REGULATING THE TRADITIONAL AND ALTERNATIVE MEDICINE PRACTISE: REGULATEES AWARENESS, ADHERENCE AND REGULATING CHALLENGES IN DAR ES SALAAM, TANZANIA

Simon Emmanuel Rusigwa

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By

Simon Emmanuel Rusigwa

A Dissertation Submitted in (Partial) Fulfillment of the Requirement for the Degree of Master of Public Health of

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CERTIFICATION

The undersigned certifies that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: ‘‘***Operational functions, Capacity and Implementing challenges of Traditional and Alternative Medicines Regulatory Framework in Dar es Salaam***’’ in (partial) fulfillment of the requirement for the degree of master of Public Health of Muhimbili University of Health and Allied Sciences.

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Prof. Phare G.M, Mujinja BA (Hons), CIH, MPH, MA (Econ), PhD

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

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

Signature…… **Date**….....

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DEDICATION

This dissertation is dedicated my beloved parents; late Joyce Samwel Kagezi and Emmanuel Simon Rusigwa.

ABSTRACT

Background: Ineffectiveness of traditional medicine practices regulation has been a major challenge worldwide especially in the developing world. In Tanzania, regulation to traditional medicines has not been well documented regarding the extent to which it meets the WHO (2016) requirement. Although the Traditional Medicine Act was enacted in 2002, there are no studies that have focused on the functioning and effectiveness of the traditional medicine regulatory framework. This study therefore aimed at exploring regulatees' awareness and adherence to TAM regulations and obstacles/barriers face by both regulatees and regulators in fulfilling the regulatory requirement in Tanzania.

Objective: To assess awareness and adherence of the regulatory process among regulatees and challenges faced by regulators in implementing the the regulatory process in Tanzania.

Materials and Methods:: A cross-sectional study design was used employing qualitative data collection approach and analysis. A purposive and snowballing sampling were used to select participants. In-depth interviews were conducted with regulators and regulatees. Dthematic data analysis started with organizing, breaking it into manageable units, synthesizing and searching for patterns, discovering what was important to be learned and coded them into nodes.

Results: The findings of the study revealed that awareness of the regulatory framework among the traditional/ alternative medicine practitioners is low and still a challenge that needs to be addressed in order to promote the subsector. Non-adherence to regulations was also revealed to be pronounced among regulatees. Non-adherencees is influenced by both regulatees' awareness of the process and their ability to comply with the regulatory requirements; there is lack of direct public private partnership in regulating traditional and alternative medicine sub sector; and lack of enough manpower was reported to be a hindrance in implementing the regulatory process. There is lack of infrastructure, transport and human resources; and also regulators interviewed revealed lack of professional knowledge, proper task scheduling and interest on traditional/ alternative medicine.

Conclusion and Recommendation: The study concludes that some regulatees are not aware of the regulatory framework; non-adherence is a problem among regulatees. Lack of professional human resources, interest, skills, and means of transport are the problems that affect the capacity and effectiveness of the regulators. So we recommend more frequent education provision on regulatory framework to regulatees by the regulatory body and regulating body should appoint regulators who are interested in TAM to improve efficiency and effectiveness in regulating TAM subsector.

TABLE OF CONTENTS

CERTIFICATION i
DECLARATION AND COPYRIGHT ii
ACKNOWLEDGEMENT iii
DEDICATION iv
ABSTRACT v
TABLE OF CONTENTS vii
LIST OF TABLES x
LIST OF FIGURE x
ABBREVIATIONS xi
DEFINITION OF TERMS xii
CHAPTER ONE 1
1.1. Background introduction 1
1.2. Problem statement 4
1.3. Rationale of the study 5
1.4. Research questions 6
1.4.1. Main Research question 6
1.4.2. Specific Research Questions 6
1.5. Research objectives 6
1.5.1. Broad objective 6
1.5.2. Specific Objectives 6
1.6 Conceptual framework 7
CHAPTER TWO 9
2.0. LITERATURE REVIEW 9
2.1. Introduction 9
2.2. Arguments for regulating Traditional and Alternative Medicine 9
2.3. Knowledge on Regulation of Traditional and Alternative Medicine Globally 11
2.4. Existing regulation and legislation in Different Countries 12
2.5 Challenges of regulating the Traditional and Alternative Medicine 14

2.6. Awareness of overall regulatory pprocess and its outcomes among regulatees and regulators 15
CHAPTER THREE 16
3.0. METHODOLOGY 16
3.1 Study Area 16
3.2 Study design 16
3.3 Study population 16
3.4. Sample size and Sample Selection 17
3.5 Data collection Instruments (Tools) 17
3.6 Hiring and training of Research Assistants 18
3.7 Pre-testing of data collection Instruments 18
3.8 Data collection procedure 18
3.9 Data Analysis 19
3.10 Ethical consideration 20
3.11 Study limitations and mitigation 20
CHAPTER FOUR 22
4.0. RESULTS 22
4.1 Introduction 22
CHAPTER FIVE 34
5.0. DISCUSSION 34
5.1 Introduction 34
CHAPTER SIX 38
6.0. CONCLUSIONS AND RECOMMENDATIONS 38
6.1 Introduction 38
6.2 Conclusions 38
6.3 Recommendations 38
REFERENCES 39
APPENDICES 43
Appendix 1a: Consent Form English Version 43

Appendix 1b: Consent Form Swahili Version 46
Appendix 2a. Questionnaire 49
Appendix 2B. In-depth interview to regulate Questionnaire: (English Version) 51

LIST OF TABLES

Table 1: Distribution of Respondents according to their roles in traditional/alternative medicine……...22

Table 2: Traditional/ Alternative medicine practitioners' experience……...23

LIST OF FIGURE

Figure 1: Conceptual framework…….8

ABBREVIATIONS

CAM	Complimentary and Alternative Medicines
e.g.	Example
et al	And others
IDI	In depth Interview
MA	Market Authorization
MoHCDEC	Ministry of Health Community Development, Gender and Elderly and Children
NRA	National Regulatory Authority
TAM	Traditional and Alternative Medicines
TM	Traditional Medicines
TMK	Traditional Medicines Knowledge
TMRA	Traditional Medicines Regulatory Authority
WHO	World Health Organization

DEFINITION OF TERMS

Regulation

We define regulation as the capacity of intervention in the process of service provision, making arrangements to or giving instructions for the provision. This intervention can occur through a variety of mechanisms: mechanisms that can induce some kind of action, mechanisms that stabilize mechanisms that regulate or mechanisms that limit or restrict actions. The intervention in issues involving demand and direct provision of health care services, in their several aspects, can be characterized as regulatory mechanism (Santos, 2006).

Traditional Medicine

This study uses The World Health Organization (WHO) definition of traditional medicine as "health practices, approaches, knowledge, and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singular or in combination, to treat, diagnose and prevent illnesses or maintain well-being. African Traditional medicines and the Traditional and Alternative Medicine Act, 2002 define as total combination of knowledge and practice, whether applicable or not, used in diagnosing , preventing or eliminating a physical , mental or social disease and which may rely exclusively on past experience and observation handled down from one generation to another orally or in writing.

Alternative Medicine/Complementary Medicine

Complementary medicine and alternative medicine are used interchangeably with "traditional medicine" in some countries. Complementary/ Alternative medicine often refers to the traditional medicine that is practiced in a country but is not part of the country's own traditions. While complementary and alternative refer to health care that is considered to allopathic medicine.

Herbal Medicine

Herbal medicine also called botanical medicine or phytomedicines refers to using a plant's seeds, berries, roots, leaves, bark, or flowers or whole plant for medicinal purposes (Sharad, 2011).

Traditional/Alternative Health Practitioner (THP)

The Traditional and Alternative Medicine Practitioner is a person who is recognized by the community as competent provider of health care using plants, animal, mineral substances and other methods based on social, cultural and religious background as well as on the knowledge, attitudes and beliefs that are prevalent in the community regarding physical, mental and social well being and the cause of disease and disability

CHAPTER ONE

1.1. Background introduction

Traditional Medicine(TM), variously known as ethno-medicine, folk medicine, native healing or complementary and alternative medicine (CAM), is the oldest form of health care system that has stood the test of time. According to World Health Organization (WHO) traditional medicine refers to health practices, approaches, knowledge , and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being (WHO, 2002). It is known that many countries in African, Asian and Latin America use traditional medicine (TM) to meet some of their primary health care needs. In Africa, up to 80% of the population uses traditional medicine for primary health care (WHO, 2003). Traditional medicine has maintained its popularity in all regions of the developing world and its use is rapidly spreading in the industrialized countries. (Kabede, et al, 2016, Lwoga, 2013, Daza, 2002).

Historically, it is commonly agreed that traditional medicine in Tanzania is an outcome of a long-standing struggle of indigenous people towards managing their environment and health status. Apart from the modern health services based on Western-oriented cosmopolitan health care, Tanzanians have used their own indigenous medicine as a sub-system of traditional medical system of East Africa. Evidence shows that about 70-80% of the patients use traditional medicine for their primary medical needs (Chirangi , 2013).

In the case of Tanzania, the colonial government had little interest with traditional medicine and therefore it remained unregulated for quite a long time but recognized it in some instances. For example, the colonial government in Tanganyika enacted the medical practitioners and dentists' ordinance which recognized the status of traditional practitioners. Chapter 92.20 of the Act states that "Nothing contained in this ordinance shall be construed to prohibit or prevent the practice of systems of therapeutics according to native methods by persons recognized by the community to which they belong to be duly trained in such practice. Provided that nothing in this section shall be construed to authorize any person to practice

native systems of therapeutics except amongst the community to which he belongs, or the performance of an act on the part of any persons practicing any such system which is dangerous to life." This colonial legislation continued to be operational even after independence of Tanganyika in 1961. It can aptly be said that during the colonial epoch traditional medicine was, by and large unregulated, compared to modern medicines.

Furthermore in Tanzania, there has been a call to recognize traditional health system into National Health Service. This idea had been raised by the World Health Organization which called on member states to not only implement primary health care programmes based on low-cost providers and decentralized facilities in order to achieve "health care for all by the years 2000", but also to evaluate the role traditional medicine might play in primary health care delivery . The recognition of traditional medicine was everywhere a controversial subject, given the reduction of its status under colonialism and the co-existence of a modern health care sector that remained convinced of its preeminence (Waite, 2000). Since then the regulation of traditional medicine had been an agenda from different stakeholders. According to Tanzania's National Health Policy, the Ministry of Health Community development, Gender, Elderly and Children (MoHCDGEC) recognizes the role and contribution of traditional and alternative health care in the health status of Tanzanian people (Wenzel, 2011 and URT, 2007). Furthermore, the Ministry has directed that, the traditional and alternative health practitioners will be accountable to their own prescriptions, remedies and therapies; the village community government will appraise, assess and recommend in particular locality traditional practitioners for registration by an approved authority; and legislation to provide for regulation of practitioners, therapies and remedies and other related treatments (Ministry of Health, 2003).

As a sign of recognition and a process to regulate the sub sectors of traditional medicine in Tanzania, the parliament enacted the Traditional and Alternative Medicine Act, 2002 and its regulations of 2008. The Act intends to make provisions for promoting control and regulations of traditional and alternative medicines practices in the country, Tanzania. The Act has nine parts, and Part II of the Act caters for the establishment of the Council to be known as the Traditional and Alternative Health Practice Council. Section 5 (1) (a)-(d) of the Act provides

for the composition of the Council. The Functions of the Council are enumerated under section 6 (1) (a)-(n) of the Act, which other things includes its role of controlling and regulating the sub sectors. But generally the functions of the Council shall be to monitor, regulate, promote, and support the development of traditional medicine (URT 2002, 2008)

In Tanzania, Tanzania Food and Drug Authority (TFDA) was established in 2001, among other things to regulate the pharmaceutical sector on the quality, safety and efficacy of medicines. Furthermore there is also a Pharmacy Board that regulates Pharmaceutical professionals and medicines. However, both of these regulators do not regulate traditional medicines and products. This could be because of the complexity and heterogeneonity of traditional and alternative medicine. This subsector is therefore regulated by the Ministry of health, Social welfare, gender, Children and Elderly with a registrar based in the ministry.

The non inclusion of herbal products and traditional medicine practices in modern regulatory frameworks in Tanzania could be explained by the fact that there are complexities in determining standards, safety and efficiency like in the medicines and practices. Therefore in 2002 the Government of Tanzania enacted an Act to regulate Traditional Medicines Practices in the country.

While there have been studies in Tanzania and elsewhere on the modern medicines regulatory framework and its effectiveness in the regulatory process (Kumaranyayake, et al, 2000, Mujinja et al, 2002, Mujinja et al, 2007 and Mujinja 2015).Such studies that focus on the operational capacity and functioning of regulatory practice in Tanzania have not been documented.

This study therefore focused on exploring awareness and adherence of the regulations and regulatory process among reguletees and challenges that are encountered by regulators and regulating bodies in the process of implementing the regulatory framework of traditional and alternative medicine subsector. This was important to understand the extent of the regulatory effectiveness and challenges that could be addressed to improve the functioning of the regulatory conditions. A cross sectional descriptive study using qualitative data collection was employed to carry out the study.

1.2. Problem statement

Regulation and intergration of Traditional or Complementary Medicine products and practise (market) in the health system has been a global challenge, including Tanzania (WHO, 2016). Regulation of TAM is geared towards ensuring quality, and efficacy standards and protecting consumers' safety (White House Commission 2001 cited by Alamede et al 2011) wwithout effective regulation, TAM users could be exposed to numerous risks including those bring about serious life threatening adverse reactions (Cohen,et al,2005 cited by Alamede et al 2011).In some countries, including Tanzania, there have been reported issues of false labeling and advertising of TAM products; false claims of a 'magic and efficacy treatment (Burton,2005 cited by Alamede et al 2011). Due to information as symmetry between the TAM products manufacturers and consumers, governmental interventions are necessary to protect customers against false claims on efficacy of the products in treating health problems; possible cheating on safety tests results and that of products; good manufacturing processes and ingredients in products (Loff and McKelvie, 2003 cited by Alamede et al 2011).

Tanzania enacted the Traditional Medicine Act in 2002 and its operational guidelines as a basis for regulatory framework for traditional medicines practices. For assessment of operational functioning of regulatory framework, WHO has suggested guidelines for good and functioning regulatory framework for medicines and health practices. The guideline stipulates that the assessment should base on clarity, effectiveness, transparency, efficiency, flexibility, proportionality, consistency and impartiality on the regulatory framework. (WHO 2016).

A number of studies, although implemented before the have used some of the above mentioned WHO concept in assessing regulatory framework of modern pharmaceutical regulatory framework in different countries. These studies, in Tanzania, have mainly analyse effectiveness roles, functions of regulatory framework of the modern medicines sub sector. (Kumaranyayake, et al, 2000, Mujinja et al, 2002, Mujinja et al, 2007 and Mujinja 2015). The regulatory framework in modern medicine has been

There is a dearth of studies that have assessed and explored TAM regulatory process and its challenges. Studies have rarely been conducted in exploring how regulatees view the TAM

regulatory process and challenges that are encountered by the regulators. Since the regulatory framework was officially enacted in a decade ago in Tanzania, there are no studies that have focused on the demand (practitioners) and supply (regulators) factors affecting implementation of the regulatory process in Traditional and Alternative Medicine subsector in Tanzania.

The regulation of the markets for Traditional and Alternative Medicine (TM) market presents an operational challenge among regulators in developing countries.

This study therefore focused on exploring regulates' awareness of and adherence to the regulation process and challenges faced by the regulators in the process of implementing the regulatory process in Traditional and Alternative Medicines subsector. Specifically, the study focused on the finding out views of the regulators and regulates on the issues that may affect the effectiveness of the regulatory process.

This study has generated information that may be used in understanding and finding out challenges facing the regulatory process for improving the regulatory framework in Traditional medicines practice.

1.3. Rationale of the study

The findings of this study will feed in more information in the literature of regulation in the traditional medicine sector. The findings will also raise awareness to policy makers light on the functions of traditional and alternative medicines regulatory framework. The information will also be useful source of information to the traditional medicine regulators in Tanzania and will be used in developing awareness activities and streamlining the guidelines for regulation and supervision of the sub-sector.

1.4. Research questions

1.4.1. Main Research question

To what extent are regulatees aware of and adhere to the regulatory process and what are challenges encountered by regulators in implementing the Traditional and Alternative Medicine regulatory framework in Tanzania?

1.4.2. Specific Research Questions

1. What is the extent of awareness of regulatees on regulatory guidelines in the traditional and alternative medicines subsector in Tanzania?
2. What is the extent of regulatees` adherence to the regulatory requirements in the traditional and alternatives medicines subsector in Tanzania?
3. What are the factors that affect the regulatory capacity of regulating bodies?
4. What are the operational challenges that affect the regulators' functioning in implementing the regulatory process in the traditional and alternative medicines subsector in Tanzania?

1.5. Research objectives

1.5.1. Broad objective

To explore regulatees' awareness of and adherence to the regulatory process and what are challenges encountered by regulators in implementing the Traditional and Alternative Medicine regulatory framework in Tanzania?

1.5.2. Specific Objectives

1. To assess awareness of regulatees on regulatory guidelines in the traditional and alternative medicines subsector in Tanzania?
2. To explore the extent of regulatees` adherence to the regulatory requirements in the traditional and alternatives medicines subsector in Tanzania?
3. To explore the factors those are perceived to affect the regulatory capacity of regulating bodies?

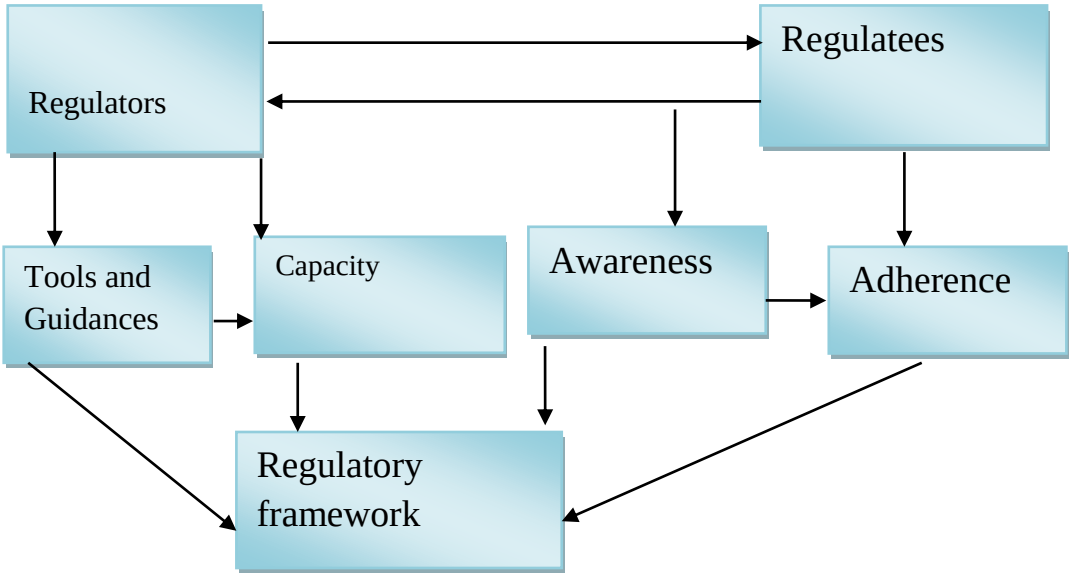
4. To identify operational challenges that affect the regulators' functioning in implementing the regulatory process in the traditional and alternative medicines subsector in Tanzania?
5. To explore operational functioning, capacity and implementing challenges of the regulatory process encountered by the regulators and regulatees in Traditional and Alternative medicines subsector in Tanzania.

1.6 Conceptual framework

This is a written or visual presentation that: explains the concepts focused on in this study and the presumed relationship among them". (Miles and Huberman, 1994, P18).

This conceptual framework shows the conceptualized relationship of different components of the study concepts. The main assumption of this study is that the effectiveness of a regulatory process is influenced by the behaviour, actions and knowledge of both regulatees and regulators. On the supply side, the effectiveness of the regulation process is influenced by the capacity of the regulatory body that includes, among other things, resources- both human and financial-, tools that guide inspection and supervision-laws, standard operation procedures, policies and guidelines-, and other infrastructure. For the regulatory process to be functional, the demand side, the regulatees, has to be responsive; the extent of response depends on the awareness level of the regulatees and also the extent to which they adhere to the laws and guidelines that govern the regulatory process. This conceptualization is derived from the WHO (2016) proposed guidelines for effective and efficient regulatory process for traditional and alternative medicine and functioning of the Traditional and alternative medicine regulatory bodies.

Fig 1: Conceptual framework



CHAPTER TWO

2.0. LITERATURE REVIEW

2.1. Introduction

The need for regulating the traditional/complementary and alternative medicines sector has been widely documented worldwide. However the practice of traditional medicines has been differently approached in many countries. This has led into different ways on how the sub sector is regulated in different countries. Despite the rising need for regulation of the traditional/complementary and alternative medicine, its regulatory effectiveness and the proper functioning of the regulatory bodies, has been of great concern by WHO (WHO, 2016). The role of regulators, regulatees and other stakeholders in improving the effectiveness of the regulatory process have been mainly documented as important issues to be considered (WHO< 2016). This chapter reviews the literature in those areas that are related to the focus of the implemented study.

2.2. Arguments for regulating Traditional and Alternative Medicine

Regulation of TAM products and its market is geared towards ensuring quality, and efficacy standards and protecting consumers' safety (White House Commission 2001 cited by Alamede et al 2011). Without effective regulation, TAM users could be exposed to numerous risks including those bring about serious life threatening adverse reactions (Cohen,et al,2005). In some countries, including Tanzania, there have been reported issues of false labeling and advertising of TAM products; false claims of a 'magic and efficacy treatment' (Burton,2005). Due to information as symmetry between the TAM products manufacturers and consumers, governmental interventions are necessary to protect customers against false claims on efficacy of the products in treating health problems; possible cheating on safety tests results and that of products; good manufacturing processes and ingredients in products(Loff and McKelvie, 2003).

It may be true that some of the products are extracted from sources that are scientifically known in treating some health conditions, their preparations may not meet the required level that would guarantee safety to the consumers. Furthermore, false claims could cause consumers to modify or stop the use of essential prescribed medications without proper medical people avoiding modern treatment. The KIKOMBE CHA BABU in Tanzania is one of those such claims that resulted into such problems. Such actions jeopardizes the safety of consumers and calls for governments intervention and lead to enact regulatory frameworks. Furthermore, in Lebanon acute or chronic overdose has been reported indicating that people who falsely believe that increased consumption of the 'All Natural' Complementary and Alternative Medicine (CAM) products dol enhance their acclaimed benefits and lead to faster recovery or relief [19].

Consumers of TAM have also been reported to concurrently use the products and modern medicines. Studies from South Africa and Lebanon have shown that biological interactions between CAM products or between CAM products and pharmaceuticals have been reported(Shaw, 1998:WHO,2013). This threaten life of consumers and therefore calls for regulations necessary to protect consumers, health.

Note that the cost of CAM products in the EMR is usually covered out of pocket, since private or social insurance programs do not cover such costs. Therefore, improper utilization of CAM products could cause a financial burden on the stretched resources of poor and middle income families. Furthermore, using CAM products could delay the use of orthodox medicine which increases the burden of disease on governments or individuals, who might incur greater costs to cure once easy-to-manage diseases (Shaw,1998). In conclusion, in the absence of regulation the use of CAM products may harm consumer either directly through adverse events, or indirectly by creating an unwarranted financial and emotional burden on users (Cohen and Kemper 2005).

The economic and human rights arguments of information assymmetry and protection of consumers health against TAM agents who are not acting perfectly acting for the benefit of consumers, are strong arguments in support of government intervention in TAM market.

Governmental regulation is crucial to protect against such harms and could facilitate the public private partnership integration of TAM products into modern healthcare systems. However, regulation of the TAM market presents a challenge for many countries across the globe, regulation is particularly challenging in countries with a weak public sector; such as Tanzanian and similar developing cuntries [Mujinja,, 2015; 21].

2.3. Knowledge on Regulation of Traditional and Alternative Medicine Globally

The International organizations representing various interests have been awakened by the call to regulate traditional and alternative medicine (Ande,2010). However, a notable defect in the efforts by these organizations is that there seems to be little comprehensiveness in their efforts since most of these organizations view and regulate traditional medicinal practices from their perspectives only. The lack of comprehensive international regulation of TMK may have arisen from two causes. Firstly, the existing international instruments cover traditional medicine knowledge as part of a larger mass-traditional knowledge. Secondly, he argues that even the instruments directly related to the regulations, such as those developed by the World Health Organization (WHO 2003), cover a specific interest-health, in the case of WHO, for example, has failed to address other interests such as trade and property rights, which are indispensable in regulating traditional medicines knowledge.

All countries where there is use and practice of traditional medicine, the need to regulate the use of these medicinal substance becomes important (Vishel, et al, 2011). The WHO has tried to establish internationally recognizable regulatory guidelines to define basic criteria for the evaluation of quality, safety and efficacy of botanical medicine. The guidelines for assessing the quality of botanical materials mainly emphasize the need to ensure the quality of medicinal plant products by using the modern techniques and applying suitable standards. The legal process of regulation and legislation of herbal medicines differ from country to country. The World Health Organization has published guidelines in order to define basic criteria for evaluating the quality, safety, and efficacy of herbal medicines aimed at assisting national regulatory authorities, scientific organizations and manufacturers in this particular areas (WHO,2003)

The introduction of integrative and complementary practices in the primary health care seek the improvement of services provided as well as the number of different approaches in the process of delivering health (Rosa, 2012). Public health policies coupled with the WHO encouragement materialize such as priority, revealing the necessary safety, efficacy, and quality from the perspective of integral health care. The author reveals that not many countries have national policies for traditional medicine. Regulating traditional medicine products, practices and practitioners is difficult due to variations in definitions and categorization of traditional medicine therapies.

2.4. Existing regulation and legislation in Different Countries

Although Traditional Medicine has a great influence on health care practices, there is wide variation from country to country in policies, laws, and regulations governing the safety, quality, and efficacy of Traditional Medicine therapies. Many consumers use herbal products to treat themselves often without a health practitioner's knowledge or advice

In Tanzania for example, private practices in the Health sector was actively discouraged and in 1977 was prohibited by the law. The major concern of the authors is on the practice of conventional medicine had nothing to do with the practice of traditional medicines. Currently there is a law in place that regulates traditional medicine which is more restrictive and therefore ineffective in regulating and promoting traditional medicines in Tanzania. The public sector includes both conventional and unconventional means of providing health care to the public. It is serious oversight to concentrate on conventional medicines leaving the unconventional medicines aside.

The herbal medicines sector is in dilemma in terms of its regulation (Walker, 2015). The major problem is that some world wish to continue practicing traditional medicines without any regulation while others are account of public safety would wish regulation to ensure that the consumers of herbal medicines are protected. It is important that there is a regulatory framework in place. But it is more important that the regulation framework should have an elaborate of objectives to ensure that a traditional medicine is effectively regulated to ensure that its promotion is of paramount importance. The regulation framework of Tanzania is not as

effective as it should be and leaves the traditional medicines practitioners to operate at the pleasure of the council even without adherence to the law created by the parliament to regulate traditional medicines.

The regulation of herbal medicines varies from country to country (Sharad et al 2011). Some of African countries have no even legislation in place to regulate, control and promote traditional medicines. In case of Tanzania the regulatory framework seems to be more of controlling one instead of promoting the growth of traditional medicines. The authors have not examined the law regulating traditional medicines which was enacted in 2002 despite writing this article in 2011. The Medical Practitioners and Dentists Ordinance which was since colonial times is not essentially the law regulating traditional medicine in Tanzania today despite recognizing the same. This research therefore seeks to assess the traditional and alternative medicine regulatory framework and its implementing challenges in Tanzania.

The implementation of the traditional medicines Act 2002 and its regulations is still a problem in Tanzania, because most of policy implementers are converts of conventional medicines practitioners (Kayombo et al, 2013). The author further states that the conventional medicines practitioners are shying away from traditional health practitioners and traditional medicine itself. If this is the case the traditional medicines being mainly administered by conventional medicines practitioners turns the regulatory framework ineffective to yield desired results of promoting traditional medicine. Since the conservation of medicinal plants is of paramount importance for continued sustainable traditional medicine, the authors suggest that legal framework should be developed to safeguard the practice of traditional medicine.

While the law is made to regulate traditional medicine, the management of the same is mostly done by conventional medical practitioners who partially support the use of traditional medicines. The authors also point out that though traditional medicine is recognized by the Act of 2002, attitude of some doctors and researchers towards traditional medicine and its practitioners as relate to partnership, treatment and care was negative. This as a result created gap for effective collaboration of the two healthcare systems in the country. In such undeclared tug of war between the conventional and traditional practitioners may have serious

repercussions on the broad spectrum of regulation of traditional and alternative medicine. The implementation of the law therefore is more of prohibitive in nature than being progressive.
Many countries organize their National Regulatory Authorities (NRAs) as small units or sections under division of Ministries of health, which results in a low profile for the authorities (Perspective, 2003). This weak organization structure tends to results in very limited government allocation of human, financial and other resources. In this circumstance, the council of traditional medicine in Tanzania is a weak institution which is characterized by inadequate funding from the government and being understaffed to undertake its functions across the country.

2.5 Challenges of regulating the Traditional and Alternative Medicine

For the last the two decades a number of studies have reported challenges of regulating the traditional and alternative medicine subsector. These studies have observed that a variety and mix of factors make TAM regulation and integration as a global challenge. These factors include absence of guidelines for TAM practice, insufficient research to prove cost-effectiveness and the limited commitment of insurers for reimbursement (Grimaldi 2008: Meeker 2000). These factors have resulted into week and ineffective regulatory processeses and outcomes in most

Furthermore, 0ther challenges related to actors, providers and direct regulators have also been reported by various studies. These include: ignorance about TAM, lack of licensing for TAM professionals, fear and resistance to change by medical professionals, lack of data on usage of TAM, lack of provider networks, as well **as** lack of coordination and communication between TAM providers and the existing health systems (Meeker 2000: Fink 2002]. Our study explored some of these factors among practioners and regulating officials Tanzania . Both, the demand and supply sides, of the traditional and alternative medicine subsector seem to be experiencing similar problems and challenges as reported in other countries.

The WHO global survey report on national policies on traditional medicine and regulation of herbal medicines reports that the major challenges are related to "regulatory status, assessment

of safety and efficacy, quality control, safety monitoring and lack of knowledge about TAM" (WHO,2005). In our study we explored knowledge among regulatees and we found disparities among them regarding the regulatory process, and lack of knowledge on TAM among regulators.

CAM products regulation

2.6. Awareness of overall regulatory pprocess and its outcomes among regulatees and regulators

Regulations in the countries for assessment of the quality ,safety and efficacy of medical plants and the work of WHO in supporting the preparation of model guidelines in this field, have been helpful in strengthening recognition of their role in health care. It is hoped that assessment of these traditional remedies could become the basis for a future classification of herbal medicines as well as for evaluative studies on their efficacy and safety and their potential use in national health care systems in different parts of the world. Thus emphasizing the new foreign or domestic players to provide their products and share the ever regulatory requirement. (Sharad et al 2011). On effective regulation state, the public is protected through consumer legislation and prevent false claims, restricting the use of herbal products which are known to be hazardous to health and through the use of environmental controls to ensure hygiene and infection control risks are minimized. In this scenario it is important to encourage good professional standards through voluntarily accreditation or self regulation schemes (Walker D, 2015).

CHAPTER THREE

3.0. METHODOLOGY

3.1 Study Area

The study was conducted in dar es salaam, Tanzania. The study was done in Dar es Salaam because the ministry and the regulatory body, and most of the TAM practioners, the regulatees, are located in Dar es salaam; this was also convinient to the researchers. The regulators- officials from the Ministry of Health, Connunity Development, Gender, Elderly and Children and City Council and regulatees were conviniently reached.

3.2 Study design

A qualitative study design a was employed to implement the study in one region, Dar es Salaam. A series of key informant interviews were carried out with regulatees practioners of the TAM who owned premises in Dar es Salaam. A total of 15 respondets were interviewed, we opted for in-depth interview because we aimed at getting opinions deeply and widely on their feelings and perceptions as well as awareness of the regulatory process in TAM. We felt that such depth of, valuable and objective information could be obtaind by a well-conducted key informant interviews, and could not be successfully obtained by another approach. We also aimed at obtaining diverse perspectives and information from practitioners of various types of TAM products and practises.

3.3 Study population

The study population included two major players involved in the regulatory process of traditional and alternative medicine practices, namely the regulators of traditional/alternative medicine and the regulatees/practitioners..

3.4. Sample size and Sample Selection

Both regulatees an regulators- officials from the Ministry of Health, Connunity Development, Gender, Elderly and Children and City Council-were involved in the study. Three regulators, one from the ministry and two from the council were interviwed during the survey. For the regulators, we aimed at exploring the capacity, effectiveness and operational challenges that impede the functioning of the regulatory process. A total of 11 practitioners were conviniently recruited for the study. In the choice of regulatees interviewees, we aimed at investigating the different views and perspectives of the multiple practitioners in the TAM market. We obtained a list of all registered TAM practitiners in Dar es Salaam from the TAM regulatory Board. We conviniently selected TAM premises and clinics and who did and sold both local manufacturing of products and those who sold products from other sources.

3.5 Data collection Instruments (Tools)

Two semi-structured Key Informant interview guides for the regulators and regulatees consisting 13 and 17 questions respectively were utilized for data collection in this study. The interview guides was developed by the research team to investigate the regulatess awareness of and adherence to the regulatory process and regulations of TAM. The questions focused on the types of products available in the market, awareness of the regulatory frameworks in place and sources of information, the process of obtaing licenses, kinds of regulations, supersion vits and what supervision involves, the extent of adherence, problems related to adherence, clarity and complexity of guidelines, barriers to following gidelines \. Interviewees were further asked to share with the research team any relevant documents and also asked to suggest and opinions on how regulating the subsector could be improved. They were further asked to mention a practitioner who could contribute information to the research team for his study.

For the regulators the instrument contained questions on regulatory guidelines and tools, regulatory process, resources used to regulate, human, financial and infrastructural and logistics, scheduling of supervision visits, punishments, operational challenges, to mention some.

3.6 Hiring and training of Research Assistants

The principal researcher recruited two research assistants who assisted in data collection. The research assistants involved people with experience in qualitative data collection. The research assistants were trained on how collect data qualitatively. Training was conducted by principal researcher on the familiarization of research purpose, data collection tools and sampling techniques.

3.7 Pre-testing of data collection Instruments

Interview guides was pre- tested in Dar es Salaam in clinics and traditional shops that we're not be included in the study before data collection to ensure reliability and trustworthiness of the tool. The questions were adjusted according to the pre test results.

3.8 Data collection procedure

A total of 11 regulatees (practitioners, owners of premises or business, owners of clinics) were initially conviniently identified and later snowballigly invited to participate in the study. Snowball sampling was subsequently used to identify additional respondents. This process of interviewing was continued until the "saturation" point was reached; i.e., until no new information altered the results already obtained and the names identified by interviewees for additional interviews were repeated,

All key informants were approached and explained on the objectives of the study and invited to a face to face personal interview. The consent form and the interview guide, approved by the Muhimbili University of Health and Allies Science Institutional Review Board (ethics), were used to ask respondents to participate in the study. A total of a[[15 respondents approached accepted and participated in the study.

All interviews were conducted in June spring of 2017. Interviews lasted an average of 45 minutes. At the beginning of each interview, interviewees were asked to sign the consent form, which also included details about their rights as participants in this research and acquired their approval for tape recording the interviews. All interviews were tape recorded. Along with tape recording, the interviewers took field notes to facilitate data analysis and provide a backup for important findings in case certain data elements were missed during the taping of interviews.

3.9 Data Analysis

Thematic analysis was utilized in analyzing the data collected from the key informant interviews. In performing the thematic analysis, themes that emerge from the interview narratives we detected recurring issues and patterns from the data rather than from predetermined codes (Ritchie, 2002). Primary source of data such as field notes, transcripts, and audio tapes notes, were coded and analyzed manually.

Two members of the researchers, the principal researcher and an assistant, read each transcript thoroughly. The first readings steps of the scripts were done to gain an initial general insight of the text and relate them to the research objectives. In the second step, each of the questions of the interview script was used as a broad theme and the responses were classified under each theme. The statements that did not fit under any of these questions were regarded as miscellaneous. The relevant data were further transcribed by categories based on the study objectives. Themes were generated from reading literature and the study objectives. More themes and sub themes were generated as the process went on. Themes from each study objectives were respectively coded into main themes. These themes were used to describe the

findings and list of key points were developed as a result of categorizing and sorting data. Explanations of the data collected were determined by objectives of the study.

The data was revisited several times to verify, test or confirm the themes and patterns that were identified. After the primary coding of all transcripts, analysis sheets were re-coded into comprehensive broad themes and subthemes by the two members of the research team. Any coding disagreements between the two were resolved in a series of research meetings until a final list of sub-themes were generated. The final analysis sheet innate by information collected from the regulatees and the review of secondary data.

3.10 Ethical consideration

Permission to conduct the study was obtained from the Muhimbili University of Health and Allied Sciences ethical review committee. In addition, written consent was received from the respective traditional medicines practitioners and Ministry of health officials dealing with traditional medicines. Voluntary participation was encouraged, and the participants were assured of confidentiality. Privacy and confidentiality were highly maintained by avoiding unauthorized persons from accessing study information. Anonymity was maintained by using participants ID. No name of the key informant was recorded in the questionnaire. The details of the study were clearly explained to the participants. The detail included purpose of the study with respect to the benefits associated. The results from data were saved in a confidential manner. No harm was expected from this study as there was no invasive procedure.

3.11 Study limitations and mitigation

Since this study focused on exploring the capacity the regulators to regulors, they are likely to respond strategically. The regulators are likely to have had reported only information that favored their sides. However, this was mitigated by probing questions asking for written evidences where possible. Additionally, the information provided by the regulators further corroborated by information collected from the regulatees and the review of secondary data.

Regulatees were also likely to have had reported information that favored their businesses. This bias was mitigated by using triangulation methods to validate the soundness and validity of response from the regulatees. This included interpretation of the laws and policies, studying the response of the regulators, asking for written records and relevant documents, and reviewing reports from the government decisions on similar matter.

CHAPTER FOUR

4.0. RESULTS

4.1 Introduction

This chapter presents a profile of respondents as well as research findings as guided by the research questions and specific objectives/

a. Characteristics of Respondents

A total of 15 respondents were used in this study, selected form all four municipalities. Ilala, Kinondoni, Temeke and Ubungo. And the respondents were the mixture of both the regulators and regulatees. The regulatees involved in the study 13 while only 3 regulators were available for cooperation. The regulators respondents were one from the ministry responsible for healthy form the department that is responsible for the promotion of traditional/alternative medicine, and another respondent from the municipality level from the office that is responsible for coordinating and oversees and promoting traditional/alternative medicine. The study made use of few regulators who were ready to cooperate since others were not ready. Table 1 depicts the picture of respondents as they were used in this study.

Table 1: Distribution of Respondents according to their roles in traditional/alternative medicine

S/n.	Category of respondents	Number	Percentage
1.	Traditional /alternative medicine practitioners	13	86.7
2.	Traditional/alternative medicine regulators	02	13.3
	TOTAL	15	100

Source: Research data, 2017.

It was found that out of 13 traditional/alternative medicine practitioners who were respondents in this study, 15.4 percent of them have been practicing for a period of 1 to 10 years, and 69.2 percent have been into the practice for a period of 11 to 20 years. Another 15.4 percent of the

practitioners' served as respondents to this study had the experience above 21 years. This indicates that 84.6 practitioners that served as respondents have been practicing for not less than 11 years. Given such picture of respondents in this nature, a good insight into traditional/ alternative medicine is likely to be provided. Table 2 below provides a numerical explanation of this information;

Table 2: Traditional/ Alternative medicine practitioners' experience

S/n.	Traditional/ Alternative medicine practitioners' experience years	Frequency	Percentage
1.	1 up to 10	2	15.4
2.	11 up to 20	9	69.2
3.	21 and above	2	15.4
	TOTAL	13	100

Source: Research data, 2017.

b. Awareness of the regulatees on traditional/ alternative medicine regulatory framework.

Regarding awareness of the regulatees on traditional/ alternative medicine regulatory framework the regulatees were asked on whether they were aware of regulations, and reasons for being regulated. They were also asked if they were aware of the instruments used for regulating the subsector, penalties for breaching the regulations, regulating bodies and the frequency of being regulated. Furthermore, they were asked on how the regulators inform the regulatees about the regulations; how supportive the regulators are; steps and procedures for registration and licensing.

c. Existence of regulations

The regulatees were asked on the existence of regulations.. Some of them were aware while of the existence of regulations. Some of those who were aware reported to have participated in developing the law. The one who participated had this to say;

'The law was enacted in 2002 after tireless advocacy […] and I was involved in the process.' [R1Owner of the traditional/ alternative medicine/ alternative outlet]

Although majority of the respondents knew about the regulations, some were ignorant. One of these who were ignorant of the existence went further and even said the subsector was not supposed to regulated, regulations should be for conventional medicine. He said;

'I have been practicing traditional/ alternative medicine for twelve years I have Heard nothing called regulations. I wonder who set them and who was involved in developing them. Do they think this is conventional medicines?'
[R2 owner of traditional/alternative medicine outlet]

d. Reasons for being regulated

The regulatees were asked if they understand the reasons why they were being regulated. From their responses it was found out that majority were aware while some were not. Those who were aware apart from knowing the reasons they even emphasized the government to ensure practitioners' compliance with the rules laws and regulation. They added that the set rules laws and regulations intend to protect the community form possible abuses that may arise. One of them said;

'The rules laws and regulations are essential to ensure compliance with the health provision standards as a means to protect the community against possible abuse from practitioners.'
[R3 owner of traditional/ alternative medicine outlet]

On contrary there were some who were totally not aware on why they need to be regulated. Thy further wondered why regulating the practice that was inherited and is rooted from community traditions. One of them confirmed that by saying;

'We are practicing what we inherited from our parents and grandparents. Our practice is also rooted in our culture and traditions. Are these so called regulators aware of our culture and traditions?'
[R2 owner of the traditional/ alternative medicine outlet]

e. Awareness of the instruments for regulations

The regulatees were asked on their awareness of the instruments that used to regulate traditional/ alternative medicine practices. Their responses were divided. Majority of the regulatees were aware of the instruments that are used to regulate them while others were not. One of those who were aware had this to say;

'Hygiene, how we keep, pack and processing medicine are some of them instruments used to regulate us. Other includes how we keep patients' record, and if the premise is ideal for clinics.'

'[R6 owner of the traditional/ alternative medicine outlet]

Among those who were not aware, one of them confirmed by saying the following;

'I know nothing about the instruments that the so called regulator use to regulate our sub sector.'

[R9 owner of the traditional/ alternative medicine outlet]

f. Awareness of penalties for breaching regulations

Regulatees were asked on whether they were aware of the penalties associated with breaching the regulations. While majority seemed aware of the penalties, others were not. They mentioned the penalties to include written warnings, temporary closure of clinics and having their license revoked.

One of those were not aware of penalties confirmed his ignorance by saying the following;

'I know nothing of the penalties associated with breaching the rules, laws and regulations. I heard sometimes ago that some practitioners had their license revoked though I don't know the reasons behind.'

[R9 owner of the traditional/ alternative medicine outlet]

g. Awareness of the regulating bodies

Regarding awareness on the existence of regulating bodies majority were aware of, few were not. Those who were aware mentioned the regulating bodies as being the ward council, the office of the municipal traditional/ alternative medicine coordinator and the council responsible for coordinating, regulating, and promoting traditional / alternative medicine. He added that all these operate under the ministry responsible for health and community development.

On the contrary, those who were not aware could not even mention a single regulatory body. One of them confirmed his ignorance by saying;

'I don't know which body regulates me.'

[R9 owner of the traditional medicine outlest]

e. Awareness of the frequency of being regulated

Regulators are supposed to be visiting the traditional / alternative medicine practitioners. Respondents were asked if they were aware of how many times they are supposed to be visited for regulation purposes annually by regulators. All of them were found to be unaware of the frequency of visit that regulators should make annually to their premises. Furthermore, one of them confirmed of not been visited since he started practicing, and he confirmed by saying the following;

'No one has visited me ever since I started practicing traditional medicine for the past twelve years now.'

[R3 owner of the traditional/ alternative medicine outlet]

h. How the regulators inform the regulatees about the regulations

The regulatees were asked on how the regulators inform them on issues regarding regulations. Ten out of thirteen said they share information with the regulators when the regulators visit them and when they visit the regulatory offices. One of them confirmed by saying;

'We get informed of these regulations only when we visit the regulators'
Office or when they visit us. I have never been invited to any occasion
So I could be informed of these regulations.'
[R10 owner of the traditional/ alternative medicine outlet]

Three were not aware of anything regarding the regulations. They added that a part from knowing the regulations they even don't know who has them and how they are useful to them. One of them confirmed by saying;

'I know nothing regarding regulations and who should make them
available to me, and how can these so called regulations help me?'
[R9 owner of traditional/ alternative medicine outlet]

i. Sharing information and Supportive supervision

Regarding information sharing and supportive supervision two sides of the regulators were revealed. One side is those regulators who have intentions to improve the traditional/ alternative medicine practice. These are the ones who give supportive supervision, share information y instructing and coaching the regulatees on what to do or to follow.

Those with bad intentions they just look for mistakes (fault finders) and they neither give supportive supervision nor do they share information with the regulatees. One of the respondents confirmed by saying;

'To be informed and get support depend with the intentions of the regulator, and those with good intentions are supportive indeed while those with bad intentions they only look for mistake.'
[R3 owner of a traditional/ alternative medicine outlet]

j. Awareness of the steps and procedures for registration and licensing

Some of the practitioners were aware of the steps and procedures for registration and licensing. Eight out of thirteen were able to mention the registration and licensing procedures traditional and alternative medicine practitioners and their outlets.

The steps and procedures mentioned were approval by the Mtaa/Subward development committee, approval by Ward development/ Health committee, approval by Municipal Health Committee, approval by Regional Health Committee, approval by the Secretariat of the Traditional and Alternative medicine council and lastly approval by the the General Council meeting.

a. Factors that influence regulatees` adherence to the regulatory process

The regulatees were asked on the factors that influence their adherence to the regulatory process. In response to this the following factors were mentioned the; financial costs involved, the complexities of the rules, laws and regulations, and regulatee's readiness to adhere.

i. Financial Cost

Regarding financial cost, high costs of adherence to regulations was mentioned as a big hindrance to abide by required regulations. They mentioned the cost of renting a standard premise and acquiring modern as required by regulations as involving a lot of money. For instance one of them mentioned that to register one herbal medicine costs around TZS 800,000 up to 1,000,000/=

ii. Readiness to adhere and the Complexities of rules, laws and regulations

Respondents mentioned the complexities of the rules, laws and regulations as one of the hindrance towards abiding by regulations. For instance they reported that the registration process as prescribed by rules, laws and regulations are tiresome; it involves many steps. The steps include applying to the mtaa/subward committee, ward committee and to the municipal health committee recommends the request to the council general meeting which approves or disapprove the registration basing on the secretariat recommendations.

Another concern pointed out was regulatees' readiness to adhere. Some regulatees reported that they were not ready to adhere because the rules, laws and regulations were not easy to implement. One of the complaints was on premises required to register medicine, and on the number of rooms the former should have.

b. Factors that affect the regulatory capacity of regulating bodies

The regulatees were asked whether they know the factors that affect the effectiveness of the regulatory frame work. They were probed on the tools and guidelines of regulatory framework, and the enforcement of laws, rules and regulations. They were also probed on resources availability, challenges relating to capacity, ability, and skills for supervision and enforcement.

i. **Tools and guidelines for regulations**

Regarding the tools and guidelines that are used to regulate the traditional/ alternative medicine both the regulators and the regulatees were asked to mention the factors that affect the capacity of the regulatory bodies to regulate the sub sector

ii. Enforcement of laws, rules and regulations

Both the regulators and majority of the regulatees were aware of the enforcement of laws, rules and regulations process. They described the process that it starts from the municipal inspectors who launch their allegations to the council that is responsible for coordinating, regulating and promoting traditional / alternative medicine. Then the council through its meeting summons the alleged and upon hearing the council decides on whether the alleged is guilty or not. When the practitioner is not satisfied by the decision reached by the council, the law allow him to appeal to the minister responsible for health and community development, and if the appeal is not successful the practitioner is allowed to forward the matter to the court of law.

Resources availability

Regulators mentioned the resources that were needed to aid their work performance. The resources mentioned were man power, finances, and vehicles.

1. **Manpower or human resources**

Regarding man power the regulator was concerned with their number in relation to the tasks they are to perform. Being effective was said to be difficult given the fact that their number is small at the municipal level, the respondent added that at times he fail to visit the regulatees because he is alone and he added that the problem of number is associated with lack of people with knowledge in traditional / alternative medicine. He was quoted saying;

'I am alone in the office responsible for coordinating and promoting traditional/ alternative medicine at the municipal level […] as the result it become hard to attend issues on time.'

[R11 Coordinator of traditional / alternative medicine at the Municipal]

2. **Finances**

Finances in supporting the activities relating to traditional / alternative medicine were reported to hinder the capacity to implement the rules and regulations. The respondents further added that the approved budget is not enough and it doesn't even reach them on time. As a result activities such as seminars, workshops and exhibitions relating to the promotion of traditional/ alternative medicine cannot be carried out. The regulator said;

'Sometimes because of resources scarcity we fail to implement some planned activities.'

[R12 Respondent from the directorate of traditional/ alternative medicine at the Ministry of Health Community Development, Gender and Elderly and Children]

3. Transport

Resources like transport were reported to hinder capacity to regulate the subsector. The municipal regulator reported that he fail to visit the regulatees because of transport challenges. Thus, even when processing applications for registration they have to ask the applicants to pay for officers' transportation for the former to be visited timely. To this he said;

'The means of transport is a real challenge. At times I have to request a registration applicant to pay for it so I could be able to visit him.'

[R11 Coordinator of traditional / alternative medicine at the Municipal]

4. Skills and ability to regulate

The respondent mentioned that the great challenge remain to the fact that majority (of the regulators) are conventional medical doctors have little knowledge on traditional/ alternative medicine. He added that these conventional medical doctors know little about medicinal plants and how they work. He further argued that if the regulators were pharmacists the capacity to regulate would be improved. On this the municipal regulator said;

'Pharmacists are more knowledgeable on medicinal plants. They can better understand the processes involved in preparations, dispensing and storage of herbal medicines.'

[R11 coordinator of traditional/ alternative medicine at the municipal]

a. The operational challenges that affect the functioning of regulatory bodies in regulating the traditional and alternative medicines subsector in Tanzania

Both regulators and regulatees were asked on the operational challenges that affect the functioning of regulatory bodies in regulating the traditional and alternative medicines subsector in Tanzania.

i. Organizational Challenges

Regarding the organizational challenges, the regulators mentioned them to include less interest of the regulators and scheduling of activities.

1. **Less interests of the Regulators**

The respondent said that since majority of the regulators are conventional medical doctors the later are less interested and despise the traditional/ alternative medicine subsector. They further added that their attitude towards traditional/ alternative medicine practitioners is not commendable. On this one regulatee said;

'The conventional medical doctors responsible to oversee the practice of traditional/ alternative medicine in the country are not interested in promoting traditional herbal medicine and hence they are not interested in regulating it.' [R3 owner of the traditional medicine outlet]

2. **Scheduling and multiple assignment**

Scheduling of activities was said to be among the implementing challenges. The respondent said that at the municipal level the coordinator for traditional / alternative medicine is also a member of the municipal health committee (MHC) under the municipal doctor. The later is a conventional medical doctor, and the committee is dominated by the medical doctors. As a result priorities are given to issues relating to conventional medicine leaving less time and fewer resources to traditional / alternative medicine. The respondent added on interference of schedules by the ministry as another challenge where the ministry also assigns them other tasks. This results into multiple assignments.

'A municipal coordinator for traditional/ alternative medicine is a member of MHC under the municipal doctor. Under MHC the priority is on all the issues relating to municipal health and not traditional/ alternative medicine only, while speaking of their recent involvement in BRN issues at the municipal level.'

[R11 Coordinator of traditional/ alternative medicine at the Municipal]

3. **Behavioral Challenges**

The respondents said that the regulators (majorities being conventional medical doctors) do not behave and treat the traditional/ alternative medicine practitioners professionally. They

don’t count them as colleagues. They despise the traditional/ alternative medicine practitioners and this impairs their operations. One respondent was quoted saying;

‘The regulators (conventional medical doctors) despises the subsector which results into poor cooperation.’

[R3 owner of the traditional medicine outlet]

2. Corruption

The regulatees mentioned corruption to be one of the implementing challenges that faces the regulators. They revealed the presence of some corrupt officials who upon receiving bribery from practitioners pretends not to be aware of the latter’s malpractice and when not given fail to tolerate even tolerable deviations. Adding that some practitioners do not comply with the rules, laws and regulations but since they corrupt some regulators they operate with no disturbances. One of the respondents had this to say;

‘Because of corruption some practitioners do not adhere to the rules, laws and regulations. They corrupt some regulatees […] to avoid being caught.’ [R13 owner of the traditional/ alternative medicine outlet]

CHAPTER FIVE

5.0. DISCUSSION

5.1 Introduction

The main issues discussed in this chapter focuses on the regulatory framework on traditional / alternative medicine specifically on regulatees 'awareness of and adherence of regulations and challenges affecting the regulatory capacity; factors affecting regulatees' adherence to regulatory requirements; and, operational challenges facing the regulatory bodies and regulators in TMAr. The main observations from this study indicate that the regulatory framework is facing a number of challenges that need to be addressed to make it more effective and efficient.

5.1.1 Awareness of the regulatees on the regulatory guidelines on traditional/ alternative medicines.

This study reveals that awareness of the regulatory framework among the traditional/ alternative medicine practitioners is still a challenge that needs to be addressed in order to promote the subsector. Some practitioners were not aware of the regulatory guidelines; this may imply that there malpractices that are done by practitioners unknowingly. Since it is well documented that a good number of people in Africa depends on this subsector as the forts visit of obtaining their treatment malpractice may result into harming their healthy (WHO, 2013).

Awareness of the regulatory guidelines conform with the work of Vishel, et, al (2011) whose work revealed that all countries where there is use of traditional medicine, the need to regulate the use of these medicinal substances becomes important. It also conform with the WHO's (2013) assertion that her member state have established national and regional policies and regulations to promote the safe and effective use of traditional medicine. This implies that the awareness of the regulatory frame work is important in promoting the health of the population who resort to this subsector for their treatment. Walter (2015) asserted that the herbal

medicine sector is in dilemma in terms of its regulations because practitioners are not aware of the regulations and hence a need to encourage good professional standard through voluntarily accreditation or self regulation schemes. As WHO (2013) suggested that awareness of regulations among regulatees is important to ensure safety and quality traditional / alternative health care service are given to the community.

5.1.2 Factors influencing regulatees` adherence to the regulatory process in the traditional and alternatives medicines subsector

The findings of this study revealed that adherence to regulatory framework among regulatees are influenced by both their awareness of the process and their ability to comply with the same. Lack of direct public private partnership involvements especially in inspection, results into a weak regulatory regulatory process.

Due to the fact that reguulatees are not directly involved into making the laws, and direct inspections they lack that sense of involvement. This is corroborated with WHO (2013) view that a regulation process will be a success when communication and partnership between stakeholders is fostered.

The cost of adherence to the regulations was reported to be a hindrance as a result some practitioners abuse and commit to malpractice. It may attract corruption and the emergence of unknowledgeable practitioners who end up abusing the subsector.

5.1 Factors that affect the regulatory capacity of regulating bodies

A number of challenges that impair the capacity of the regulatory body to regulate were reported. Lack of enough manpower was reported to be a hindrance because regulators fail to visit and supervise all the regulatees as required by rules, laws and regulations. This may result into malpractice among the practitioners knowing that they can’t be reached easily by the regulators. Studies have also indicated that lack of enough man power has been reported to results into the ineffectiveness of the regulatory bodies to regulate the traditional/ alternative

medicine subsector in Tanzania, Zimbabwe and other African countries (Kumaranayake, et al, 2000; 2013).

Lack of enough knowledge on traditional/ alternative medicine subsector among the regulators was also reported to be another hindrance to regulating bodies' effectiveness. Their lack of essential knowledge in the field may result into making the regulatees less cooperative with the regulating bodies. These findings corroborate with the study by Kayombo et at (2013) which revealed that, the implementation of traditional medicine rules, laws and regulations is still a problem in Tanzania, because most of policy implementers are converts of conventional medical practitioners.

Shortage of transport facilities for the regulators was also reported to be another hindrance to the regulatory process. Lack of transport facility prevents the regulators from attending to their duties timely. This may results into failure to approve registration of traditional medicine practitioners because they can't reach their offices to inspect them. This corroborate with the study by Kumarayang, et al (2013) which revealed that shortage of reliable means of transport impairs regulators in medicines to effectively regulate medicines.

5.2 The operational challenges that affect the functioning of regulatory bodies

Less interests in traditional / alternative medicines among regulators was reported as one of the operational challenges that affects the functioning of regulatory bodies in regulating the traditional and alternative medicines subsector in Tanzania. Majority of the regulators being conventional medical doctors were reported to be less interested in the traditional/ alternative medicine subsector, and hence affects the regulatory process. One of the issues that WHO recommends in regulatory process of medicines including traditional medicine is the level of training of the regulators that reflects the interest of the regulators into the regulating task (WHO, 2013). Thus, if one has no interests on the task that should be implemented he/she may easily abuse the regulation process, or falsely report the results of the regulations.

Scheduling of regulators to attend to the regulating timetable was also reported to be another challenge that impairs the operations of the regulating bodies. Poor scheduling is a challenge that may results into conflicting tasks especially when those scheduled to attend to some tasks are assigned other duties. As a result some practitioners may commit to malpractice knowing that they won't be visited for regulatory purpose.

The information about the regulators, in this study, should be interpurated with caution. In this study only a few regulators were available for interval some of the regulators declined to interviewed. The fact that only a few regulators were interviewed not enough information was collected regarding the challenges of regulating it more likely that the information provided was not sufficient enough to reflect the real situation of a regulatory situation and effectiveness. Therefore regarding issues that are for the regulatory bodies may not give a wide picture of the real situation. However, although there were few despondence who gave information on the regulating side there information collaborated each other

CHAPTER SIX

6.0. CONCLUSIONS AND RECOMMENDATIONS

6.1 Introduction

The following are the conclusions from the study as per objectives.

6.2 Conclusions

1. There are some regulatees who are yet not aware of the regulatory framework;
2. Non adherence to regulations is a problem that is caused by the costs that are involved in abiding by the regulations, long procedures in being registered and licensed and ignorance on the regulations and their guidelines.
3. Human resources, skills, means of transport are the problems that affect the capacity of regulatory bodies.
4. Lack of interests, and poor scheduling of inspectors are the most prominent operational challenges that impairs the efficiency of regulating the sector.

6.3 Recommendations

1. Regulating bodies should more awareness to the regulatees in order to improve adherence to regulations among regulatees.
2. Inspectors regulating the traditional/ alternative medicine sub sector should be people who have training in traditional/ alternative medicines.
3. Studies should be done on regulatory cost to assess its implication in regulatees adherence to regulatory framework.

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APPENDICES

Appendix 1a: Consent Form English Version

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)
DIRECTORATE OF RESEARCH AND PUBLICATIONS

ID-NO……

Consent to participate in an interview

Introduction

Greetings! My name is Simon Rusigwa a student of Master of Public Health at Muhimbili University. I am conducting a research as part of my studies with the main objective of "Assessment of operational capacity and implementing challenges of traditional and alternative medicine regulatory framework in Tanzania: the case of dar es salaam

Purpose of the study

The purpose of this study is to assess operational capacity and implementing challenges of traditional and alternative medicine regulatory framework in Tanzania: the case of Dar es salaam**.** Not more than 30 respondents will be interviewed in this study, This will include 10 traditional health practitioners, 5 conventional health practitioners, 5 members of the Traditional and Alternative Health Practice Council and 10 consumers of traditional and alternative medicines.

You are one of the respondents of this study, this means I will ask you few questions regarding traditional medicines regulation framework in Tanzania. I will record and note down what you will be telling me. This will take approximately 45 minutes of your valuable time

What Participation Involves

If you agree to participate in this study, you will be required to sign this consent form and answer the questions that you will be asked by me.

Benefits

You will not get direct benefits from the study, but the information provided by you will help to feed in more information in the literature of regulation in the traditional medicine sector, raise awareness to policy makers on the ineffectiveness/effectiveness of traditional medicines practices regulatory framework which can cause risks or not to individuals and public health at large. The information will also be useful source of information to the traditional medicine regulators in Tanzania and be used in streamlining the guidelines for regulation and supervision of the sub-sector.

Risks

This study involves no invasive procedures so we expect that no harm will be done to any participant

Confidentiality

I wish to assure you that, this information will be treated in confidentiality between you and the researcher. All the information collected in the questionnaire forms will be entered in the computer with only the study identification number.

Voluntary participation

Taking part in this study is totally voluntary, that is, you can decide to participate or not. You can stop participating in this study at any time, even if you have already given your consent.

Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Who to contact if you have any question about this study

In case of any questions about this study please don't hesitate to contact **Principle Investigator, Simon Rusigwa;** Muhimbili University of Health and Allied Sciences (MUHAS), P.O. Box 65001, Dar es Salaam (Tel. No. +255716444888). And any questions about right to conduct this study, you may call **Chairman of University Research and Publication Committee,** Dr Joyce Masalu P.O .Box 65001, Dar es Salaam Tel, 2150302-6, **and Prof. Phares Mujinja** who is the supervisor of this study**.**

Do you agree? Yes…….. No……

Participant agrees ……..... Participants does not Agree. ……...…

I, …… Have read the contents of this consent form and my questions have been adequately answered. I therefore agree to participate in this study.

Signature of the participant ……Date ……

Signature of the interviewer …….. Date ……

Appendix 1b: Consent Form Swahili Version

CHUO CHA SAYANSI ZA TIBA MUHIMBILI

KURUGENZI YA UTAFITI NA MACHAPISHO

FOMU YA RIDHAA

Namba ya utambulisho……..

Utambulisho

Habari! Jinalanguni Simon Rusigwa mwanafunzi wa shahada ya uzamili katika fani ya afya ya jamii katika chuo kikuu cha sayansi cha afya na tiba Muhimbili. Ninafanya utafiti huu kama sehemu ya masomo yangu, ambao lengo kuu ni kufanya utafiti wa "Ufanisi wa sheria sera na miongozo ya uendeshaji wa tiba asili na tiba mbadala , Dar es salaam Tanzania.

Dhumuni la utafiti huu

Dhumuni la utafiti huu ni kufanya tathmini ya uwezo wa kiutendaji na changamoto mbalimbali zinazovikabili vyombo mbalimbali vinavyodhibiti tiba mbadala Tanzania**.** Jumla ya watu wasiozidi 30 watafanyiwa usahili kwenye utafiti huu.hii itajumuisha waganga 10 wa tiba asili,waganga watano wa tiba za kisasa, wajumbe wa tano wa baraza la tiba asili na tiba mbadala na watumiaji kumi wa dawa za asili ambao watachaguliwa kwa makusudi .wewe ni mmja kati ya watakao fanyiwa usahili kwenye utafiti huu.Maswali utakayoulizwa yatahusu sheria sera na taratibu zinaratibu tiba asili na tiba mbadala Tanzania.Nitarekodi na kuandika kile utakachokua unaniambia.Hii itachua takribani dakika 45 za muda wako muhimu.

Ushiriki

Kama utakubali kushiriki katika utafiti huu, itabidi usaini fomu hii ya makubaliano pia ujibu maswali utakayoulizwa na mtafiti.

Faida

Hakutokua na faida za moja kwa moja ambazo utapata,lakini majibu utakazotupatia yatasaidia kuongeza taarifa kwenye vitabu na maandiko yanayohusu sheria sera na miongozo/taratibu za tiba asili na tiba mbadala,pia yataongeza uelewa na utambuzi zaidi kuhusu uthabiti wa sera,sheria na miongozo ya tiba asili na tiba mbadala kwa watunga sera. Pia majibu yako yatasaidia kuwafungua wadhibiti wa uendeshaji wa tiba asili na tiba mbadala na Tanzania na kunyoosha miongozo,sheria na sera na udhibiti wa sekta.

Vihatarishi

Utafiti huu hausishi vitendo vyovyote vya kudhuru mwili wako kwa hiyo hatutegemei mshiriki yoyote kupata madhara.

Usiri

Taarifa zote zitakazokusanywa zitashughulikiwa kwa usiri wa hali ya juu kati yako na mtafiti. Taarifa hizi zitaingizwa kwenye mfumo wa komputa kwa namba na sio kwa majinayenu.

Ushiriki wa hiyari

Kushiriki kwako katika utafiti huu ni wa hiyari. Una weza kujitoa katika utafiti muda wowote hata kama ulikubali kujiunga hapo mwanzo. Kukataa kushiriki au Kujitoa katika utafiti hakuta kuwa na adhabu yoyote wala hupotezi haki zako za hapo awali.

Mawasiliano

Tafadhali, kamautakuwana maswaliyoyotekuhusuutafiti huu wasiliana namtafitimkuu: Simon Rusigwa wa S.L.P. 65001,chuo cha sayansi za tiba Muhimbili Dar esSalaam, au Mwenyekiti wa kamati yau tafitinauchapishaji Dr Joyce Masalu, S.L.P 65001, Dar es Salaam Tel No: 022-2150302-6.

Je unakubali kushiriki katika utafiti huu? Ndiyo…….. Hapana……

Mimi …….....……...… , …… nimesoma /nimeelezwa yaliyomo yote katika fomu hii na maswali yangu yote yamejibiwa.nakubali kushiriki katika utafiti huu.

Sahihiyamshiriki …… …….Tarehe ……

Sahihiyamtafitimsaidizi …… ……Tarehe ……

Appendix 2a. Questionnaire

IN-DEPTH INTERVIEW TO REGULATORS: (English Version**)**

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES(MUHAS)

DIRECTORATE OF RESEARCH AND PUBLICATIONS

OPERATIONAL FUNCTIONS, CAPACITY AND IMPLEMENTING CHALLEGES OF TRADITIONAL AND ALTERNATIVE MEDICINE REGGULATORY FRAMEWORK IN DAR ES SALAAM

1. Questionnaire no……..
2. Date of interview……
3. Place …….
4. Name of Interviewee ……

1. How many consultative meetings have you had with regulatees? Which regulatees?
   ……
   ……
2. How often do you visit regulatees?.....
3. What do you normally inspect when you visit?.....
4. What are the things that you normally regulate?.....
   ……
5. Are there other agencies that you cooperate to regulate the subsector?.....
   ……
6. Do you give guidance materials to regulatees? ……...

a) What is the main content of these guidance materials?.....
……
……..

b) Do you conduct seminars to elaborate the guidance materials?.....
……
……

7. How do you usually communicate with your regulatees? ……
……
……

8. Do you have any feedback mechanism to and from your regulatees? How often? ….
……

9. What are the regulatory instruments that you use to regulate? …….
……
……

10. What is the level compliance among regulatees? ……...
……
……..

11. In the past one year how many regulatees have been persecuted or warned for not …
……
……...

12. What are the common mistakes that are committed by regulatees? ……
……
……

13. For you to be very effective in regulating the subsector what do you need to have?
……..……
……

Appendix 2B. In-depth interview to regulate Questionnaire: (English Version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

OPERATIONAL FUNCTIONS, CAPACITY AND IMPLEMENTING CHALLEGES OF TRADITIONAL AND ALTERNATIVE MEDICINE REGGULATORY FRAMEWORK IN DAR ES SALAAM

1. Questionnaire no……..
2. Date of interview……
3. Division ……..
4. Ward……..
5. Name of Interviewer ……

1. What do you understand by being regulated?.....

   ……

   ……..

2. Can you mention what the regulations required you to do?

   ……

   ……

   ……..……

3. Have you ever been regulated? on what/? And how frequent?

   ……..……..

   ……

   ……..……..

4. What are the instruments that are used to regulate?

   ……..……...……..

   ……

   ……..…….

5. Do you understand the content of these regulatory instruments?

   .....

   ……

   …….....

6. In your opinion are these instruments effective in regulating the sectors?

   .....

   ……

   ……..…….

7. Have you ever been invited to attend a meeting by any of the regulatory bodies and what did you learn there?

   .....

   ……

   ……..…….

8. In the past one year how many times were you visited by the regulators? What did they do?

   ……

   …….

9. Do you think the regulators that visit you have the capacity of doing their work?

   ……

   ……

   ……..……..

10. Are the regulators acting on what they are supposed to do?

    .....

    ……

    ……..

11. On

    i) Registration process:

    ……

12. In your opinion do you think the way regulations of the sector are conducted: doe it address the most important issues?.....

    ……

    ……..

13. How do you rate the capacity of the regulatory bodies in regulating the subsector for the purpose of improving the sector?

    ……

    ……

    ……..

14. What are the factors that influence the low capacity of the regulatory bodies?

    ……

    ……

    ……..

15. In your opinion what are the challenges facing the regulators and regulating bodies?
16. What would you suggest as a way to improve the regulatory policies and actions in traditional medicine?

    ……...

    ……

    ……..

17. In general, what are other things that you think should be regulated in traditional medicines that are not currently regulated?

    ……..…….

    ……

    ……..……..

18. Do you think there are some operational issues that hinder these guys to operate the way they should?

    ……

    ……

    ……..……..