the supervisor must be equipped to the authority.

The retail shop owner has the option of closing down his/her shop at their own wish but he/she must officially inform the authority in advance, so that the disposal of pharmaceutical products is done under the immediate supervision of the supervisor.

According to TFDA (2008) Act 5, any business that has been issued with a closure order shall surrender the premises registration certificate and valid permit to the district or regional drug inspector or TFDA. This will happen depending on where the business premise is located. The district, regional or TFDA inspectors are the relevant authorities equipped with mandate to see to it that the closure and revocation of business permit and to ensure that no registration certificate or permit remain in unauthorised hands.

The very act maintains that businesses that have been issued with closure order shall immediately be deleted from register and in any case they would wish to re- open their premises, these business owners shall be required to apply as new applicants. In any case it happens that, may be, the supervisor dies, the authority shall give there tail pharmacy owner 90 days closure notice to look for another registered supervisor whereas, failure to adhere to such procedural practices, a requirement shall be made to see that the business and the stock is disposed to lawfully registered dealers. During that time the business may be under the immediate supervision of a diploma holder in the related profession.

A written permission shall be ensured for representatives of the deceased persons' representative, in case the deceased before demise, had a lawfully possession of any permit to offer pharmaceutical businesses, or any appointed liquidator, receiver or

other person dealing with the property of any person who has ceased to be entitled to possess any pharmaceutical permit to deal with pharmaceuticals. The very benefactor is entitled to continue with the business by a licensed body of registration, or wholesaler or seller of drugs.

2.2. Empirical Literature Review

2.2.1 Pharmacy Regulation Practice in India

In India, there is a measure that is taken by pharmacy council of that particular country: the measure is taken with private pharmacy practices. These practices are governed by pharmacy Practice regulations of 2015.

These regulations contains that stipulated the location of pharmacy premises as well as the duties of registered pharmacists to their patients. The authorities have maintained that some duties are obligation to the sick and the injured but shall be mindful of the high character of his mission and responsibility (Government of India press, 2015).

There are registered pharmacists and in case they experience any incapacity unfavourable to the patient or which can affect his/her performance with patients, he/she is will not whatsoever have permission to practice his profession. Patience delivery, confidentiality on patients' weakness shall characterize the registered pharmacist, forecast the registered pharmacist shall neither exaggerate nor minimize the gravity of patients' condition.

The registered pharmacist shall ensure himself that the patient his relatives or his responsible friends have such it is important that pharmacy practitioners have an awareness and some knowledge of the patient's condition and should also serve the best interest of the patient and the family patient must not be neglected in anyhow. The pharmacist who is registered shall not wilfully commit an act of negligence that may deprive his patient or Patients from necessary medical care (Annand, 1999).

In India, laws are put and strictly followed so as to cut down the any increase in pharmacy retail businesses illegally. Such stipend rules are provided for in their Pharmacy regulations Act. It is for these rules that India is considered one of the countries in Asia with not only a big population but also a country experiencing best health practices in retail pharmacy businesses.

Lastly, the Government of India works closely with respective bodies that regulate pharmacy business control centres so as to provide efficiency and reliable service to its citizens. For instant, any complaint raised by the public about retail pharmacy practices that are questionable is directly addressed by the Government, which amounts to closure or suspension of the business.

2.2.2 Pharmacy Regulations Practice in South Africa

In South Africa there is the South African Pharmacy Council. This council performs the regulation under pharmacy Act 53 of 1974. It stipulates how good pharmacy practice requirements is, which in this case could have the following characteristics. The regulation takes into consideration the welfare of the patient as its prime concern before that of the public in general.

The primary activities of these accredited pharmacists are to offer supply and to distribute medicines and other health related support to both the patients and to the public. These services are but not limited to provision of appropriate information and advice to the patient, ensuring the correct use of medicine and monitoring the effects of the use of medicines.

Also, where applicable, the pharmacists are advised to adhere to good manufacturing practice as determined by the medicines control council and this would ensure the safety, quality and efficacy of medicine distributed. An integral part of the pharmacist's contribution to health care is the promotion of rational and economic prescribing and optimal use of medicines.

The objectives are well defined in the medical practitioner Act in the very country, whereas, each element of the care provided by pharmacists is clearly defined, relevant to the individual and effectively communicated to and accepted by all those involved.

In order to satisfy these requirements, there must be a strengthened relationship with other health care professionals, and such a relationship should be seen as a healing. Any alliance involving mutual trust and confidence is welcome in all matters relating to pharmacotherapeutic then the relationship with other pharmacists should be as colleagues, that is, each seeking to improve Pharmaceutical services, rather than as competitors.

And finally, there must be input by the pharmacist regarding decisions on medicine use policy at all levels. The relationship which has been advocated for with those involved in paying for pharmaceutical services should as well observe the mutual trust, the trust that involves appropriate professional decision from the pharmacist. The pharmacist needs independent, comprehensive, objective and current information about Therapeutics and medicines in use. More so, the philosophy underlying practice must be professionally rather than commercially orientated.

2.2.3 Pharmacy Regulations in Kenya

In Kenya, effective regulation of medicines, pharmaceutical workforce, pharmaceutical services and premises has suffered partially. And this hindrance is attributed to lack of human resources and capacity within the Pharmacy Poison Board (PPB). The strategies meant to strengthen the PPB were initially given through the KNDP in 1994.

This strategy was developed by participants from various government ministries, universities, research institutions and professional institutions, among others and it was supported by WHO, Department for International Development (UK) and the government of The Netherlands (Thoithi, 2009).

The primary aim of this department was to ensure and strengthen the pharmacy department of the Ministry of Health, this ministry serves the public sector, and to reform the PPB in order to strengthen drug legislation and regulation of the profession.

According to Okalebo (2009), there was a review of the KNDP implementation plan which showed that there was lack of clarity of the role of PPB, inefficiency, inadequate representation of stakeholders in the PPB, lack of an organizational structure and scheme of service, understaffing and lack of statutory powers to enforce a code of ethics (Okalebo, 2009).

Okalebo (2009) adds that, as a result, strategies were laid out primarily to establish and more so strengthen registration of personnel and drugs, pharmaceutical inspectorate, drug information, licensing of pharmaceutical premises and the training and assessment committee.

There were other strategies put in place then, such as developing an organizational structure, standard operating procedures, terms of service and job descriptions and recruitment. Since such inception, the above-named units have been set up and more staff have been employed and trained in areas such as drug regulatory affairs and pharmacovigilance.

Additionally, the PPB has acquired better premises and facilities. Therefore, any involvement that entails varieties of stake holders in the formulation of the strategic plan, and the support of development partners, engagement of legal experts and a reasonable revenue base have proved to be viable factors primarily concerned with the strengthening of the PPB.

However, although the operations of PPB have been considerably strengthened, PPB does still experience insufficient human capacity to handle illegal and unethical activities. Such drawbacks are but not limited to the manufacture and importation of

substandard and counterfeit medicines, supply of medicines to unauthorized persons and operation of establishments by unauthorized persons (Okalebo, 2009).

Estimation has it that about two-thirds of pharmacy retail outlets are supposedly to be shut down for operating without a license. The Pharmaceutical Society of Kenya (PSK) has contributed to improved practice standards; this has been achieved through engaging media and training activities where campaigns have been tirelessly conducted to enable efficiency.

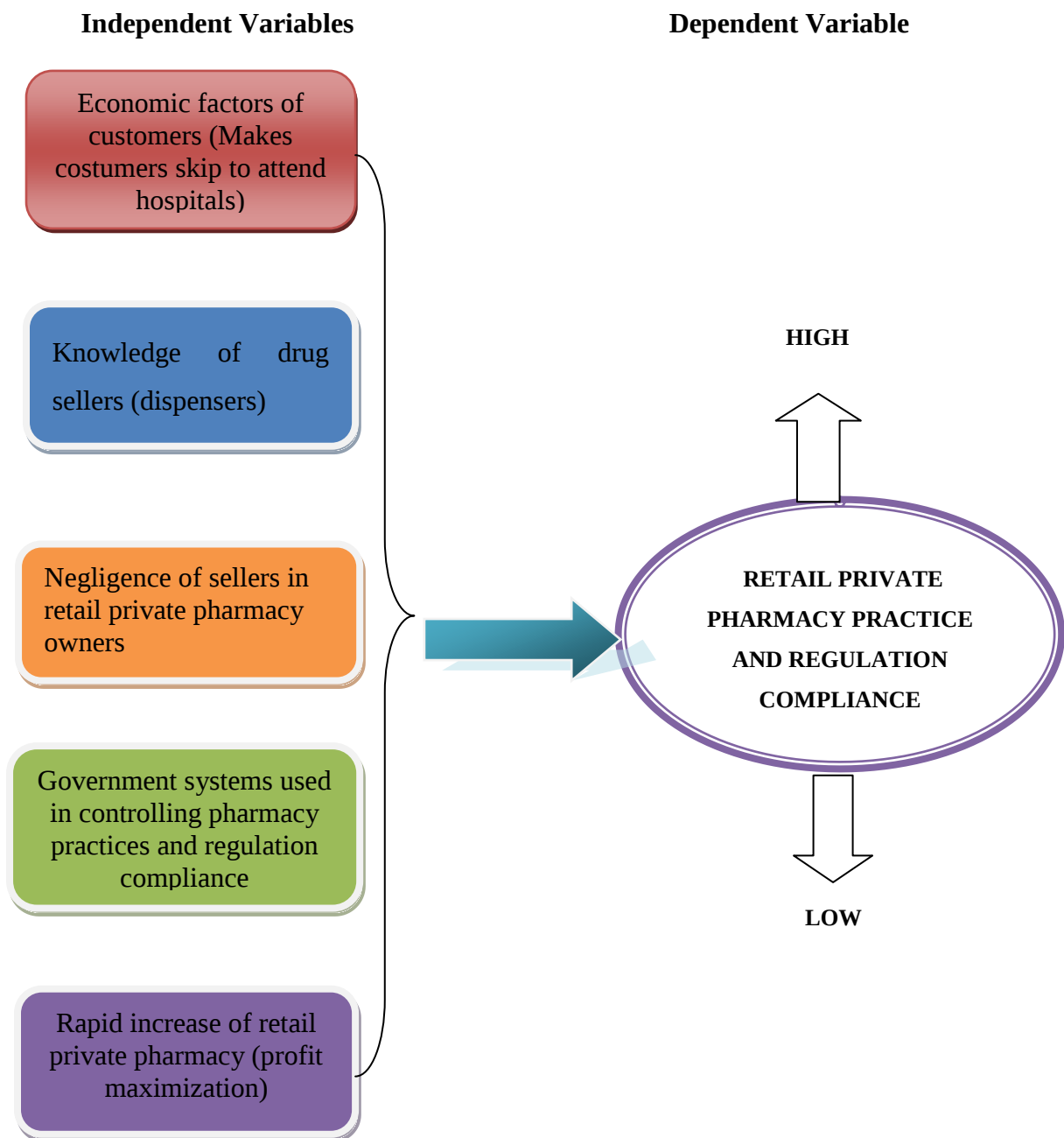
The suggestion that were presented by Continuous Professional Development (CPD) programs were carried in 1998 and the implementation was made effective in 2006 by the PSK. This initiative has been successful because it is a requirement for renewal of the annual practice license from the PPB.’

And finally, Kenya controls the number of retail pharmacies in accordance with the population of a given locality, for instance, there is unlikely possibility of licensing a new retail business without considering the demand in that particular locality. Government is also keen on closure of these businesses when they realize that the retailers fail to adhere to rules that are put in place especially on realizing that the drugs sold do not follow the placed rules and have a possibility of endangering the masses.

2.3 Conceptual Framework

This is defined as an abstract idea or a theory used to develop new concepts or to reinterpret existing one (Kothari, 2004) It shows the relationship between independent variables and dependent variable.

Figure 2.2 Conceptual Framework



Source: researcher 2016/2017

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter clarifies how a research was been conducted so as to answer the research questions proposed by providing detailed information through various basic steps. Those steps were followed in order to collect relevant information which can easily be understood by an inexperienced person who will be interested to read this report. This chapter defines the research design, area of the study, study population, sampling technique, and data collection and analysis methods.

3.2 Study Design

A case study design was selected and used to carry out this research from October 2016 to June 2017. A case study Approach was used in order to come up with detailed information about different factors contributing to retail private pharmacy practice and regulations compliance in drugs dispenses services delivery at the municipal level since the design is susceptible to biasness more than other study design it enables a researcher to select a particular area and collect data through application of various data collection techniques.

This study used questionnaires, documentary review and interview during data collection, also the study design is economical in terms of cost and time. The results of this study will be generalized to municipal health system in Morogoro Municipal Council.

3.3 Study Area

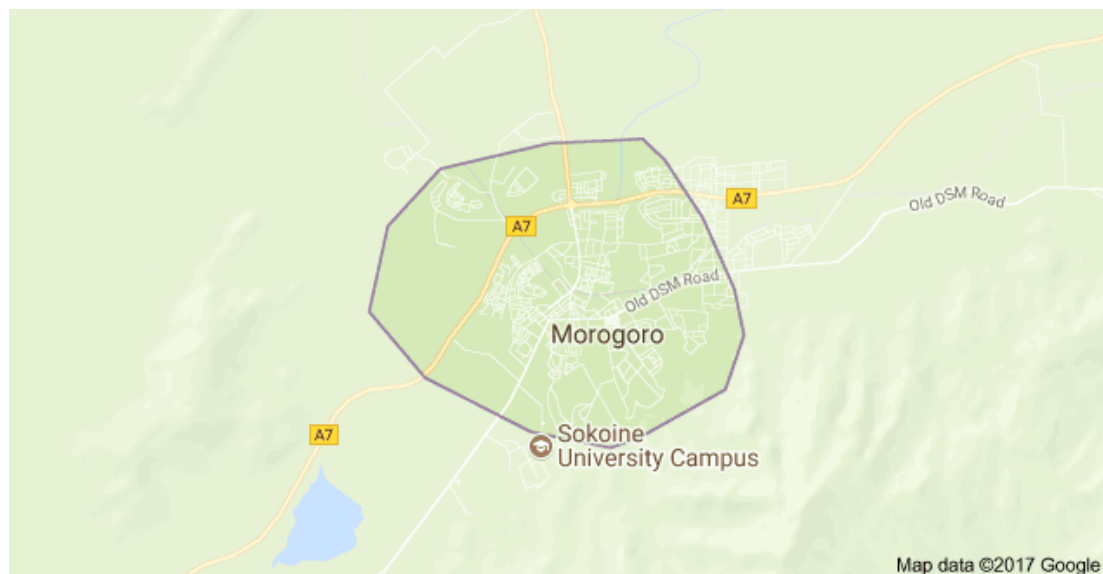
This study was conducted in Morogoro Municipal Council, Morogoro Municipal Council is a city with a population of 315,866 (NBS, 2012). Located in the eastern part of Tanzania, 196 kilometres west of Dar es Salaam, the country's largest city and commercial centre, and 260 kilometres east of Dodoma, the country's capital city, Morogoro Municipal is the capital of the Morogoro Region. It is also known

informally as "Mji kasoro bahari", which interprets as "city with short of an ocean or port".

This Study area was been chosen because of the growing problem of poor retail private pharmacy practices and regulations compliance in that particular area and no Studies had been done so far to assess such problem, The researcher was curious to assess the factors contributing to retail private pharmacy practices and regulations compliance in that place.

Also the place was economical to the researcher since researcher is very familiar with that particular area.

Figure 3.1. A Map Showing Morogoro Municipal Council



Source: www.google.com

3.4 Study Population

The target population of this study is inclusive, that is, a population of all residents of Morogoro Municipal Council with the primary study population being retail private pharmacy shopkeepers (sellers), Pharmacists, health officers, and general population

(Costumers of drugs aged above 15 years) living in different parts of Morogoro Municipal Council.

3.5 Sample Size

The sample size for this study was approximately to be 120 calculated using the following formula from the population of 315,866 (NBS, 2012) and if residence above 15 years are excluded then the target population was found to be 248,446 then the sample size was guided by the formula.

$$n = \frac{N}{1+N(e)^2} \text{ (Yamane, 1967) in (Kothari, 2004)}$$

n = the minimum sample size when the population is more than 10,000

N=Target population

248,446 Morogoro residences above 15 years per National census of population and housing of 2012

e = Marginal of error can be 0.05(5%) indicating 95% confident level or 0.1(10%) indicating 90% confident level I opted 90%

1= constant

$$\text{Whereby } n = \frac{248,446}{1+248,446(0.1)^2} = 120$$

Respondents were coming from different categories in the Morogoro Municipal Council which includes the following wards; Sabasaba, Kiwanja cha Ndege, Uwanja wa Taifa, Mji Mpya, Kingo, Mji Mkuu, Sultan Area, Mafiga, Mazimbu, Mwembesonga, Kichangani, Kilakala, Boma, Mlimani, Mbuyuni, Kingolwira, Bigwa, Mzinga, and Kihonda (NBS, 2012). Respondents were included; retail pharmacy sellers, pharmacists, Healthy officers and costumers of retail pharmacies.

3. 5.1 Sampling Technique

The technique applied in selecting sample was both probability and Non probability sampling techniques in probability sampling researcher deployed Simple random sampling technique due to its effectiveness and appropriateness to get number of

retail shops and Multi-stage sampling was used because the study covered many stages which involves different techniques sampling at each stage.

Non probability sampling deployed in this study were Purposive sampling (judgemental sampling (Kothari, 2004) the reason for the choice of purposive sampling was that, the focus of the study primarily aimed at specifically assessing issues attached to retail drugs trade and service they offer, this technique was used to obtain healthy officers and pharmacists, also convenience sampling was deployed to get the number of customers in which case, they were solely the researcher's target. Thus, all respondents selected in this study were provided with questionnaires, documentary review and subjected to interview.

The sample was selected by using the following steps.

Step 1. the researcher selected 10 wards out of 19 wards available in Morogoro Municipal Council (NBS, 2012) their names were written on pieces of paper which were then closed and placed in the Bucket and being sampled using rotary method, here only ten wards namely Mji mpya, Mji mkuu, Sultan Area, Mafiga, Mwembesoya, kilakala, Sabasaba, kihonda, Boma, Kingolwira were obtained

Step 2. Each wards the same rotary method was used to obtain two (2) Shops names of drug shops were obtained from the regional pharmacy officer, makes a total of 20 Sellers whom were administered 20 questionnaires.

Step 3. Each wards having selected 2 shops Rotary sampling also was deployed to get one (1) shop were by each selected shop was responsible to get 9 customers which in turn it brought a total of 90 customers whom were administered 90 questionnaires using Convenience sampling technique to select customers.

Step 4. Purposive sampling was deployed to get a total of 10 healthy officer and Pharmacists whom were given an Interviews.

Table 3.1 Table drawn shows how the samples were obtained

	Sellers	Customers	Health officer and Pharmacists	Total
Questionnaires	20	90		110
Interviews			10	10
Total	20	90	10	120

Source: Searcher (2017)

3.6 Types of Data

This study administered the application of both primary and secondary data. Primary data was used to collect information from the field using different data collections which were questionnaires, interviews as well as documentary review was also used to enable a researcher to collect relevant information for this study.

Secondary data were obtained after reviewing various documents containing different information which had already been collected and stored. Such documents include books, journals, articles and past researches, websites as well as information from the library.

3.7 Data collection Techniques

These thesis were using different data collection techniques in order to enable a researcher to collect relevant information concerning this study. Data collection techniques involved were questionnaires, documentary review and Interview.

3.7.1 Questionnaire

Both closed and open questions were used for this study. With limited access to time, this involved the retailer pharmacy sellers who were given 20 self-administered questionnaires and 90 self-administered questionnaires were given to the general population (customers). The questionnaires were used because it enabled the researcher to reach many people even those who were not able to talk: response could be obtained at his/her convenient time.

3.7.2 Interview

Interview was used to collect data (primary data) from pharmacists and health officers were by a total of 10 pharmacists and health officers were given in-depth interview (by using guided questions) the interview was used because it saved time, less expensive, and could be conducted to someone at a far distant (remote area).

3.7.3 Documentary review

Documentary materials, literature and other relevant information were used in this study to gain some information relevant to the study documentary material were found in Morogoro Municipal Council, library and information from websites.

3.8 Data Processing and Analysis

The researcher analysed the collected data by using Statistical Package for Social Sciences (SPSS) 22. This method helped the researcher to analyse data and present results in tables, graphs and percentages depending on the data collected. Information obtained were translated from Swahili to English language and checked for accuracy and completeness.

3.9 Ethical Considerations

Ethical consideration for this study and permission for data collection through questionnaires, interview and documentary review was voluntary and written informed consent of prospective participants.

The study observed the importance of addressing ethical issues. In this regard, the researcher observed ethical issues during the entire research process. The researcher collected information after the consent of the respondents, and no step was attended without their consent.

To ensure confidentiality, all respondents were assured with protection of their individual and personnel identities, names or other personnel identifiers. Also more importantly, rules, regulations and ethics of the municipal council were observed by the researcher by providing the pre education on the importance of the study.

However the study ensured that there is neither invasion of private space, physical or social harm to human participating in the research, no respondents forced to take part in the study, and no false promises made in order to win the participants to agree in research study.

3.10 Reliability and Validity

3.10.1 Reliability

Reliability means how consistent a research procedure is (Kothari, 2005). This implies that stability and dependability of an instrument or procedure in order to obtain information. For this research, the researcher employed pilot survey to ensure the degree to which the assessment tools produce stable and consistent results. Pilot survey was done independently to enable the researcher to have prior information of what he actually sought to achieve in this area of study.

During the research, reliability was ensured through the application of more than one method of data collection. The varieties of methods were engaged to ensure consistencies in the data were collected. The researcher therefore applied; questionnaire, interview and documentary review. The study used secondary data methods by passing through several articles, journals and books.

3.10.2 Validity

Validity is the universal laws, evidence, objectivity, truth, actuality, deduction, reason, facts and mathematical data (Kothari, 2005). Validity can therefore be said to determine whether the research truly measures what is intended to be measured.

It refers to whether the means of measurement are accurate and whether they are actually measuring that what they should. Thus, applying that a valid research should

claim credibility and believability, the researcher made this possible by the use of accuracy.

To ensure validity of measures, data were gathered from various categories of respondents within the study area. Respondents were selected basing on different gender, age, occupation as well as different marital status and experience.

For this research, the researcher ensured validity by using the correct research tools for obtaining data. The respondents were drawn for interviews and questionnaires from Regional Health Officers and drug dispensers (customers) respectively.

Pilot survey was conducted in order to make this research valid. The researcher visited various pharmacy retail shops prior to the actual research, pilot survey enabled validity by ensuring that these established premises were actually carrying out such the drug business.

CHAPTER FOUR

RESEARCH FINDINGS

4.1 Introduction

This part, shows the findings which were emphasised during the study. The researcher observed, investigated and discusses the findings from the realistic data by considering research questions. Data were analysed by using (SPSS) 22, and interpreted.

4.2 Characteristics of the Respondents

The sample size for this study was 120 respondents with inclusion criteria that, a respondent must be above 15 years of age and a permanent resident of Morogoro Municipal Council. The dominant age group was that of people aged between 15 to 25 years which in this case were 77 (64%) of all respondents. Female group dominated the gender group whereby there were 70 (58%) female while the remaining 50 (42%) were males. In case of occupation, the group of doctors, nurses and pharmacist which had 25 (21%) of respondents was the leading group, and lastly on education level, the dominant group was that of people with secondary education which had 68 (57%) of all respondents.

Table 4.1 Characteristics of Respondents by Gender, Age, Education level and Occupation.

Characteristic	Frequency	Percent
Gender		
Female	70	58
Male	50	42
Total	120	100
Age		
15- 25	77	64
26- 35	30	24
36-45	10	8
46- 55	2	2
56- 65	1	1
Total	120	100
Education level		
Not attended school	5	4
Primary	1	1
Secondary	68	57
Diploma	18	14
Degree/masters/Phd	28	23
Total	120	100
Occupation		
Teacher	13	11
Farmer	10	8
Business man/woman	16	13
Doctor/Nurse/Pharmacist	25	21
Police/Soldier	4	4
Any Other	52	43
Total	120	100

Source: Field data 2016/2017

4.2 Retail Private Pharmacy Practice

Retail private pharmacy refers to retail pharmacy that is not direct affiliated with any chain of pharmacies and is not owned or operated by a publicly traded company. Retail private pharmacy practice means repeated exercise in or performance of drugs (medicine) selling so as to acquire or maintain proficiency during the performance of such activity (RUCA, 2000).

A complete private pharmacy practice comprises different components that make it perfect. The question of retail private pharmacy practice was asked to the pharmacy was asked to both customers and retail pharmacy sellers, the following results were obtained.

Table 4.2 Sellers Response on Components of Retail Private Pharmacy Practice

Component	Response	Percent
Authentic drugs (Approved by TFDA and TBS)	Yes 18 No 2 Total 20	91 9 100
Shelves, ceiling fan, ventilation and light	Yes 15 No 5 Total 20	73 27 100
Store	Yes 20 No 0 Total 20	100 0 100
Pharmacy registration certificate	Yes 20 No 0 Total 20	100 0 100

Source: Field data 2016/2017

On the other hand, the question on how retail private pharmacies perform their daily activities was asked to the population (customers) and the following were revealed; pharmacies which were found to have sign of pharmacy displayed or posted for public view. It was revealed by 53 (59%) respondents that they have seen the sign showing the presence of retail pharmacy in their area.

When asked about resting place in the pharmacy, the response was that, 23 (26%) of all respondents said they had seen a resting place in the pharmacy while the remaining 67 (74%) respondents mentioned that they had never seen a resting place in retail private pharmacies visited.

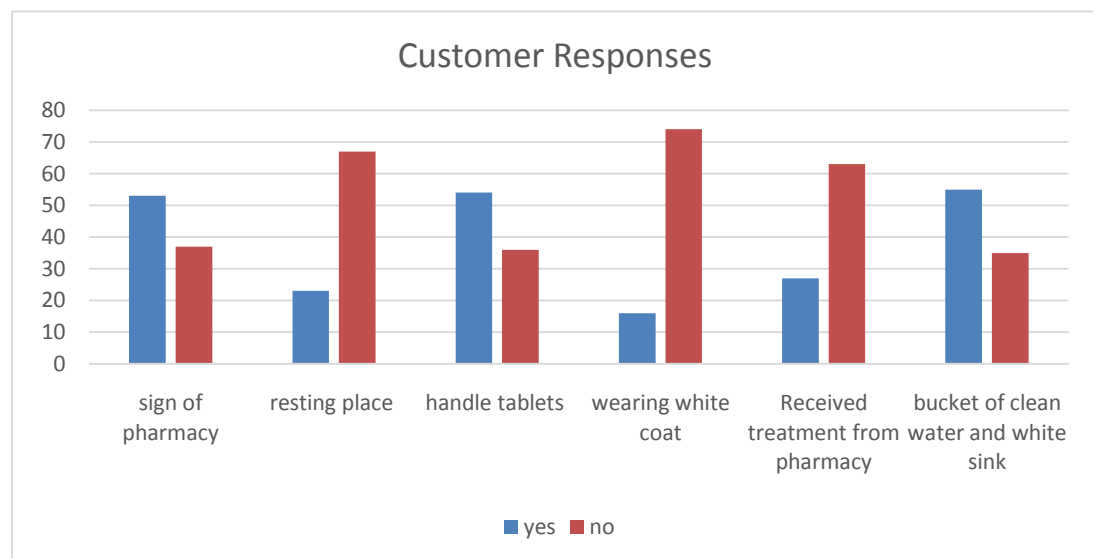
On matter of handling drugs during dispensing, it was found from 54 (60%) that they had seen pharmacy sellers handling drugs by using spoon the remained 36 (40%) mentioned that they have witnessed pharmacy sellers handling drugs using other means such as bare hands or gloves.

Only 16 (18%) of respondents mentioned that they have seen pharmacy seller dressed in white coat while the remaining 74 (82%) mentioned that they had never seen them wearing white coat however they had seen white coats hanged on a wall in the pharmacies.

27 (30%) respondents agreed that they had received such treatment from the pharmacies while the remaining 70 (70%) respondents mentioned that they had never received any restricted services from the retail pharmacies.

Bucket of clean and safe water as well as white sink are important components of retail private pharmacy practice. Then, when asked whether they had seen such things in the retail pharmacies, 55 (61%) respondents mentioned that they had seen them while the remaining 35 (39%) mentioned that they had never seen them.

Figure 4.1 Customer Responses on Retail Private Pharmacies Practice



Source: Field data 2016/2017

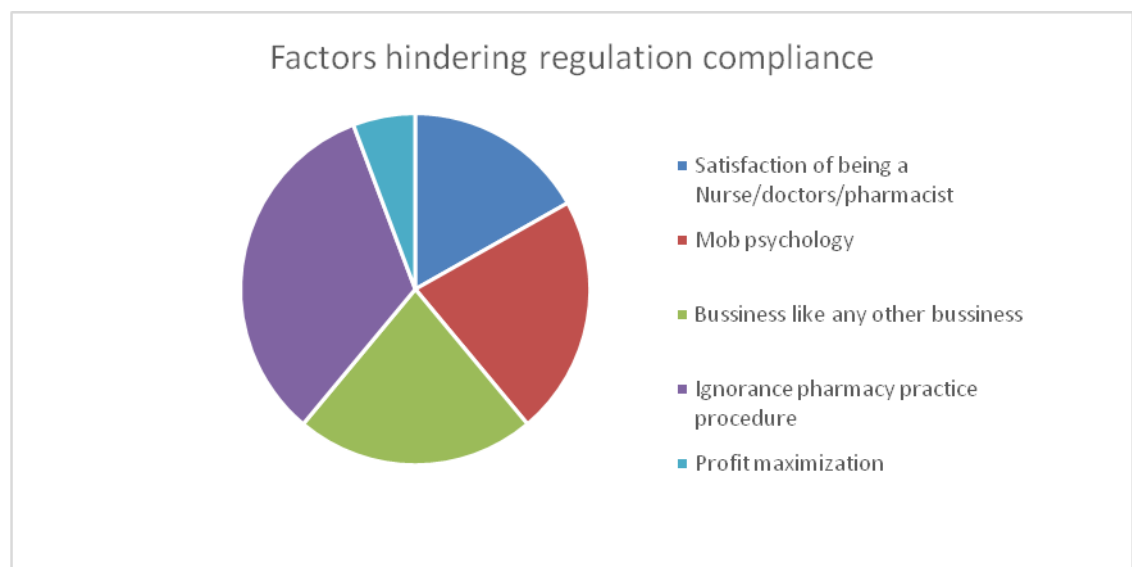
4.4 Factors Hindering Retail Private Pharmacy Regulation Compliance

Pharmacy regulation refers to principles, rules or Laws designed to control or govern conduct in retail and wholesale pharmacies (RUPRT, 2000). There are many factors that hinder retail private pharmacies from complying with stated rules and regulations which includes; satisfaction of being a nurse or doctors or pharmacist whereby it was revealed from the interview that 4 (40%) respondents out of 10 respondents mentioned this as a factor that hinder regulation compliance by pharmacy sellers.

Mob psychology was mentioned by 5 (50%) respondents out of 10 respondents who were interviewed, regarding pharmacy service as a business was mentioned by 5 (50%) respondents as another factor for poor retail private pharmacy practice and regulation compliance, on the other hand ignorance of pharmacy practice procedure was mentioned by 8 (80%) as a factor for poor pharmacy practice and regulation compliance.

Desire for profit maximization was mentioned by 1 (10%) respondent out of 10 as another factor for poor retail private pharmacy practice and regulation compliance.

Figure 4.2 Factors Hindering Regulation Compliance



Source: Field data 2016/2017

4.5 Challenges Faced by Retail Private Pharmacy Sellers

The question of challenges faced by retail private pharmacy sellers was asked so as to identify major challenges that come across them when they are performing their daily activities. The following are challenges mentioned by retail private pharmacy sellers.

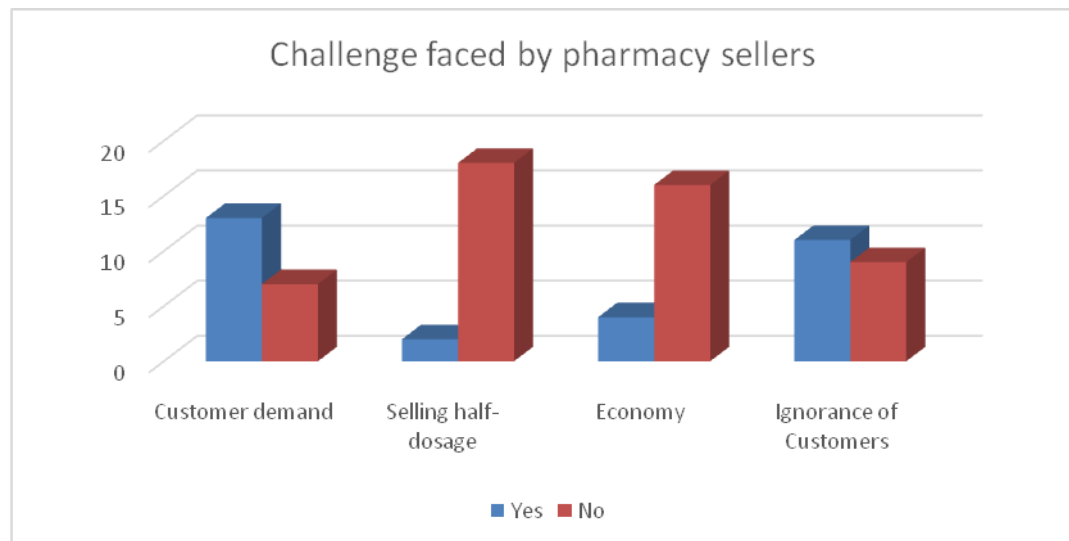
Customer demand for certain medicines was mentioned by 13 (65%) respondents out of 20 respondents as a major challenge to their work.

Selling half dose was mentioned by 2 (10%) out of all 20 respondents who were given questionnaires.

On the other hand, economy or lack of enough capital to run pharmacy business was mentioned by 4 (20%) respondents out of 20 respondents as a challenge to their daily activities.

Ignorance of the customer was mentioned by 11 (55%) respondents out of 20 as a challenge to their business.

Figure 4.3 Challenge Faced by Pharmacy Sellers



Source: Field data 2016/2017

4.6 Government System Regulation of Retail Private Pharmacy Practice and Regulations Compliance.

In Tanzania only the government and its agencies are allowed to regulate retail private pharmacy practice and regulation compliance. The duty has been imposed under TFDA and Pharmacy Council of Tanzania.

The question of how regulation of retail private pharmacy practice and regulation compliance is carried was asked through interview to government officials who oversee this process. The question of how effective the government system is on regulating retail private pharmacy practice and regulation compliance was asked to the government official concerned with this matter.

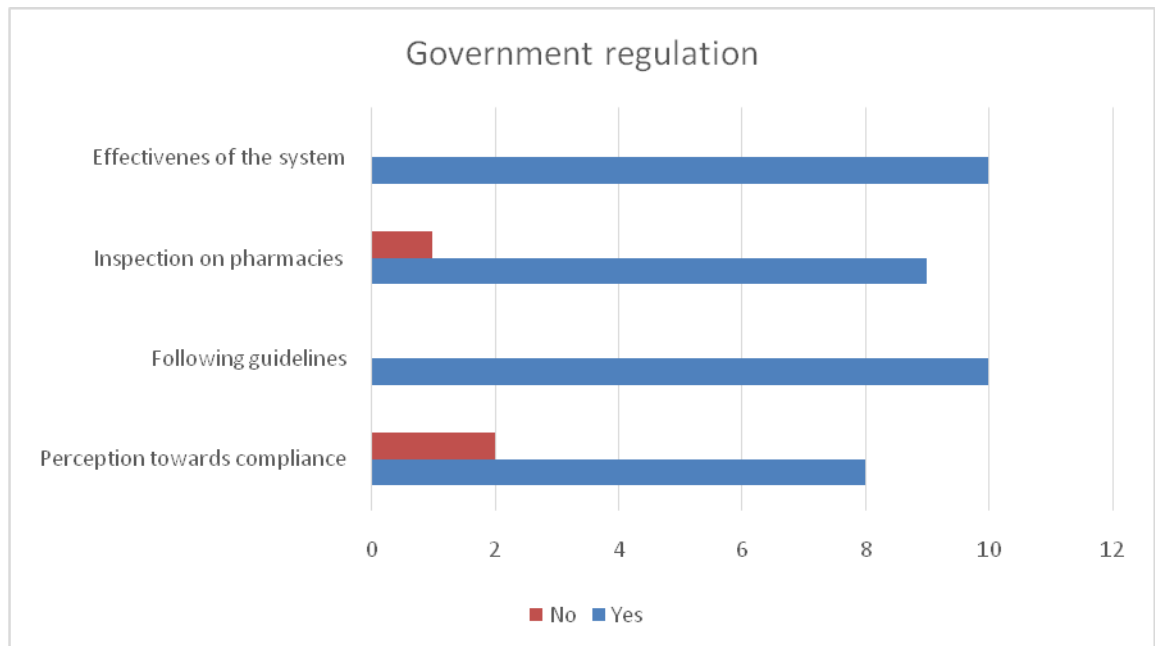
It was revealed by all 10 (100%) respondents that, the system used to regulate retail private pharmacy practice and regulation compliance is effective however there are minor problems which need to be addressed.

It was then mentioned by respondents 9 (90%) respondents that inspections are carried out four times per year while the remaining 1 (10%) said it is done whenever necessary that inspection of retail private pharmacies.

Apart from inspection, the issue of whether inspection officers follow guidelines and regulation was asked and the results show that all (10) respondents who were interviewed consider all the directives stated under TFDA Act and PCT Act together with other available local rules and regulations before they perform inspections on retail private pharmacy.

The issue of how they perceive regulation compliance of retail private pharmacy as well as pharmacy practice procedure by owners and sellers revealed that 8 (80%) respondents mentioned that all guidelines were followed by majority of pharmacy sellers. The remaining 2 (20%) respondents said there are infringement of regulation and practice procedure observed during inspection.

Figure 4.4 Government Regulation of Retail Private Pharmacy



Source: Field data 2016/2017

4.7 Challenges faced by Government officials during Retail Private Pharmacy Inspection.

The work of inspecting retail private pharmacy is not always an easy task because of the nature of the work itself. Any small mistake may lead to disastrous outcome to the public hence the work require careful measurements during inspection.

The question of what challenges they encounter when performing inspection of retail private pharmacy practice and regulation compliance, the following outcome were revealed.

It was revealed by 5 (50%) respondents out of all 10 respondents who were interviewed that sometimes they come across pharmacies which are owned by their co- workers hence it is a big challenge to them.

Another challenge facing them is financial constraints which were mentioned by 9 (90%) respondents out of all 10 respondents who were interviewed.

On the other hand, performance of restricted services is another challenge that was mentioned by retail pharmacy inspection officers. It was mentioned by 9 (90%) that it is very common to find prescribed drugs like antibiotics being sold in retail private pharmacies something which is against the rules. Furthermore some retail private pharmacies have been found to perform injection to the patients while others have accused of being the major centres where abortion is carried out.

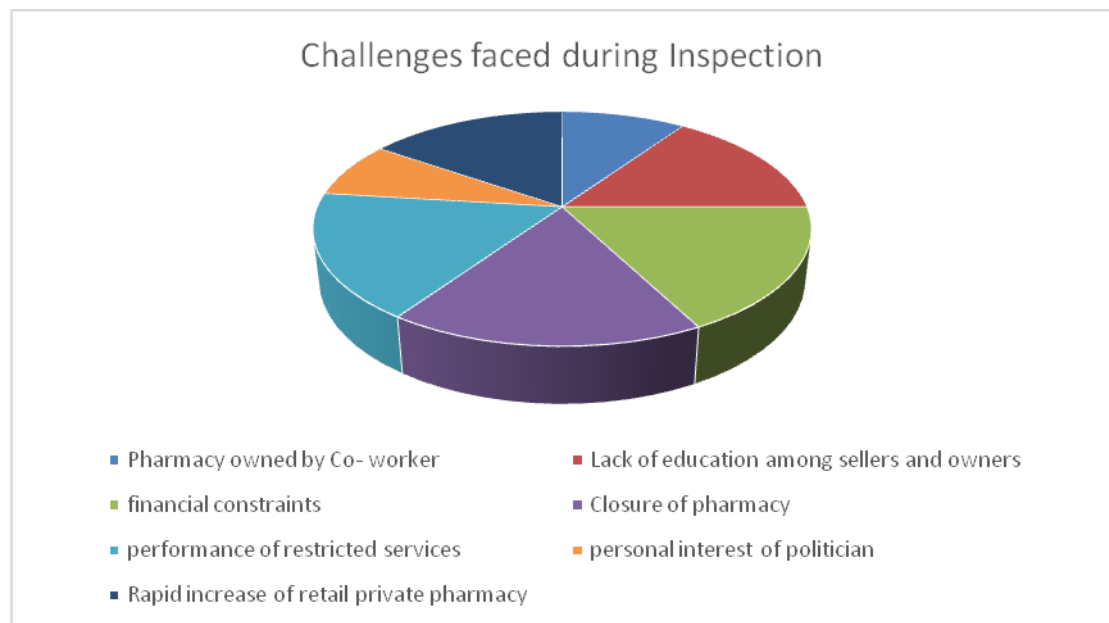
Personal interest of politician who own retail private pharmacies is another challenge facing pharmacy inspectors. It was revealed by 4 (40%) respondents that sometimes they are obstructed from performing their duties effectively because some politician have interest in retail private pharmacy.

Rapid increase of retail private pharmacy was mentioned by 8 (80%) out of all 10 respondents as a challenge to the pharmacy inspectors.

Another challenge mentioned was lack of education among sellers and owners. According to the report provided by retail private pharmacy inspectors who were interviewed, it was revealed by 8 (80%) that in the field there are pharmacy sellers who lack basic ADDO training from recognised authority even though it is mandatory.

Lastly, closure of pharmacy during the time of inspection was mentioned by 8 (80%) respondents who said that some retail private pharmacy sellers close their shops when they hear about inspection.

Figure 4.5 Challenges Faced During Inspection



Source: Field data 2016/2017

CHAPTER FIVE

DISCUSSION OF FINDINGS

5.0 Introduction

This chapter presents summary in narrative form the research that was carried out in Morogoro Municipal Council on assessment of poor retail pharmacy practices. The chapter addresses discussion of findings, in areas including retail private pharmacy practice, factors hindering retail private pharmacy regulation compliance and government system towards pharmacy practices and regulation compliance.

5.1 Discussion of Findings

The study was carried out among residents of Morogoro Municipal Council area with most of the respondents being female and over 64% of respondents were aged between 15 to 25 years. Majority of respondents had secondary education while medical practitioners (nurses, doctors and pharmacists) dominated the group of occupation.

5.1.1 Retail Private Pharmacy Practice

Respondents had generally had knowledge of what retail private pharmacy practice means which almost all respondents answered that “it is how the pharmacy is being operated either by the owner or seller”. Pharmacy sellers and customers despite knowing what retail private pharmacy means, still sellers there has been infringements in daily activities carried out in pharmacy.

From the findings it was observed that some shops have been selling drugs (medicines) which have not been approved by TFDA while other shops have found selling counterfeit drugs manufactured from outside the country.

On the other hand, some pharmacies had no dispensing room, sign of pharmacy, resting place for patients as well as their sellers were found not wearing white coats as directed. In addition to that, some pharmacy were found performing restricted

services like injection while spoons, bare hands or gloves were commonly used to provide medicines to the customers.

From the responses in questionnaires, all pharmacies had certificate of registration which was issued by TFDA. However on the study carried out at Kilombero by Goodman (2004), the study showed that among 30 retail private pharmacy that were inspected during the study only 19 of them had pharmacy registration certificates. Of the 9 stores with permits in, 2 permits were out of date, and in 7 shops the seller specified on the permit was not working there.

Regardless of infringements that are happening in daily retail private pharmacy practices, majority of pharmacies were found to follows regulation during practices.

5.1.2 Factors Hindering Retail Private Pharmacy Regulation Compliance.

Regardless that some pharmacies were found to be infringing regulation compliance, this study explored the reasons that lead retail private pharmacy sellers and owners to infringe the stated regulations of retail private pharmacy practice.

It was mentioned by the respondents that, some pharmacy sellers or owners have prior medical background (medical practitioners), thus they do not bother to attend any further training on drug dispensing such as ADDO training. A study carried out in Dar es Salaam by Kamuhabwa in 2012 show that majority (70.4%) of pharmacy sellers were not trained pharmaceutical personnel. The level of dispensing skills ranged from low (25.7%) to medium (70.4%).

Majority of drug dispensers had low (11.4%) to medium (83.2%) levels of knowledge about dispensing of `prescription only` medicines. It is thus recommended that the responsible authorities should ensure that prescription only medicines are dispensed by trained and certified pharmaceutical personnel. On job training and continuing professional development should also be emphasized to build

capacity of pharmacy sellers. Failure to do so is regarded as failure to comply with stated regulation as a result of negligence.

On the other hand, some pharmacy sellers and owner fail to comply with because they observe other service providers or pharmacy owners infringing set regulation and thus they become influenced to do the same.

It was also revealed that some retail private pharmacy sellers and owners consider pharmacy service as a business like any other business. This has led to the rise of negligence in provision of services making customers at risk of developing various complications such as drug resistance and allergy to the drugs according to the study carried out (WHO, 2000) it shows 90% of population are resistance to first line antibiotics such as ampicillin and cotrimoxazole for treatments, up to 70% of population are resistance to penicillin for pneumonia and bacterial meningitis.

Also up to 98% of population is resistance to penicillin for gonorrhea and up to 70% of population is resistance to both penicillin and cephalosporin for hospital acquired and some contaminations, all are results of negligence of sellers during service delivery to the customers.

It was revealed that ignorance of pharmacy practice procedure is another reason for poor retail private pharmacy regulation compliance. It was found that some pharmacy owners were not aware of the proper practices which have been set by the relevant authorities to regulate pharmacy practice. From that perspective, it is thus the duty of the relevant authorities to ensure that regulations are well known to the pharmacy owners and sellers.

A study carried by Kachur, (2004)which was conducted at Ulanga showed that only a minority of drug store staff had copies of the Pharmacy Board regulations and such copies if found were often outdated, and neither drug store staff nor district level regulators had lists of registered medicines. This shows that the problem of poor

retail pharmacy practice and regulation compliance has been activated by ignorance of pharmacy sellers.

Motives to maximize profit which implies desire to generate more income through selling drugs has led to the infringement of regulation compliance among retail pharmacy owners and sellers. As a result some pharmacy sellers have been selling drugs with low quality or even counterfeit drugs for the purpose of generating more income something which put population at high risk of morbidity.

Apart from the factors which lead to retail private pharmacy regulation compliance, it was revealed that sometimes retail private pharmacy owners are forced to infringe regulation because of challenges they come across.

The following were mentioned as challenges that influence them to infringe pharmacy practice regulation; customer demand was mentioned as a challenge by majority of retail pharmacy sellers as they lamented that some customers demand certain medicines from them even if they are not appropriate to them depending on their illness. Some even demand to be given prescribed medicines which are not allowed to be sold in retail pharmacy. Bad enough some customers demand medicine without even being diagnosed first.

Apart from that, pharmacy sellers have been forced to sell half dose as a result of customer's desire and poverty. Some customers demand to be given half of the required dose something which put retail private pharmacy in dilemma of violating regulations.

Lack of enough capital to run pharmacy business has been mentioned as a constraint to their business since sometimes they fail to purchase necessary components like refrigerators and other medical devices and medicines due to low capital. In this case, they find themselves violating the stated rules and regulation for running retail pharmacy services.

In addition, ignorance of customer has been a challenge to retail private pharmacy sellers in such a way that when they are given medicine for treatment some do return back every time to ask for directives of use while others have found to use such medicines in a wrong ways.

5.1.3 Government systems of carrying Retail Private Pharmacy Practice and Regulations Compliance.

As the law states clear that regulation of retail private pharmacy practice must be carried out by the government and its agencies, the issue of government effectiveness on retail private pharmacy regulation was asked.

It was then reported that the system is very effective in regulating retail private pharmacy. It was also reported that inspections of retail private pharmacies are carried out at least four times per year or else it is done whenever necessary. This is contrary to the study that was done at Kilombero district in 2004 which revealed that environmental health and drug regulatory inspections were reported to take place, although not as regularly as specified in the regulations. Over three-quarters of drug shops recalled being visited by District Healthy Officers once in a year (Goodman, 2004).

Furthermore, it was discovered that inspection officers have been following guidelines when performing their daily activities. They consider all the directives stated under TFDA Act and PCT Act together with other available local rules and regulations before they perform inspections on retail private pharmacy. It is likely that the process used during inspection is open and participatory to both officials and retail private pharmacy owners.

Regardless of efforts made by inspection officers in ensuring that retail private pharmacies abide the stated regulation, the officers have been facing challenges when performing their duties.

Challenges include; some pharmacies were found to be owned by co- workers. It was revealed that sometimes they neglect certain procedures so as to avoid conflicts with their co- worker because some retail pharmacy belong to their superiors or close friends. According to Abdullah (2004), a study carried out in Rufiji found that drug inspectors were at least partially aware of regulatory violations, but still allowed them to continue.

The foregoing discussion on challenges' may have reflected the links between drug stores and the formal health care system. In his study, of the 30 drug stores, 9 owners and one server had jobs in the formal health sector, the majority being health-care workers at local government facilities. According to his findings, inspectors may also have been personal acquaintances of shop staff, as in the case of owner, thus this poses a great challenge in retail private pharmacy inspection.

Financial constraints as a result of lack of enough funds from the government were mentioned to be another challenge that hinders retail private pharmacy inspection. It was said that, funds released by government are not enough to cover supervisory costs hence it becomes difficult to conduct inspection as required by regulations.

Performance of restricted services is challenge that was mentioned by retail pharmacy inspection officers. It was found that during inspection they come across some retail private pharmacy selling or performing restricted services. It is very common for them to find prescribed drugs like antibiotics being sold in retail private pharmacies something which is against the rules.

Furthermore some retail private pharmacies have been found to perform injection to the patients while others have accused of being the major centres where abortion is carried out.

In addition to that, personal interest of politician was mentioned as another challenge facing inspection officers. They claimed that sometimes they are obstructed from performing their duties effectively because some politicians have interest in retail private pharmacy. This is due to the fact that some of these pharmacies are owned by local politicians and hence it turns out to be difficult to inspect them effectively.

Rapid increase of retail private pharmacy as a result of change from service oriented to business oriented has turned hard the process of retail private pharmacy inspection. This is due to the limited funds provided by the government which actually it is not enough to cover all expenses needed for inspection.

In addition rapid increase of retail private pharmacies has led to the violation of regulation and pharmacy practices as identified by TFDA. Retail private pharmacies are supposed to be 300m from consecutive retail private pharmacy shop (TFDA, 2008).

Furthermore, lack of education among sellers and owners especially those who lack basic ADDO training from recognised authority even though it is mandatory is a challenge to inspection officers. Some sellers are found to have counterfeit ADDO certificates and hence they are not allowed to dispense drugs but they are performing such activities hence it is a biggest challenge to them to identify them every time they perform inspection.

Lastly, closure of some retail private pharmacy during the period of inspection has become a normal thing. However they have been trying to find other ways to ensure that all pharmacies are inspected by doing surprise inspection when sellers are off guard.

CHAPTER SIX

SUMMARY, CONCLUSION AND RECOMMENDATION

6.0 Introduction

This chapter addresses summary, conclusion and recommendation of the findings on the poor retail pharmacy practices and regulations compliances the presentation is done thematically to reflect emerging trends in the discussion. The issues addressed are respectively put as summary, conclusion and recommendation of the findings.

6.1 Summary

The purpose of this study was to assess retail private pharmacy practice and regulations compliance in Morogoro municipal council. The study intended to find out how retail private pharmacy practice is carried out, the reasons that lead to retail private pharmacy practice and regulation compliance as well as to find out how government carry them out. This study was conducted in Morogoro Municipal Council where by nineteen Wards were involved which includes, Mji mpya, Kingo, Mji Mkuu, Sultan Area, Mafiga, Mazimbu, Mwembesonga, Kichangani, Kilakala, Boma, Mlimani, Mbuyuni, Kingolwira, Bigwa, Mzinga, Kihonda, Sabasaba, Kiwanja cha ndege and Uwanja wa Taifa. Respondents who were involved include retail pharmacy shopkeeper, pharmacists, and costumers.

During the assessment it was revealed that there are infringements occurring in daily pharmacy practice as it was found that; some pharmacy were selling unauthenticated medicine, others had no sign of identification, place of resting customers, sellers were not wearing white coats while drugs were sometime handled with bare hands. Factors for such infringements mentioned were; sellers are satisfied of medical professionals, mob psychology, pharmacy service is regarded as business, ignorance of pharmacy procedures as well as desire to maximize profit.

Challenges that face pharmacy sellers were identified and they involved; customer demands, selling half dose, economy of pharmacy owners and customers as well as ignorance of customers. On the side of how government system works in regulating pharmacy practice and regulation compliance, it was revealed that the system is effective and people officers follow guidelines during inspection which was said to done more than three times annually.

Challenges facing government officials during inspection mentioned are; some shops are owned by their co- worker, financial constraints, rapid increase of pharmacy, and lack of education among sellers and owners of pharmacy, closure of pharmacy during inspections as well as political interest.

6.2 Conclusion

This study revealed that, despite the government efforts of ensuring that health services are available to all people which led to the introduction of retail private pharmacy to reach the majority population, still there infringement occurring which if not properly addressed may results to disastrous consequences to the population. A national program to solve this problem is required at all levels so as to reduce unnecessary risk that may occur as a result of infringement of pharmacy procedure and regulation compliance.

6.3 Recommendation

After careful consideration, this study recommends the following;

- Education to sellers, owners and general population which will help to bring awareness to them so that they may improve the standard of services they are delivering to their customer by following regulation and pharmacy procedures as stated.
- Review available guidelines so as to identify weaknesses (areas of improvement) and make necessary changes to improve standard service delivery to all legalized services provided under retail private pharmacy.

- Participatory approach which will include all stakeholders from local level to national level so as to establish sound and reasonable regulations and guidelines which will be approved at all levels.
- Avoidance of biasness in registration of retail private pharmacy by providing certificate of registration for running pharmacy services something which will improve delivery of standard services to the customers.
- Increase funding in supervision of retail private pharmacies to all organizations or institution which are responsible for supervision. This will help to improve check and balance if it is done regularly, thus it will ensure the safety of customers who buy medicine from retail private pharmacy.

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APPENDICES

Appendix 1: Questionnaire for respondents (sellers)

Greeting!

Firstly, I would like to acknowledge you for taking time to meet with me and talk about your experiences concerning '*Assessment of retail private pharmacy practice and regulations compliance at Morogoro municipal council*' as I am making its assessment.

My name is **Anthony Angelo**, a post graduate student at Mzumbe University. As I am conducting this research I would appreciate for your active contribution with an inclusion of the correct answers in accordance with your participation and understanding. The information you provide will be used for writing a report which will be shared among different stakeholders and beneficiaries from all levels for improvement.

All responses will be kept confidential. This means that your responses will only be shared with research team members who are going to be involved in the completion of this report and we will ensure that any information we include in our report does not identify you as the participant. Remember, you don't have to talk about anything you don't want to and you may end the process at any time. Thank you.

Do you have any question about what I have just explained?

Are you willing to participate? Yes (), No ()

Instructions:

Please put the appropriate number you have selected in the space written code for the option and for the open ended question write in the space provided in each question.

S/N	QUESTION	CODED RESPONSES	CODE FOR THE OPTION
A	Background and personal information		
1	Age		
2	Gender	1. Female 2. Male	
3	Occupation	1. Teacher 2. Farmer 3. Businessman 4. Police/army 5. Doctor/Nurse/pharmacists 6. Human Resources 7. Any other specify	
4	Education level	1. I have not attained any education 2. Primary 3. Secondary 4. Diploma 5. Degree /Master/PHD	
5	Marital status	1. single 2. married 3. divorced 4. widow/widower	
B	GENERAL QUESTIONS		
6	Does regular inspection of retail pharmacy shop carried out?	1. Yes..... 2. No.....	
7	Do you sells drugs which were not prescribed by Physicians?	1. Yes..... 2. No.....	
8	Do you have Drugs which have no stamp of TFDA or TBS (counterfeit drugs)?	1. Yes 2. No	
9	Does drugs your selling have expire date?	1. Yes..... 2. No.....	
10	Do you have refrigerator for storing Drugs?	1.Yes 2.No	
11	Do you have well ventilated store for keeping Drugs?	1.Yes 2.No	
12	In your views do you think retail private pharmacy (Owners) follow proper practices such as registrations when they perform	1. Yes 2. No	

	their daily activities?		
13	If 'No', what factors do you think they hinder private pharmacy from performing proper practices as they are supposed to?	1..... 2..... 3..... 4..... 5.....	
14	Do you have Accredited Dispensing Drugs Outlets (ADDO) or Any other authorized certificates for Drugs	1. Yes 2. No	
15	How far is the distance between your neighbour retail pharmacy Shops?	1. 300m 2. 200m 3. 10m 4. 20m 5. 5m	
16	Is there any direct contact between the seller and customer in the pharmacy?	1. Yes 2. No	
17	How many times do those Healthy officers visit at your Shop for inspection monthly?	1. 2 times 2. 1 time 3. 3 times 4. Non	
18	Does your shop have Shelves, Enough Light, ventilations, ceiling fans?	1. Yes 2. No 3. Non	

Appendix 2: Questionnaire for respondents general population (Customers)

Greeting!

Firstly, I would like to thank you for taking time to meet with me and talk about your experiences concerning *'Assessment of retail private pharmacy practice and regulations compliance in Morogoro municipal council'* as I am making its assessment.

My name is **Anthony Angelo**, a post graduate student at Mzumbe University. As I am conducting this research I would appreciate for your active participation with an inclusion of the correct answers in accordance with your participation and understanding. The information you provide will be used for writing a report which will be shared among different stakeholders and beneficiaries from all levels for improvement.

All responses will be kept confidential. This means that your responses will only be shared with research team members who are going to be involved in the completion of this report and we will ensure that any information we include in our report does not identify you as the participant. Remember, you don't have to talk about anything you don't want to and you may end the process at any time. Thank you.

Do you have any question about what I have just explained?

Are you willing to participate? Yes (), No ()

Instructions:

Please put the appropriate number you have selected in the space written code for the option and for the open ended question write in the space provided in each question.

S/N	QUESTION	CODED RESPONSES	CODE FOR THE OPTION
A	Background and personal information		
1	Age		
2	Gender	1.Female 2.Male	
3	Occupation	1.Teacher 2.Farmer 3.Businessman 4.Police/army 5.Doctor/Nurse/pharmacists 6.Human Resources 7.Any other specify 8. students	
4	Education level	1. I have not attained any education 2.Primary 3. Secondary 4.Diploma 5.Degree /Master/PHD	
5	Marital status	1. single 2. married 3. divorced 4. widow/widower	
B	GENERAL QUESTIONS		
6	Do you buy drugs which you were not prescribed by Physicians?	1. Yes 2. No	
7	How sure you are that those drugs you bought can assist your disease while the drugs were not prescribed by physician?		
8	Do you consider expire date of your Drugs you are buying?	1.Yes 2.No	
9	Does drugs sellers ware White Coat? While selling Drugs?	1. Yes 2. No	
10	Have you ever get any treatment in any Pharmacy e.g. injected?	1.Yes 2. No	

11	Is there any sign which shows there is a pharmacy? Bucket of clean water?	1.Yes 2. No 3. Non	
12	Is there any resting place for Patients in Pharmacy?	1.Yes 2. No	
13	Does retailer shops have refrigerator for storing some drugs?	1.Yes 2. No	
14	How does the seller handle the cold drugs or tablets when they provide services or you bought?	1.barehands 2. with a spoon 3. wearing gloves 4. using any other materials	

Appendix 3. An interview guide (Pharmacist / health officers)

Dear respondent,

My name is **AnthonyAngelo**, a student of **Mzumbe University pursuing Master of Health System Management**. Here in is a list of questions intended to collect information on the '*Assessment of retail private pharmacy practice and regulations compliance Morogoro municipal council*' purposely for academic uses only and not otherwise. I would be very thankful if you would spare some few minutes to answer these questions. The information that you give will be treated confidential and your identity will not be exposed.

- 1) Age
- 2) Education level
- 3) Occupation
- 4) How do you consider retail private pharmacy practice in this particular area?
- 5) Are there any guidelines that guide retail private pharmacy practice in this particular area?
- 6) Do you follow guidelines that guide retail private pharmacy practice when you carry out your daily activities?
- 7) What factors do you think causes poor retail private pharmacy practices?
- 8) Do you conduct Inspections to those private retail pharmacy? If yes How many times annually?
- 9) Do you think retail private pharmacy complies with the available regulations when performing their daily activities?
- 10) What factors do you think causes poor retail private pharmacy regulation compliance?
- 11) Do you think the government system of controlling retail private pharmacy practice and regulation compliance is effective?
- 12) If 'No' what do you think should be done to solve the problem of poor retail pharmacy practice and regulation compliance?
- 13) Generally does those retail pharmacy sellers have Certificates such as ADDO or any certificates from Authorised Bodies

- 14) In your experience did you Observe Drugs counterfeit during Inspections drugs entered without stamps of TFDA or TBS?
- 15) In your experience does those retail Pharmacy sellers dispensing drugs with Traditional medicines all together?
- 16) In your views what challenges are you facing to supervise retail pharmacy practice and regulation compliances?

Appendix 4: Work plan

Activity	Month 2016/2017											
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Apr	May
Research concept writing												
Proposal write up												
Submission of proposal												
Data collection												
Data analysis												
Dissertation writing and defending												
Consultation												

Appendix 5: Budget

S/N	CATEGORY/ITEMS	UNIT PRICE	QUANTITY REQUIRED	COST IN TZS
1	Stationary			
	Secretarial services	300,000/=		300,000/=
	Ball point pens	1000/=	30	30000/=
	Spring file	6000/=	4	24,000/=
	Shorthand note book	3000/=	10	30,000/=
	Photocopy and binding services	300,000/=	-	300,000/=
	SUB TOTAL			684,000/=
2	Personal supporting	400,000/=	-	400,000/=
	SUB TOTAL		-	400,000/=
3	Other services			
	Computer services	300,000/=	-	300,000/=
	Communication	400,000/=	-	400,000/=
	SUB TOTAL		-	700,000/=
	TOTAL			1,784,000/=
	Contingency (10%)			178,400/=
	OUTSTANDING TOTAL			1,962,400/=