Evaluation and Comparison of Current Legal and Regulatory Framework for Traditional Medicines in Five Selected African Countries: A Move Towards Harmonization of Regulation of Traditional Medicines in Africa.

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A mini thesis submitted in partial fulfilment of the degree M.Sc. in Pharmacy Administration and Policy Regulation at the School of Pharmacy, Faculty of Natural Sciences, University of the Western Cape.

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Keywords:

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Abstract:

Evaluation and comparison of current legal and regulatory framework for traditional medicines in five selected African countries: A move towards harmonization of regulation of traditional medicines in Africa.

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Background: In Africa, traditional medicine (TM) practice has been in existence since time immemorial as the major source of pharmacotherapy. However, unlike orthodox medicines TM policies and regulations are not formalised let alone standardised. African nations have different approaches and regulatory requirements whereas in some states policies are even non-existent.

Aim: The aim of the mini thesis was to assess the current policies and guidelines for regulation of TM in five selected sub-Saharan African countries relative to the WHO recommendations on traditional medicine policy.

Method: The mini thesis was a desk review of current policy frameworks and guidelines for regulation of traditional medicines relative to WHO recommendations on TM policy in sub-Saharan Africa using five selected countries.

Result: The results from the five selected countries showed significant difference in the current policies and guidelines on the regulation of TM, but no significant difference in the actual WHO TM policy indicators that the countries implemented.

Discussion: Regularisation of TM practice by integrating it into main health systems could make it more acceptable. The complexity of TM/herbal products needs a different yet integrated approach. Harmonisation of regulatory requirements eliminates the need for redundant testing, ensures consistency across regions and improves implementation of WHO TM policy indicators.

Conclusion: Notwithstanding its popularity across Africa, there was a significant difference in the current TM legal and regulatory frameworks among the five selected countries. There was a growing tendency towards more of tolerance than acceptance of traditional medicine use.

August 2019

Declaration:

I declare that this mini thesis that I now submit for assessment on the programme of study leading to the degree *Master of Science in Pharmacy Administration and Policy Regulation* has not been submitted for the purpose of a degree at this or any other higher education institution. It is entirely my own work and has not been taken from the work of others save to the extent that such work has been cited and acknowledged within the text of this work.

I agree to deposit this thesis in the University of Western Cape's Library and Healthcare-Learning's institutional repository and or allow these institutions to do so on my behalf, subject to South African and British Copyright Legislation and the University of Western Cape's conditions of use and acknowledgement.

John Ratiso Chikwari Date: August 2019

Signed… 

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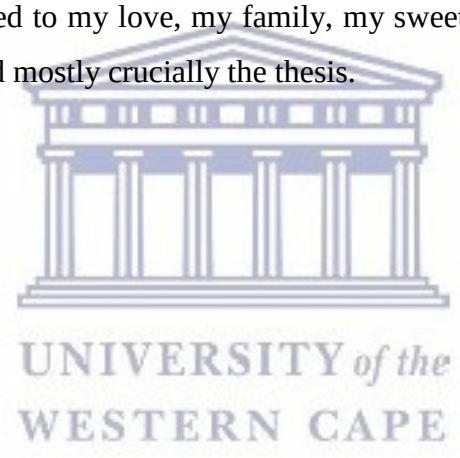

List of Abbreviations:

AMA African Medicine Agency

AMRH African Medicines Regulatory Harmonization Initiative

AU African Union

GCP Good Cultivating Practices

GDP Gross Domestic Product

GMP Good Manufacturing Practices

HDI Human Development Index

LDC Least Developed Countries

MDG Millennium Development Goals

NMRA National Medicines Regulatory Authorities

PHC Primary health care

REC Regional Economic Community

TMP Traditional Health Practitioner(s)

TM Traditional Medicine(s)

WHO World Health Organisation

Table of Contents:

CHAPTER ONE:

1.1. Introduction:

Traditional Medicine (TM) is the ancient foundation of healthcare system that humans used to cope and deal with various ailments that could threaten their existence and survival since time immemorial (Abdullahi, 2011). By definition, World Health Organisation (WHO) connotes TM as the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses (WHO, 2005). TM takes the holistic approach based on the premise of interconnectedness of the physical world and spirituality and may include indigenous herbalism in its treatment (WHO, 2001). Africa has a rich and diverse traditional medicine history from time immemorial. However, the development of TM had been stymied for long particularly during the scramble for Africa which resulted in complete banning of the practice in some extreme cases (WHO, 2001; Kale, 1995). The European settlers proclaimed African traditional medicine as inferior to their western based medical practice thus marginalising and stigmatising the local remedial norms.

The use of TM is inseparable with people's culture. Scholars have agreed that up to 80% of Africans use TM to help meet their healthcare needs (Peltzer, 2009; WHO, 2001). For instance; fever, mild pain, flu symptoms, in addition to complicated healthcare needs such as snake bites, cancers, HIV/AIDS, chronic pain may be met with indigenous interventions in one form or the other (Peltzer, 2009). The WHO (2013) noted that the worldwide uptake of TM remains comparably high across the globe. It is predictably so because TM is the care that is closest home (WHO, 2001), over and above its accessibility and affordability that make it more attractive at a time of soaring health-care costs and nearly universal austerity (WHO, 2013). Nonetheless, in spite of the widespread usage, the practice is shrouded in subjectivity. It is recognised that TM has complicated issues that need to be addressed surrounding the quality of the herbs, quality assurance/control, in processing and preparation of herbal medicines, herbal mechanisms of action, bioavailability, and herbs′ chemical constituents, herb–drug interactions; herb-herb interactions; and efficacy measurements (WHO, 2013).

Furthermore, in terms of the rational use of traditional medicine, WHO (2003) underscored the two main obstacles that are: lack of appropriate training for providers and of proper qualification and licensing schemes, which make it difficult for national authorities and consumers to identify qualified providers; and the lack of organized networks of traditional practitioners. The WHO Global Atlas for traditional, complementary and alternative medicine (2005) revealed that African states have different approaches and regulatory requirements to TM with some countries not having any guideline in place. The differences in the practice across Africa reflect the continent's rich cultural diversity and capacity. Hitherto, each individual country in Africa has the responsibility to regulate TM practice and the registration of TM products so as to guarantee their safety, quality and efficacy. However, WHO estimates that 30% LDC cannot maintain a proper registry of allopathic medicines (WHO, 2003) let alone herbal products mainly due to lack of resources. The basic tenets of rational use of TM encompasses updated national policies, regulated traditional medicine professionals (TMPs) and controlled TM products among others leading to the integration and official acceptance of the practice as part of implementation of WHO TM policy recommendations. There are however very few laws, if any, that address the issue of traditional medical system in its entirety. The project intends to find out whether there is a pattern or consistence in the regulations of traditional/herbal medicines using five selected sub-Saharan African countries.

The evaluation of medicinal products in general is highly technical, lengthy and costly. Collaboration among regulatory agencies around the globe is core element of a modern regulatory system that enhances effectiveness. In order to achieve efficient regularisation of TM practice, harmonisation is of particular value to camouflage the individual country's infrastructural problems and deficits in regulatory laws. Harmonisation utilises the scarce human and capital resources by exploiting the various experiences and expertise across the continent. Thus this study seeks to evaluate, compare and contrast the current legal and regulatory framework for TM in five sub-Saharan Africa covering the various geopolitical/regional economic zones for purposes of finding common themes and advance collaborative initiatives to resourcefully implement the WHO recommendations on TM policy.

1.2. Aim:

The aim of the project is to assess and compare current legal and regulatory framework for Traditional Medicines in five selected Africa countries.

Null hypothesis:

There will be no significant difference in the current legal and regulatory framework for Traditional Medicines in the five selected Africa countries.

1.3. Specific objectives:

1.3.1. To study the regulatory guidelines for traditional medicine (TM) in five African countries (Cameroon, Ethiopia, Uganda, Ghana and Zimbabwe).

1.3.2. To identify the main themes in the traditional medicine (TM) registration requirements and guidelines of the five African countries (Cameroon, Uganda, Ghana and Zimbabwe) relative to WHO TM policy guidelines.

1.3.3. To compare the regulatory guidelines for traditional medicine (TM) in five African countries (Cameroon, Ethiopia, Uganda, Ghana and Zimbabwe).

1.3.4. To highlight differences in the current registration requirements for TM in the five African countries.

1.3.5. Propose possible areas for harmonisation of traditional medicine (TM) registration requirements and guidelines of the five African countries (Cameroon, Uganda, Ghana and Zimbabwe).

CHAPTER TWO:

2. Literature Review:

Western based medicine is the most prominent form of healthcare today the world over; however, it is neither widely accessible nor is it the first choice for everyone (WHO, 2001). The Management Science for Health (2012) noted that traditional medicine (TM) is the diverse, flexible, widely accessible, and extensively accepted treatment in developing countries, comparatively low in cost and has lesser need for modern technological capability. There is an overwhelming belief that TM is effective and safe. The perceived efficacy of TM in treating chronic, debilitating diseases that defy conventional pharmaceuticals, and/or coupled with the failure of allopathic medicine treatments as well as the desire for a healthy lifestyle led to TM establishing its niche over and above the primary role it plays in the daily health lives of people (WHO, 2013).

The WHO estimations show that there is a modern resurgence in TM practice, albeit with varying usage across the globe. Estimates of up to 80% in Africa and other developing countries use traditional medicines (WHO, 2002; Peltzer, 2009; WHO, 2001). Whereas there is a notion of associating TM with least developed countries (LDCs), on the contrary TM use has become popular in developed countries where the health system structure is typically well established such as North America and many European countries (WHO, 2013). In these developed countries where statistics are properly maintained, the prevalence of traditional, complementary and alternative medicine use as a whole ranges from 41% in Spain to 70% in Canada and as high as 82% in Australia (WHO, 2003; WHO, 2013). Traditional medicine accounts for around 40% of all health care delivered in China, whilst in Chile 71% of the population, and in Colombia 40% of the population, have used such medicine (WHO, 2003). The rural areas in LDCs are exposed to TM and use it as the basic source of health intervention. For instance in India, 65% of the population in rural areas uses Ayurveda and medicinal plants to help meet their primary health care needs (WHO, 2003).

The disparity in health-care coverage, lack of equitable, accessible and affordable healthcare for all; and problems with availability of realistic resources for health services and

medications are daily realities for the indigent, marginalised and underprivileged (WHO Global Atlas, 2005). In turn, traditional medicine plays the primary role in such people's lives. In Ghana, Mali, Nigeria and Zambia, herbal medicines are the first line of treatment for more than 60% of children with high fever (WHO, 2003). Prenatal, postnatal care and management of uncomplicated deliveries have so far been the best documented evidence-based interventions of TM in Africa (DeJong, 1991). The system of home deliveries have worked well in rural African settings, where clinics are far away and transport arrangement is inadequate. Therefore TM has been indispensable to healthcare across the globe.

The merits of TM use include accessibility, affordability, and holistic integrative approach (Tahir et al, 2016) and being rooted in the customs and beliefs of the population (Hussan and Malik, 2013). There is an amazing ratio of traditional practitioners to African population that can go as low as 1:500 compared to ratio of medical doctors that can go as high as 1:40 000 in some settings (WHO, 2013), making it paramount to strongly consider formalisation of TM practice in Africa so as to help meet the health specific Millennium Development Goals (MDGs). Training and development of traditional medicine practice is critical in reducing child mortality, improving maternal health and combating HIV/AIDS, malaria and other diseases as per the MDGs (WHO, 2000).

Integrating TM with modern evidence based medicine as integral part of the formal health system has been a challenge. However, the feasibility has been demonstrated particularly in Asian countries such as China, Japan, Korea, and India, among others (WHO, 2001). The strategies describing the commonly used traditional therapies and therapeutic techniques, including Ayurveda, Chinese, Arabic and Unani are well documented. Traditional Chinese medicine and Indian Ayurveda, Siddha and Unani are practiced as official systems of medicine in their respective countries. They have even become popular beyond their historical borders. These systems are powerfully extending a significant healthcare coverage to the population especially in rural areas (Baoyan et al, 2005). These countries took advantage of the existence of a traditional medical infrastructure which is rooted in the customs and beliefs of their population making it easier for acceptance (Bodekar, 2001). China has bilateral integration system of medicine, were both traditional and conventional systems are

recognised. China managed to decrease mortality rate and achieve good health with its unique integrative model of health care delivery system that has 95% of its conventional hospitals having traditional, complementary and alternative medicine (TCAM) departments (Bodeker, 2001; Baoyan et al, 2005). The regulatory and educational needs of practitioners are extensively covered in China and India. Universities offer degrees, while hospitals and manufacturers absorb the graduates. As highlighted in the WHO Global Atlas (2005), the Indian policy has resulted in a good institutional framework for education, healthcare, research and drug manufacturing.

There is a need for African countries to exploit their rich traditional medicine/herbal resource and integrate it into their official health systems. The World Health Assembly (WHA) urged member states, inter alia to: integrate traditional medicine within national healthcare systems by developing and implementing national TM policies and programmes; promote the safety, efficacy and quality of TM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards; establish systems for the qualification, accreditation or licensing of Traditional Medicine Practitioners (TMPs), and increase the availability and affordability of traditional medicines (WHO, 2005). The TMPs ought to have clear qualification guidelines that enable accreditation by their representative council. This builds confidence in their practice and acts as the basis of developing the transitional integration of TM into healthcare infrastructure. Some of the African countries have or are integrating TM into their health system and many more are following. The Ugandan and South African governments amongst others have started with the integration of TM into their health system (Management Science for Health, 2012). There has been commitment by WHO member states to integrate traditional medicine and ensure access to effective, safe, and high quality treatments; however resource constraints make these obligations difficult to fulfil (WHO, 2003; AMRH Consortium, 2010). For instance, despite the Abuja Declaration of 2001, only six African member states that are Liberia, Madagascar, Malawi, Rwanda, Togo and Zambia had reached the agreed 15% target for budget allocations to health, evidence that health is apparently not prioritised by policy and decision makers across the continent (AU, 2016).

In many countries, there is still resistance to officially accept traditional medicine as part of the healthcare system (Hillenbrand, 2006). By and large, the resistance stems from the primary philosophical distinctions between conventional medicine, which is based on the results of experiments and views illness as the result of pathological agents, and traditional medicine, which accepts that disease can have supernatural causes (Kahissay et al, 2017). Scepticism on the part of the conventional doctor or scientific researcher is reinforced by the widespread and well-founded conception that modern traditional practitioners are increasingly charlatans, or fakes (Hillenbrand, 2006). In Cameroon, the head of the AIDS-Cameroon Program seemed doubtful about the possibility of collaboration with traditional practitioners, declaring that the majority of healers are unreliable (Hillenbrand, 2006). However, in order to achieve any successful form of integration and acceptance, African countries must invest in interpersonal relations between stakeholders alongside investments in structures and systems (Krah et al, 2017). In particular, governments must establish national policies that are healthy towards integrating TM and allopathic medicine and strengthening research and development. Consequently, a successful integrated healthcare system would facilitate use of domestic medical resources, enhance self-sufficiency in health development and improve outcomes of community healthcare in resource poor nations (Krah et al, 2017).

The concerns of the adversaries of regularising and integrating TM into national health policy are based on issues of safety, quality and efficacy. The travesty of TM comes in its inexplicit nature, sacredness and inadequate or lack of documented evidence. Consumers and practitioners may not be adequately informed about the potential adverse effects, drug interactions and how to use herbal medicines safely albeit natural does not mean safe (WHO, 2013). There is lack of strict standards for the production and manufacture of herbal medications that can cause quality problems such as adulteration, misidentification of ingredients, contamination and variability in the amount of the active ingredient (Management of Science Health, 2012). Use of poor quality, adulterated or counterfeit products; unqualified practitioners; misdiagnosis, delayed diagnosis, or failure to use effective conventional treatments; exposure to misleading or unreliable information; direct adverse events, side effects or unwanted treatment interactions are quite common with unregulated traditional medicine use (Ndomondo-Sigonda, 2017). Equally, conservationists are concerned by the

threats that a growing traditional medicine market will pose to biodiversity through overharvesting of medicinal plants or increased use of body parts from endangered animals such as tigers, rhinos and elephants (Shetty, 2010). However, regularising TM will bring forth issues of Good Cultivating Practices (GCP) and Good Manufacturing Practices (GMP) which when followed will not necessarily result in threats to biodiversity. Some African countries such as Ghana, Senegal and Zimbabwe are reported to have established policies related to conservation of medicinal plants while Cameroon and Mali developed guidelines related to the collection and conservation of medicinal plants (Kasilo et al, 2010). Although there has been noted significant progress made in implementing the 2002 to 2005 WHO traditional medicine strategy around the world, WHO member states continue to experience challenges related to development and enforcement of its policy and regulations, integrating TM into national and primary health care, research and development, safety and quality assessment, and educational training of TM practitioners (WHO, 2013).

Internationally, herbal products are regulated under different classifications, some of which include: complimentary medicines, natural health products, prescription medicines, over the counter medicines, supplements and traditional herbal medicines (Sharma, 2015). In Japan, Kampo medicine, as TM is popularly known, combines modern medicinal preparations. A worldwide review of regulatory situation of herbal medicines revealed that at least 147 Kampo medicines for ethical use are included in the National Health Insurance (NHI) drug price tariff (WHO, 2018). Their acceptance took place without clinical validation studies. However, new Kampo products are regulated in essentially the same way as orthodox medicines with data for three-phase clinical trials required (WHO, 2018b). While most individual herbal medicinal products continue to be licensed nationally by member states, the process for licensing and information on herbal substances and preparations is increasingly harmonised across the EU (WHO, 2018b). The Committee on Herbal Medicinal Products (HMPC) issues scientific opinions on herbal substances and preparations, along with information on recommended uses and safe conditions, on behalf of the European Medicines Agency (EMA). This gives companies and national competent authorities a clear reference point when preparing or assessing an application for marketing authorisation or registration of herbal medicinal products in European Union (EU) member states (EMA, 2018). The

evidence of traditional use is accepted as evidence of efficacy of the product. However, authorities may still ask for further evidence to support safety. Quality control requirements require physicochemical and microbiological tests to be included in the product specifications. The product should comply with the quality standards in relevant pharmacopoeias of the member state or European Pharmacopoeia (EMA, 2018). In the USA, herbs and other botanicals, vitamins and minerals fall under the definition of a dietary supplement although used by many as folk medicines (WHO, 2018b). The Food Drug Administration (FDA) regulates the dietary supplements under the Dietary Supplement Health and Education Act of 1994. These products do not require premarket approval and it is the responsibility of the marketer to ensure the safety and labelling compliance of their products with the regulations as such, most of the regulatory action occurs in the area of safety (Sharma, 2015). However, for any herbal medicine claims to be allowed, the same procedures must be followed as for a chemical drug (WHO, 2018b).

The 54 National Medicines Regulatory Authorities (NMRAs) governing drug registration across Africa typically differ in the requirements of paperwork, technical requirements, and other registration steps forcing manufacturers to invest significantly in time and effort for each registration, so a limited set of countries are targeted (AMRH Consortium, 2010). It has been noted that the regulation of traditional medicines varies greatly from country to country and region to region in terms of policies, laws and regulations governing the safety, quality and efficacy (WHO, 2013). Inevitably, manufacturers face a landscape of disparate regulations, frequent delays and limited transparency to register their products. There has been blame on African NMRAs such as: unclear timelines for a drug to clear registration and be ready for the marketplace; and little transparency before or during the process (Anderson, 2017). Developing globally acceptable products are hindered by differences in regulatory requirements related to quality, safety and efficacy data, and differences in the status of ingredients and excipients (Sharma, 2015). Understanding the current state of NMRAs in Africa provides a basis for identifying gaps and existing opportunities for improving regulatory capacity, promoting public health and advancement of traditional medicine industry (Ndomondo-Sigonda et al, 2017). The project is evaluating the current status the of

TM policies to assess major themes and areas that are lacking in view of advancing collaboration.

A WHO report showed that only 7% of African countries had moderately developed capacity with more than 90% having minimal or no capacity to carry their regulatory obligations (WHO, 2018a). The solution is in harnessing the capacity of the few capable NMRAs and extending the achievements to the rest of the African countries. It might be the wholesome solution to the availability and/or consistence of traditional medicine regulation in Africa. Accordingly, Mahlangu, the Director-General of Medicines Control Authority of Zimbabwe (MCAZ) noted that 'it is increasingly evident that no single country has enough resources and capability to efficiently and effectively regulate the whole medicine supply chain system alone in this globalised world' (Chisango, 2018). The establishment of African Medicines Agency (AMA) is thus poised to occupy a distinct position to leverage various regulatory assets and capabilities to improve access to safe, effective, good quality and affordable essential medicines and health technologies (Chisango, 2018). AMA will provide regulatory guidance and scientific opinions on complex molecules, as well as traditional medicines and emerging issues, such as pandemics. It will keep an eye on adverse effects of medicines and vaccines once they reach the market (Anderson, 2017). Such a harmonised initiative will be able to galvanize technical support, expertise in various countries and regional economic communities (RECs), and resources at a scale that cannot be matched at national or regional level (AU, 2016). The success of harmonisation is subject to political commitment across the African Union member states. NMRAs can ride on the AMA backbone to build TM harmonisation framework so as to initiate policies and regulations in those countries that do not have at all, to improve regulations in countries with weak TM regulations and eventually have consistent regulatory requirements and guidelines. Global harmonization of regulations on herbal products would work in the direction of providing the much-needed impetus to this potential segment.

Harmonisation ensures efficiency and effectiveness. It allows mobilising regulatory expertise across the continent and beyond to provide scientific opinions in consultations (Chisango, 2018). Harmonisation will cut the breath of political, legal and regulatory barriers that often

make it difficult for local producers to exploit regional economies of scale (AU, 2016). Therefore, regional integration is key in supporting local pharmaceutical manufacturing as it provides economies of scale that permit greater access to capital markets and pooling of resources for large infrastructure projects in transport and energy that are important for driving industrial growth (AU, 2016). Harmonisation thus facilitates fair competition and promotes trade. Consistency of regulatory requirements is a landmark opportunity to develop local industry and deliver medicinal products quicker across the whole continent. However harmonisation maybe derailed by language barriers as for instance African Union has six official languages Arabic, English, French, Portuguese, Spanish and Kiswahili (Ndomondo-Sigonda et al, 2017). Countries with ability to self-regulate may not want to follow common African guidelines which maybe a compromise to fit and benefit all. There have been various regional harmonisations already, although currently they exclude herbal products. There has to be a sustainable financing mechanism for the harmonisation program to allow continuity without burdening individual countries or their NMRAs (AU, 2016). The project may bring out the different strengths and experiences of the countries that could assist in collaborative initiatives.

Africa is the second largest continent with a population of over 1.2 billion (UN, 2013). It boasts of an expansive culture that translates to rich and diverse herbal resource. In 2007, the global market for herbal medicines was estimated to be more than US$60 billion with 80% of Africans using TM (Kartal M, 2007). There is potential of health and economic benefits if Africa embraces efficient, effective and consistent use of its natural herbal resources. Analysis from U.S. National Cancer Institute researchers showed than two-thirds of all drugs discovered in the previous quarter-century were derived from natural products (Newman and Cragg, 2007) including *Artemisia annua* now first line of malaria treatment in many countries. Medicines such as aspirin (from willow bark), digoxin (from foxglove), quinine (from cinchona bark), and morphine (from the opium poppy) are all from plant origin (Vickers et al., 2001). Herbs continue to play an important role in the health of people. However, lack of and/or unclear regulations on quality standards and evaluation of safety and efficacy of these products may cause problems resulting in marketing of unsafe/ineffective TM products. As consumers treat themselves without proper advice from practitioners/manufacturers, there is

risk of incorrect usage of herbal medication therapies that may inadvertently result in fatal outcomes. Evaluating, comparing and contrasting the current TM policies will help understanding if there are significant differences across the five sub-Saharan African countries and advance collaborative initiatives accordingly.

CHAPTER THREE:

3. Methodology:

3.1. Study design:

A desk review of current policy and guidelines for regulation of traditional medicines in five sub-Saharan African countries was conducted.

3.2. Sample population:

The research focused on sub-Saharan African countries. The WorldAtlas (2017) recognises five geopolitical regions in Africa that is Southern Africa, East Africa, Equatorial Africa, West Africa and the African Transitional Zone. The five strata were superimposed onto the regional economic blocs of sub-Saharan Africa. The African Regional Economic Communities (RECs) was established by the 1991 Abuja Treaty to provide the overarching framework for continental economic integration and includes: Intergovernmental Authority on Development (IGAD), the Common Market for Eastern and Southern Africa (COMESA), the Economic Community of Central African States (ECCAS), the Economic Community of West African States (ECOWAS), East African Community (EAC) and the Southern African Development Community (SADC). However, the final country to represent the geopolitical and regional economic bloc was chosen based on availability of English policies, updated national medicine regulatory authority (NMRA) websites, and skewed to countries with a rich history of TM usage. The selection of the countries *vis-à-vis* geopolitical and regional economic community is attached as Appendix I.

3.3. Data collection tool:

The mini thesis focused on the legal and regulatory framework regarding TM practice in five selected sub-Saharan African countries. For this study, applicable indicators were taken mainly from the module 2 'National Regulatory System' and module 3 'National Regulatory Authority' sections of the 'WHO Data Collection Tool for the Review of Drug Regulatory Systems' WHO (2007). Other indicators were plucked from the 'WHO Global Atlas for Traditional, Complementary and Alternative Medicine' WHO Global

Atlas (2005) and 'WHO Global Survey Report on National Policy on Traditional Medicine and Regulation of Herbal Medicines' WHO (2005). The indicators included: existence of national policy, legislation and/or committees of TM; availability of support of TM through public funding or private insurance; state of professional traditional practitioners in terms of education, training and regulatory bodies; existence of local commercial production; reference materials; inclusion in essential drug lists and many more. The complete data collection tool used is attached as Appendix II, whereas the real data collected were set out in the 'Data Collection' subsection and attached as Appendices IIIa - IIIe.

The WHO data collection tool as envisaged in WHO (2007) ''WHO Data Collection Tool for the Review of Drug Regulatory Systems' was developed with acknowledgement of the importance to strengthen regulatory systems. The most basic tenets of a regulatory system are the same around the world therefore the tool applies in both developed and developing countries. Regulatory guidelines provide a clear framework and predictability of procedures for public confidence. The WHO data collection tool was therefore chosen for the study as the minimum of international standards for regulatory systems.

3.4. Data Collection:

The demographic characteristics and socioeconomic indices [population, Gross Domestic Product (GDP) per capita, Human Development Index (HDI), literacy rate] of each country were sourced from relevant publicly available literature and reported in table 1 below. General assessment of legal and regulatory framework for TM registration in sample population was based mainly on literature review of publicly available documents, including respective websites of national medicine regulatory authorities and ministry of health. A comparison of the indicators adopted from the 'WHO Data Collection Tool for the Review of Drug Regulatory Systems' (WHO, 2007), the 'WHO Global Survey Report on National Policy on Traditional Medicine and Regulation of Herbal Medicines' (WHO, 2005) and the 'WHO Global Atlas for Traditional, Complementary and Alternative Medicine' (WHO Global Atlas, 2005) for each selected

African was done to reveal major differences or similar themes in the legal and regulatory framework for TM. The following responses were attributed to each indicator/variable, after reviewing of the relevant documents: Yes (when there is evidence that the indicator is provided for in the legal and regulatory framework), No (when there is no evidence that indicator is provided for in the legal and regulatory framework). To enable the use of quantitative statistical analysis methods to analyse this data, responses were coded 1 for 'Yes' and 0 for 'No'. The results were subjected to statistical analysis as set out in 'Data Analysis' subsection.

3.5. Data Analysis:

A simple frequency or percentage proportion was used to summarize the response attributed to each indicator/variable adopted from the 'WHO Data Collection Tool for the Review of Drug Regulatory Systems' (WHO, 2007), the 'WHO Global Survey Report on National Policy on Traditional Medicine and Regulation of Herbal Medicines' (WHO, 2005), and the 'WHO Global Atlas for Traditional, Complementary and Alternative Medicine' (WHO Global Atlas, 2005). Analysis of Variance (ANOVA) was used to test the null hypothesis, which was 'There will be no significant difference in the current legal and regulatory framework for Traditional Medicines in the five selected Africa countries.' Tukey's multiple comparisons test, as a post-hoc follow up, was chosen. The Chi square null hypothesis was 'There is no significant difference in the percentage of WHO indicators implemented amongst the countries.' The association between demographic characteristic and socioeconomic indices of each country and overall implementation percentage of WHO recommendations on TM policy were assessed with Pearson correlation analysis. The results section describes these in detail.

3.6. Ethical Considerations:

The mini thesis was a comparative literature review on the current legislative/ regulatory requirements of TM registration in selected African countries. There were no subjects directly involved. The mini thesis utilised existing publicly available information and documents.

CHAPTER FOUR:

4. Results and Discussion:

4.1. Results:

	Key Indicator	Cameroon	Ethiopia	Ghana	Uganda	Zimbabwe	Source
1.	Population (1000) 2016	23 439	102 403	28 207	41 488	16 150	WHO (2016)
2.	GDP per capita (2017) USD	1 446.7	767.6	1 641.5	604. 0	1 079.6	World Bank (2018)
3.	Human Development Index 2017	0.556	0.463	0.592	0.516	0.535	UNDP (2018)
4.	Literacy Rate (2007-2012)	71	39	67	73	84	WHO (2016)
5.	Total expenditure on health as % GDP (2014)	4.10	4.88	3.56	7.22	6.44	WHO (2016)
6.	Private expenditure on health as % of total expenditure on health (2014)	77.13	41.29	40.15	75.06	61.70	WHO (2016)
7.	General government expenditure on health as % of total government expenditure (2014)	4.26	15.75	6.82	10.97	8.49	WHO (2016)
8.	Doctor density/1000 population (2014)	0.083	0.025	0.096	0.093	0.077	WHO (2016)
9.	Birth attended by skilled health personal (%) (2012-2014)	64.7	27.7	70.8	74.2	78.10	WHO (2016)
	*Average Gross Domestic Product (GDP) for sub-Saharan Africa is USD1 553.8						

Table 1: Demographic characteristics and socio economic indices of five selected African countries: The information gave an understanding of socioeconomic stratification of the five countries that were studied. The countries represented both the geopolitical regions and regional economic blocs of sub-Saharan Africa.

The demographic characteristics and socioeconomic indices of the five countries were summarised in Table 1 above. In terms of the Gross Domestic Product (GDP) per capita as at 2017, sub-Saharan Africa had an average of US$1553.80. Ghana was the highest ranked of the five selected countries, having GDP per capita of US$1641.50, followed by Cameroon (US$1446.70) and at the bottom were Ethiopia (US$767.60) and Uganda (US$604). The statistic composite index of life expectancy, education and per capita income better known as Human Development Index (HDI) as at 2017 classified Ghana among medium ranked countries with a score of 0.592, while the rest of the study sample were classified as lowly ranked countries. The results also captured literacy rates which ranged from lowest of 39% (Ethiopia) to highest of 84% (Zimbabwe), with an average of 66.8% (n=5).

Traditional medicines (TM) regulatory provisions/indicators of five countries (Cameroon, Ethiopia, Ghana, Uganda and Zimbabwe) were compared against the WHO Data Collection Tool for the Review of Drug Regulatory Systems (WHO, 2007), indicators from the WHO global survey report on National Policy on Traditional Medicine and Regulation of Herbal Medicines (WHO, 2005) and the WHO Global Atlas for Traditional, Complementary and Alternative Medicine (WHO Global Atlas, 2005). A total of nineteen indicators were used ranging from availability of national policy, traditional medicine committees/councils to guidelines used in registration of traditional medicines. Figure 1 below shows the percentage implementation of recommended policy by the five selected sub-Saharan African countries.

There was a general appreciation to regulate TM in African countries with four of the five studied countries having set up their national policies to guide and spearhead TM policy implementations. A 100% support from all five governments was observed, although resources were mainly channelled towards supporting traditional medicine related research institutes. None of the countries offered health insurance on TM/herbal medicine use. According to the survey results, TM was highly practiced in Africa although there was no country open to entitlement of conventional medical practitioners to practice traditional medicine as part of their conventional practice. The regulation of traditional medicine practitioners (TMP) recorded 100% positives on both the state of professional traditional practitioner regulation and voluntary self-regulatory body of traditional medicine practitioner indicators from all studied countries.

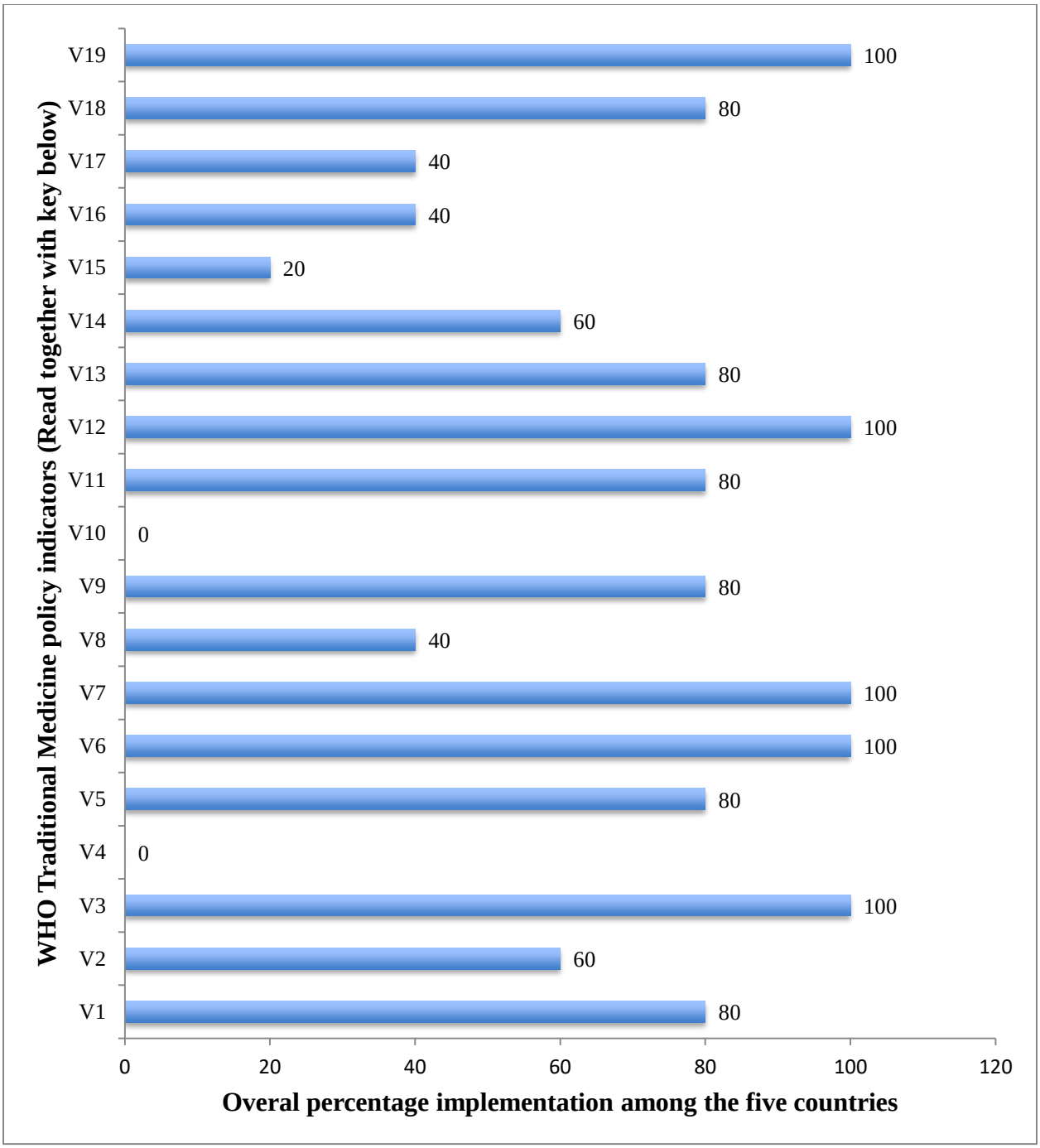

Figure 1: Percentage implementation of recommended policy by the study sample. The WHO indicators considered in the mini thesis were unevenly implemented in the five countries, with two indicators not having implemented at all, while five indicators were implemented across all studied countries.

Indicator in short	WHO Traditional Medicine Indicator in full
V1	Existence of national policy and legislation of traditional medicine
V2	Existence of national traditional medicine committee
V3	Availability of support of traditional medicines through public funds
V4	Medical insurance reimbursement on traditional medicines
V5	State of professional traditional practitioners recognition
V6	State of professional traditional practitioners regulation
V7	Voluntary self-regulatory body of traditional medicine practitioners
V8	State of professional education for traditional practitioners
V9	State of formal education and training regulation on traditional medicine
V10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice
V11	Established traditional medicine registration system
V12	Conservation of medicinal plants
V13	Availability of regulation on traditional medicine
V14	Existence of local production of traditional medicines
V15	Traditional medicines in National Essential Drug List
V16	Existence of national pharmacopoeia
V17	Post-marketing surveillance system in place
V18	Legal recognition of traditional medicine
V19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.

Table 2: Key for interpreting the WHO Traditional Medicine indicators as used in the mini thesis. The table should be read together with Figure 1 above that shows percentage implementation of the WHO indicators in the five selected countries.

Among the study population, major weak areas of implementing the WHO recommendations on TM policy were noted on professional education of practitioners (two of the five countries implemented this indicator), availability of herbal products on national drug lists (only one of the studied countries implemented this indicator), development of national pharmacopoeias

(two of the five studied countries implemented this indicator), and a weak post-marketing surveillance of herbal products (two of the five studied countries implemented this indicator).

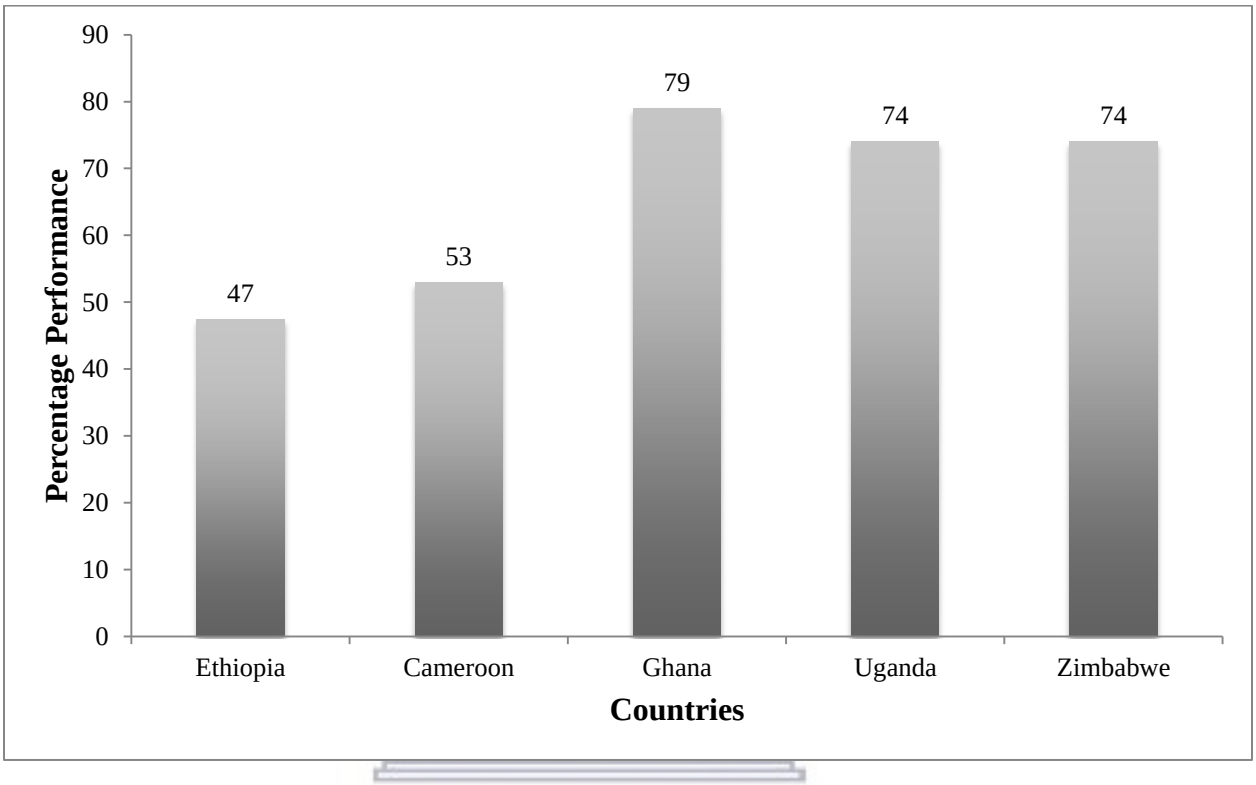

Figure 2: Performance of countries in implementing the WHO recommendations in traditional medicine (TM) policy. The percentage implementation ranged from 47% (Ethiopia) to 79% (Ghana). Three countries were outstanding scoring above 70% in implementing the WHO TM policy recommended indicators, while a single country (Ethiopia) had under 50% score.

The results were subjected to Analysis of Variance (ANOVA) and showed that the countries (column factor) accounted for 7.14% of the total variance observed (p-value = 0.04). The WHO traditional policy implementation indicators (row factor) accounted for 44.28% of the total variance observed (p-value = 0.0001). The same trend was observed with F-test statistic of 3.646 for the row factor with degrees of freedom (df) (18,72), where the F-critical value lied between $1.75<F<2.04$, at alpha = 0.05. For column factor, F-test statistic was 2.644 with df (4,72), where the F-critical value for statistic was $1.99<F<2.04$, at alpha = 0.05. The assumption was no

interaction hence the decision was based on the two main effects that is column factor and row factor.

Pearson correlation was used to find the relationship of the socioeconomic indices and percentage performance of implementing the WHO TM policy recommendations. The results showed a lot of weaker correlations corresponding to GDP per capita (0.2), total expenditure on health as percentage GDP (0.35), private expenditure on health as percentage of total expenditure on health (0.02), general government expenditure on health as percentage of total government expenditure (-0.33). However, there were strong correlations corresponding to percentage birth attended by skilled health personal (0.83) and literacy rate (0.77). The results also showed notable correlation associated with doctor density/population (0.67) and Human Development Index (0.62).

In order to determine if there was a significant difference in the percentage of WHO indicators being implemented amongst the countries, a Chi square test was run. The null hypothesis for the Chi square test being: 'There is no significant difference in the percentage of WHO indicators implemented amongst the countries.' At 95% level of significance the results showed there was not enough evidence to suggest a significant difference in the percentage of WHO indicators implemented amongst the countries. Chi square = 6.78 (df = 4), p-value 0.15. (NB: For Chi square with 4 degrees of freedom at the 95% level of significance the critical value is 9.49, thus the chi square statistic of 6.78 is less that 9.49 hence it falls in the rejection region, as shown by the p-value which is greater than 0.05).

As a follow up to the ANOVA test, Tukey's multiple comparisons test was done to determine if there was significant differences in the WHO indicators implemented by the countries. This was principally done to identify pairs of indicators with a significant difference. For the row factor variables, ANOVA showed that there was a significant difference in the indicators implemented. By using Tukey's multiple comparisons tests, the following indicators, as illustrated in table 3 below, were found to be significantly different. However the same cannot be said for countries because there were no significant differences in the column means, hence there was no significant difference in the WHO indicators implemented by the countries.

[V3] Availability of support of traditional medicines through public funds	versus	[V10] Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice
[V6] State of professional traditional practitioners regulation	versus	[V10] Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice
[V7] Voluntary self-regulatory body of traditional medicine practitioners	versus	[V10] Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice
[V10] Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice	versus	[V1] Existence of national policy and legislation of traditional medicine

Table 3: Tukey's multiple comparisons tests showing the indicators that were found to be significantly different when compared to each other. However, the same cannot be said for countries because there were no significant differences in the column means. Overally, there was no significant difference in the WHO indicators implemented by the countries.

African countries were starting to implement the WHO recommendations on TM policy and there seemed to be an order of implementing the indicators. A traditional medicine national policy would naturally start, that acknowledges and defines the direction to take regarding TM use. This would likely be followed by regulating TMPs and research and development of herbal products in order to satisfy safety, efficacy and quality parameters. As TM usage matures comes the approval and listing of herbal products in the National Essential Drug List and post-marketing surveillances.

4.2. Discussion:

The average Gross Domestic Product (GDP) per capita as at 2017 stood at US$1553.80 for sub-Saharan Africa (World Bank, 2018). Except for Ghana which had GDP per capita of US$1641.50 the other four countries had below average GDP per capita for sub-Saharan Africa. Ghana was the only country rated among medium countries in terms of Human Development Index (HDI) which was 0.592 in 2017. Unsurprisingly, Ghana commanded the highest percentage implementation of WHO TM policy recommendations at 79%. However there was no pattern observed in GDP per capita and overall implementation of WHO recommendations on TM policy as Uganda with GDP per capita of US$604 stood at 74% implementation, the same as Zimbabwe which had US$1079.60 GDP per capita, way ahead of Cameroon with GDP per capita of US$1446.70 and 53% implementation. Although Sub-Saharan Africa has huge amounts of natural resources and a source of strategic minerals, economic conditions are alarmingly poor. The GDP per capita of African countries are among the bottom list in the world.

The socioeconomic indices that had positive correlations with the implementation of WHO TM recommendations were literacy rate (r = 0.77) and percentage births attended by skilled health personal (r = 0.83). This was consistent with findings in other research work that show WHO estimations pointing to a modern resurgence of TM practice worldwide particularly in countries where there is extensive health infrastructure (Buckley and Gostin, 2013). According to DeJong (1991) level of education seems not to affect consultations and use of TM. On the contrary, use of TM ranges highly in the developed countries with up to 82% in Australia (WHO, 2013). The world is becoming more open to TM use.

The prestige and credibility of traditional practitioners had weaned in the face of colonialism and modernisation, however Africans still continue to use TM to meet their healthcare needs (WHO, 2001). African countries have been battling to modernise and regulate TM practice and results of the mini thesis showed official forms of appreciation or acknowledgement such as the existence of national policy or legislation defining how TM should be practiced. The five selected countries had shown to have at least one of the indicators that define documented existence of traditional medicine regulations. All the 54 countries in Africa have

a national medicine regulatory authority (NMRAs) that has a mandate to supervise medicine regulations including overseeing of herbal/complementary product registrations and distribution, although they vary in their capacity to carry out the mandate (WHO, 2018a). Interestingly, results of the mini thesis showed that some African countries established departments of TM/herbal medicines to specifically promote use of herbal medicines and these include Zimbabwe, Uganda and Ghana. There was commendable support from various governments towards scientific research of herbal medicines so as to document safety and efficacy of their use. Government support has been mainly channelled towards setting research institutes, an indicator that was attained 100% by all five subject countries. It is a fact that the challenges of herbal medicine pivots on their lack of documented safety and efficacy, therefore African governments had equally prioritised research and development of traditional medicine. Progress in terms of actual products from these research institutes had however been pathetic, with only one of the countries surveyed that is Cameroon alone having traditional medicines listed in National Essential Drug List. Without herbal products listed in National Essential Drug Lists, it is difficult to prioritise their development, marketing and post-marketing surveillance. Another major drawback was the unpreparedness of both government and private sector in reimbursing traditional medicine practice/herbal medicines with none of the subject countries offering health insurance towards TM. Without complete regulations on TM practice including its practitioners, health insurers remain sceptical to come on board. The absence of documented evidence of quality, safety and efficacy of herbal products does not help the matter. The mini thesis also revealed that at least one country did not have substantive guidelines on submitting herbal products for registration.

The ability of a practice to cut across race, to be teachable and learnable makes it easier to be registered, controlled and accepted. This was unlikely with some African traditional practices that are a challenge to either teach formally or understand the general concepts. The legal acknowledgement of traditional health practitioners (TMP) and TM products meant bringing both under regulatory scrutiny. If TM were to be prescribed, marketed and sold as part of a healthcare system recognised under national medicine laws, they must be scrutinised, governed and regulated in a more or less similar way to conventional medicines (Street,

2016). The traditional medicine practitioners have to self-regulate and give assurances to the public that they abhor unethical practices and charlatans. All the selected African countries had implemented the indicators to do with regulating and professionalism of TMPs. Nonetheless, reports of fake modern practitioners are quite common and documented (Hillenbrand, 2006). For the TMPs to be recognised they have to strive to organise themselves under various voluntary bodies and have a professional council to regulate them. There was no universally accepted prescribed minimum educational requirement for one to practice TM. Historically oral tradition has been the means of passing the sacred information within families to trusted members from generation to generation (WHO, 2001). Regardless of the progress made in regulating the profession, lack of standard educational qualifications deter the efforts of integrating TM into main stream health system. Ghana through the Kwame Nkrumah University of Science and Technology in Kumasi, established a Bachelor of Science Degree in Herbal Medicine in 2001 to train Medical Herbalists and Zimbabwe established School of Traditional Medicine and a Bachelor of Science in Natural Medicine (WHO Global Atlas, 2005), but interestingly TMPs are still churned out through the archaic informal training route (WHO, 2001).

The other areas that showed weak implementation were development of national herbal pharmacopoeias (implemented in two of the five countries) and post-marketing surveillance of herbal products (implemented in two of the five countries). There was no recorded eentitlement of conventional medical practitioners to practice traditional medicine. The scepticism of allopathic practitioners was a reflection of non-existing educational base to TM that we can build from. It is important to introduce TM courses for conventional practitioners to understand the fundamentals that built and sustained the practice over the past millenniums. Governments may start by accepting conventional doctors to practice traditional medicine if they so wish, because of their vast knowledge of medicine, medicine interactions and disease pathology. This might optimise treatment therapies where patients start opening up on mixing both herbal and conventional medications to their doctors who in turn modify treatments for optimal patient benefit.

After subjecting the results to ANOVA, the results showed that country (column) factor accounted for 7.14% of total variance observed (p-value = 0.04) while indicator (row factor)

accounted for 44.28% of total variance observed (p-value = 0.0001). The assumption was no interaction hence decision was based on the two main effects of row and column. The null hypothesis was therefore rejected in favour of alternative hypothesis. The results concluded that there was a significant difference in the current legal and regulatory framework for traditional medicines in the five selected sub-Saharan Africa countries. Most African countries recently started aligning their medicine regulations to compulsorily request quality, safety, and efficacy information on herbal products. Aspects such as national herbal pharmacopoeia developments and post-marketing surveillance are still to be implemented by most countries. The difference could also be attributed to various capacities of African NMRAs to carry out their regulatory and evaluation functions (WHO, 2003). The complexity of herbal medicines warrants a different approach to conventional medicine when evaluating their quality, safety and efficacy.

Countries have seen the need to harmonise their medicine regulatory services. Examples of international and regional medicine harmonisation initiatives include the following: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); International Generic Drug Regulators Programme (IGDRP); World Health Organisation (WHO); Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S); ZAZIBONA in Southern Africa Development Community (SADC); and the International Pharmaceutical regulator's Forum (IPRF). In resource constrained Africa, no country can do it alone (as shown by none of the five countries managing 100% implementation of the nineteen selected WHO recommendations for TM policy), and the gap between developed countries and LDC was huge and so was the gap within Africa (79% implementation of WHO recommendations for TM policy for Ghana and 47% for Ethiopia).

The references to look at such as the national pharmacopoeias were achieved by two of the five countries and so was post-market surveillance of herbal products. Although established traditional medicine registration system was implemented in four of the five subject countries, the actual guidelines for registration of herbal products were not easily accessible in one of the four countries. Africa has an opportunity to harness her strength and consider

harmonising the regulation of herbal products over and above conventional medicines. There are countries that have done significantly well, for example Ghana 79% overall implementation of the WHO recommendations on TM policy, that can share their experiences and help develop guidelines to assist those that are lagging behind such as Ethiopia with 47%. However, harmonisation should not take away the NMRA's autonomous and sovereignty in deciding what is best for their citizenry.

CHAPTER FIVE:

5. Conclusion, Recommendations and Limitations:

5.1. Conclusion:

The ANOVA results showed existence of a significant difference in the current legal and regulatory framework for traditional medicines in the five selected Africa countries as recommended by the WHO. However Chi square failed to suggest a significant difference in the percentages of WHO indicators that were implemented by the selected countries. The follow up by Tukey's multiple comparison showed no significant difference in the WHO indicators implemented by countries. Therefore, although there was a significant difference in the current legal and regulatory framework for TM in Africa, the countries implemented common WHO indicators with no significant differences in the percentage of the WHO indicators among them. The results showed correlations with human development index (HDI), literacy rate, birth attended by skilled health personal and doctor density indicators. The WHO recommendations on TM policy were better implemented in those countries with overall good quality of life, high literacy rates and better conventional doctor/population ratio.

Formal educational qualifications and proper licensing schemes of both practitioners and herbal products remain a challenge to regulate. Although some countries have universities offering degrees in TM (Kasilo et al, 2010), there was no universally accepted entry qualification which made it difficult for national authorities and consumers to identify qualified providers. Generally apprenticeship under an experienced TM practitioner has been the commonest entry point (Hillenbrand, 2006). Besides a 100% implementation of voluntary professional regulatory bodies in all the selected five countries, Africa suffers from modern day fake and cunning traditional medicine practitioners (Hillenbrand, 2006). TM regulations in Africa have not been up to scratch and not punitive enough to deter would be offenders. By and large, WHO Traditional Medicine Strategy for 2014-2023 noted significant progress made in implementing the 2002 to 2005 strategy on WHO recommendations on TM policy (WHO, 2013). However on the ground, there was need for actual follow up and evaluation of the effectiveness and impact of these policies as they were integrated into the national health policies.

The differences in regulation demands across countries constitute trade restrictions and can lead to increased services trade (AU, 2016). There are great benefits of harmonising regulatory requirements such as reduction of costly duplication of effort; encouraging sharing of experience and knowledge among regulators and scientists; requiring fewer clinical trials; and optimising use of limited resources (AMRH Consortium, 2010). Consequently there would be significant reduction of the large gap in regulatory capacity and expertise between emerging and developed countries. The potential in Africa needs her to utilise combined continental resources to have an impact on the global scene where her citizenry uses 80% of herbal medicines which was estimated to be a USD107 billion market in 2017 (Nirali and Shankar, 2016). Africa countries had to work on the need to provide a framework for obtaining the evidence required for validation of traditional herbal medicinal products and defining a well comprehensive regulatory system which allows adequate research funding and protection of resulting intellectual property as a priority (Kasilo and Trapsida, 2010). Various tools and guidelines developed by WHO and other partners can be adopted and adapted by Africa at large and applied by countries to their unique circumstances with easy and great benefits. At the moment there was only tolerance of TM by conventional practitioners and no acceptance in African countries.

5.2. Recommendations:

TM in Africa is complex and mainly inexplicable. Nevertheless, there has to be prescribed minimum educational curriculums, ethical and professional conducts for TMPs preferably adopted on regional basis, better still continentally. This could assist in understanding the mysteries behind TM in Africa and allowing its appreciation in the scientific and regulatory world. The complexity of herbal products needs a different approach and not necessarily subject them to the same rigorous scientific evaluations as conventional medicines. Some of the NMRAs are not equipped to evaluate conventional medicines (WHO, 2003) let alone herbal products thus regional co-operation in assessment of these products could be vital. The regional co-operation will inevitably facilitate harmonisation of TM regulation. The TM research institutes that had been set up by most African governments together with their respective NMRAs have to come up with a comprehensive herbal assessment plan that would be used.

African governments should enact regulations that allow conventional medical practitioners to practice TM as an adjunct to their profession. Patients supplement allopathic medicines with herbal products without necessarily divulging it to their doctors. When doctors know that their patients are on herbal supplements, they are in a better position to optimise patient therapies. This allows acceptance of TM and gradual integration into main stream health system. Subsequently, improvements of quality of life of patients on both allopathic and herbal products may attract health insurers to come on board. Overally, there will be greater implementation of WHO indicators when there is more acceptance than tolerance.

5.3. Limitations:

While the study results were stratified across the five geopolitical/regional economic blocs of sub-Saharan Africa, the final selection of the five representative countries was not randomised but chosen based on: availability of English updated NMRAs and/or ministry of health websites and a skewed rich history of TM usage. However, there is the probability of the results pointing to significant difference of TM policies across the continent. Further work ought to be done to ascertain this rationale and generalise the results to the whole sub-Saharan Africa.

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7. Appendices:

Appendix I: Country selection vis-à-vis geopolitical region and regional economic bloc		
Country	**Geopolitical region**	**Regional Economic Community (REC)**
Ethiopia	East Africa	The Intergovernmental Authority on Development (IGARD), The Common Market for Eastern and Southern Africa (COMESA)
Cameroon	Equatorial Africa	The Economic Community of Central African States (ECCAS)
Ghana	West Africa	The Economic Community of West African States (ECOWAS)
Uganda	East Africa	East African Community (EAC); The Intergovernmental Authority on Development (IGAD), The Common Market for Eastern and Southern Africa (COMESA), ECSA
Zimbabwe	Southern Africa	The Southern African Development Community (SADC), The Common Market for Eastern and Southern Africa (COMESA)

Appendix II: Sample of data collection tool				
	Country:			
		YES	NO	Comments
1	Existence of national policy and legislation of traditional medicine			
2	Existence of national traditional medicine committee			
3	Availability of support of traditional medicines through public funds			
4	Medical insurance reimbursement on traditional medicines			
5	State of professional traditional practitioners recognition			
6	State of professional traditional practitioners regulation			
7	Voluntary self-regulatory body of traditional medicine practitioners			
8	State of professional education for traditional practitioners			
9	State of formal education and training regulation on traditional medicine			
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice			
11	Established traditional medicine registration system			
12	Conservation of medicinal plants			
13	Availability of regulation on traditional medicine			
14	Existence of local production of traditional medicines			
15	Traditional medicines in National Essential Drug List			
16	Existence of national pharmacopoeia			
17	Post-marketing surveillance system in place			
18	Legal recognition of traditional medicine			
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.			

Appendix III: Data collected per country:

Appendix IIIa: Data Collection Tool: Ghana				Comments
		YES	NO	
1	Existence of national policy and legislation of traditional medicine	√		Ministry of Health, 2005; WHO, 2005
2	Existence of national traditional medicine committee/council	√		WHO, 2001
3	Availability of support of traditional medicines through public funds	√		Government of Ghana, 2018; Centre for Scientific Research into Plant Medicine Act, 1975
4	Medical insurance reimbursement on traditional medicines		√	WHO Global Atlas, 2005
5	State of professional traditional practitioners recognition	√		Traditional Medicine Practice Act, 2000; WHO, 2001
6	State of professional traditional practitioners regulation	√		Traditional Medicine Practice Act, 2000; WHO, 2001
7	Voluntary self-regulatory body of traditional medicine practitioners	√		Adu-Gyamfi, 2015; Tabil et al., 2006 WHO, 2001
8	State of professional education for traditional practitioners	√		WHO, 2001
9	State of formal education and training regulation on traditional medicine	√		Traditional Medicine Practice Act, 2000. WHO Global Atlas, 2005
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice		√	Okine et al. 2010
11	Established traditional medicine registration system	√		FDA, (Ghana Food and Drugs Authority), 2018a WHO, 2001
12	Conservation of medicinal plants	√		Botanic Gardens Conservation International, 1999 Darwin Initiative, 2002
13	Availability of regulation on traditional medicine	√		Traditional Medicine Practice Act, 2000;
14	Existence of local production of traditional medicines	√		WHO, 2005
15	Traditional medicines in National Essential Drug List		√	WHO, 2005
16	Existence of national pharmacopoeia	√		WHO, 2005 WHO, 2001

17	Post-marketing surveillance system in place		√	
18	Legal recognition of traditional medicine	√		Traditional Medicine Practice Act, 2000
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.	√		Traditional Medicine Practice Act, 2000; FDA, 2017

NB: FDA - Ghana Food and Drugs Authority

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Appendix IIIb: Data Collection Tool: Cameroon				Comments
		YES	NO	
1	Existence of national policy and legislation of traditional medicine		√	WHO, 2001; Joseph, 2009
2	Existence of national traditional medicine committee		√	**NB*** Inadequate information found
3	Availability of support of traditional medicines through public funds	√		Through research institutes
4	Medical insurance reimbursement on traditional medicines		√	WHO Global Atlas, 2005
5	State of professional traditional practitioners recognition		√	**NB*** Inadequate information found
6	State of professional traditional practitioners regulation	√		Asonganyi et al., 2011
7	Voluntary self-regulatory body of traditional medicine practitioners	√		Nchewnang-Ngassa, 2015
8	State of professional education for traditional practitioners		√	**NB*** Inadequate information found
9	State of formal education and training regulation on traditional medicine	√		WHO, 2005 **NB*** School of traditional medicine
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice		√	Fokunang et al., 2011 **NB*** Practice is tolerated not accepted
11	Established traditional medicine registration system	√		WHO, 2005; Joseph, 2009
12	Conservation of medicinal plants	√		Fokunang et al., 2011
13	Availability of regulation on traditional medicine		√	Joseph, 2009
14	Existence of local production of traditional medicines	√		Fokunang et al., 2011
15	Traditional medicines in National Essential Drug List	√		WHO, 2005; Joseph, 2009
16	Existence of national pharmacopoeia		√	WHO, 2005;
17	Post-marketing surveillance system in place	√		WHO, 2005
18	Legal recognition of traditional medicine		√	WHO, 2005; Joseph, 2009
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.		√	FDAC, 2018 NB* Herbal Medicine department of FDAC

FDAC – Food and Drug Authority of Cameroon

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Appendix IIIc: Data Collection Tool: Uganda				Comments
		YES	NO	
1	Existence of national policy and legislation of traditional medicine	√		National Drug Authority Statute and Policy, 1993; WHO, 2005; WHO, 2001
2	Existence of national traditional medicine committee	√		NDA (Uganda National Drug Authority), 2009
3	Availability of support of traditional medicines through public funds	√		National Drug Policy and Authority Statue, 1993; WHO, 2001; NDA (National Drug Authority), 2009
4	Medical insurance reimbursement on traditional medicines		√	WHO, 2005
5	State of professional traditional practitioners recognition	√		WHO, 2001
6	State of professional traditional practitioners regulation	√		NDA, 2009
7	Voluntary self-regulatory body of traditional medicine practitioners	√		WHO, 2001; THETA, 2018; Ministry of Health, 2017
8	State of professional education for traditional practitioners		√	Weisheit, 2003; WHO, 2001
9	State of formal education and training regulation on traditional medicine	√		Weisheit, 2003; WHO, 2001
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice		√	De Coninck J
11	Established traditional medicine registration system	√		WHO, 2005
12	Conservation of medicinal plants	√		PROMETRA- UGANDA; 2017
13	Availability of regulation on traditional medicine	√		WHO, 2001; NDA, 2009
14	Existence of local production of traditional medicines	√		WHO, 2005
15	Traditional medicines in National Essential Drug List		√	WHO, 2005
16	Existence of national pharmacopoeia	√		WHO, 2005
17	Post-marketing surveillance system in place		√	WHO, 2005
18	Legal recognition of traditional medicine	√		WHO, 2005 NDA, 2009
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.	√		National Drug Policy and Authority Statue, 1993.

NB: NDA – Uganda National Drug Authority

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Appendix IIId: Data Collection Tool: Zimbabwe				Comments
		YES	NO	
1	Existence of national policy and legislation of traditional medicine	√		WHO Global Atlas, 2005
2	Existence of national traditional medicine committee	√		Traditional Medical Practitioners Act, 1981
3	Availability of support of traditional medicines through public funds	√		Traditional Medical Practitioners Act, 1981
4	Medical insurance reimbursement on traditional medicines		√	WHO Global Atlas, 2005
5	State of professional traditional practitioners recognition	√		WHO, 2001 Traditional Medical Practitioners Act, 1981
6	State of professional traditional practitioners regulation	√		WHO, 2001 Traditional Medical Practitioners Act, 1981
7	Voluntary self-regulatory body of traditional medicine practitioners	√		WHO, 2001
8	State of professional education for traditional practitioners	√		WHO Global Atlas, 2005
9	State of formal education and training regulation on traditional medicine	√		Saldi, 2014
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice		√	
11	Established traditional medicine registration system	√		MCAZ, 2015
12	Conservation of medicinal plants	√		Mavi, Shava, 1997; Chapeyama, 2009.
13	Availability of regulation on traditional medicine	√		MCAZ, 2016
14	Existence of local production of traditional medicines		√	
15	Traditional medicines in National Essential Drug List		√	EDLIZ, 2016
16	Existence of national pharmacopoeia		√	WHO Global Atlas, 2005
17	Post-marketing surveillance system in place	√		MCAZ, 2015
18	Legal recognition of traditional medicine	√		MCAZ, 2015
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.	√		MCAZ, 2015 MCAZ, 2016

MCAZ – Medicines Control Authority of Zimbabwe
MoHCW- Ministry of Health and Child and Welfare
EDLIZ - Essential Drug List of Zimbabwe

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Appendix IIIe: Data Collection Tool: Ethiopia				Comments
		YES	NO	
1	Existence of national policy and legislation of traditional medicine	√		National Drug Policy, 1993. WHO, 2005
2	Existence of national traditional medicine committee		√	National Drug Policy, 1993 **NB*** Not specific for traditional medicine
3	Availability of support of traditional medicines through public funds	√		Ethiopia Public Health Institute, 2018. Gemeda et al., 2015 Through research institutes.
4	Medical insurance reimbursement on traditional medicines		√	WHO, 2005
5	State of professional traditional practitioners recognition	√		WHO, 2005 Ethiopia Public Health Institute, 2018
6	State of professional traditional practitioners regulation	√		Ethiopia Public Health Institute, 2018 FMHACA, 2011
7	Voluntary self-regulatory body of traditional medicine practitioners	√		Kassaye et al., 2006
8	State of professional education for traditional practitioners		√	WHO Global Atlas 2005. Kassaye et al., 2006
9	State of formal education and training regulation on traditional medicine		√	WHO, 2001
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice		√	**NB*** No information to confirm although tolerated
11	Established traditional medicine registration system		√	WHO, 2001 WHO Global Atlas, 2005 **NB*** Could not get the list
12	Conservation of medicinal plants	√		Doffana, 2017
13	Availability of regulation on traditional medicine	√		WHO, 2001 WHO Global Atlas, 2005
14	Existence of local production of traditional medicines		√	**NB*** No clear information found
15	Traditional medicines in National Essential Drug List		√	Kassaye et al., 2006 WHO, 2001
16	Existence of national pharmacopoeia		√	WHO, 2005
17	Post-marketing surveillance system in place		√	FMHACA, 2011 **NB*** for general medicines

18	Legal recognition of traditional medicine	√		FMHACA, 2011 National Drug Policy, 1993
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.	√		FMHACA, 2011

EPHI – Ethiopian Public Health Institute.
FMHACA - Food, Medicines and Healthcare Administration and Control Authority (Ethiopia)

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Appendix IV:

Project Proposal

Title: Evaluation and comparison of current legal and regulatory framework for Traditional Medicines in five selected African countries: A move towards harmonization of regulation of Traditional Medicines in Africa.

1. Introduction:

WHO has defined traditional medicine (TM) as the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses (WHO, 2005). TM development was stymied for a long time with complete banning of the practice in some extreme cases (WHO, 2001; Kale, 1995) especially during the scramble of Africa, which resulted in it being viewed as inferior, and therefore stigmatised and marginalised. There has been a modern resurgence in TM practice congruent to a noted increase in chronic non-communicable diseases affecting low- and middle-income countries (Buckley and Gostin, 2013). Thus a contemporary approach to TM is more beneficial in the African setting (DeJong, 1991). Nonetheless there is need for reliability in the quality of TM medication/practice for the patients to control their conditions and improve quality of life.

Africa being the cradle of mankind has a rich and diverse traditional medicine (TM) history. Traditional medicine (TM) is based on an ancient and cultural method of healing that humans have used to cope and deal with various diseases that have threatened their existence and survival (Abdullahi, 2011). Scholars have agreed that up to 80% of Africans use TM to help meet their healthcare needs (Peltzer, 2009; WHO, 2001), that is for instance; fever, mild pain, flu symptoms, in addition to complicated healthcare needs such as snake bites, cancers, HIV/AIDS, chronic pain are all met with indigenous interventions in one way or the other (Peltzer, 2009). It therefore becomes imperative to integrate TM use into formal healthcare system and henceforth lobby for continental harmonisation of the registration requirements if Africa is to achieve health for all its citizens. The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal austerity (WHO, 2013).

The WHO Global Atlas for traditional, complementary and alternative medicine (2005) reflected that African states have different approaches and regulatory requirements to TM with some countries not having any guideline in place. The differences in TM across Africa resemble the continent's rich cultural diversity. The World Health Assembly urged member states, inter alia: to integrate traditional medicine within national healthcare systems by developing and implementing national TM policies and programmes; to promote the safety, efficacy and quality of TM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards; to establish systems for the qualification, accreditation or licensing of TM practitioners, and to increase the availability and affordability of TM (WHO, 2005). The responsibility of registration of TM, and their quality, safety and efficacy evaluations rest in the country's regulatory bodies that inadvertently require cooperation with their counterpart agencies around the globe (Institute of Medicines, 2012, WHO, 2010a). However, WHO estimates that 30% of Least Developed Countries (LDC) cannot maintain a proper registry of allopathic medicines let alone herbal products mainly due to lack of resources (WHO, 2003). Harmonisation of regulatory requirements can be seen as a solution as Africa will be able to pool both human and capital resources under one umbrella body.

The complications of TM however come in its inexplicit nature, sacredness and inadequate or lack of documented evidence. Issues surrounding the quality of herbs, quality assurance/quality control, in processing and preparation of herbal medicines, herbal mechanisms of action, bioavailability, and herbs′ chemical constituents, herb–drug interactions; herb-herb interactions; and efficacy measurements have to be addressed (WHO, 2013). Although allopathic based medicine is most prominent form of healthcare today, it is not widely accessible or is it the first choice for everyone (WHO, 2001) rather traditional medicine is the care that is closest home, accessible and affordable especially in rural Africa. It is time to revisit the Alma Atta Declaration of 1978 and promote the role of traditional medicine in health care systems in Africa so as to realise health for all.

2. Aim:

The aim of the project is to assess and compare current legal and regulatory framework for Traditional Medicines in five selected Africa countries.

2.1. Null hypothesis:

There will be no significant difference in the current legal and regulatory framework for Traditional Medicines in the five selected Africa countries.

3. Specific objectives:

3.1. To study the regulatory guidelines for traditional medicine (TM) in five African countries (Cameroon, Ethiopia, Uganda, Ghana and Zimbabwe).

3.2. To compare the regulatory guidelines for traditional medicine (TM) in five African countries (Cameroon, Ethiopia, Uganda, Ghana and Zimbabwe).

3.3. To identify the main themes in the traditional medicine (TM) registration requirements and guidelines of the five African countries (Cameroon, Uganda, Ghana and Zimbabwe).

3.4. To highlight differences in the current registration requirements for TM in the five African countries.

3.5. Propose possible areas for harmonisation of traditional medicine (TM) registration requirements and guidelines of the five African countries (Cameroon, Uganda, Ghana and Zimbabwe).

4. Methodology:

4.1. Study design

A desk review of current policy and guidelines for regulation of traditional medicines in five sub-Saharan African countries was conducted.

4.2. Sample population:

One African country will be selected to represent each of five geopolitical regions and regional economic zones in Africa. Bias will be given based on availability of English policies, updated national medicine regulatory authority (NMRA) websites and skewed to countries with a rich history of TM usage.

4.3. Data collection tool:

The project will look at the legal and regulatory framework regarding TM registration in the selected African countries. The indicators for the assessment of each country's legal and regulatory framework for TM will be adopted from the WHO Data Collection Tool for the Review of Drug Regulatory Systems (WHO, 2007). For this study, relevant indicators will be taken from mainly module 2 (National Regulatory System), module 3 (National Regulatory Authority) and module 4 (Marketing Authorization) section of the WHO Data Collection Tool for the Review of Drug Regulatory Systems.

4.4. Data Collection:

The demographic characteristics (land size, population, gross domestic product, life expectancy etc.) of each country will be sourced from relevant publicly available literature and reported. General assessment of legal and regulatory framework for TM registration in sample population is going to be based mainly on literature review of publicly available documents. Comparing indicators adopted from the WHO Data Collection Tool for the Review of Drug Regulatory Systems (WHO, 2007) for each selected African country may reveal major differences in the legal and regulatory framework for TM. The following responses will be attributed to each indicator, after review of the relevant documents: Yes (when the indicator is provided for in the legal and regulatory framework), No (when the indicator is not provided for in the legal and regulatory framework). To enable the use of quantitative statistical analysis methods to analyse this data, responses were coded 1 for 'Yes' and 0 for 'No'.

4.5. Data Analysis:

A simple frequency or percentage proportion will be used to summarize the response attributed to each indicator adopted from the WHO Data Collection Tool for the Review of Drug Regulatory Systems (WHO, 2007). Chi-square test and/or Analysis of Variance (ANOVA) will be used to test the null hypothesis. The association between demographic characteristic of each country and specific indicators will be assessed with Spearman's correlation and/or Chi square analysis.

5. Ethical Considerations:

The research is going to be a comparative literature review on the current legislative/ regulatory requirements of TM registration in selected African countries. There are no subjects directly involved in the research. The information and documents that will be used is available in the public domain. The information gathered will be used for this survey and if need arise for reference towards initiatives to harmonise regulation requirements in Africa.

6. Expected outcomes:

The project expects to reveal differences in current legal and regulatory framework for Traditional Medicines in selected African countries. We hope to propose strategy for possible harmonization of regulation of Traditional Medicines in Africa.

7. Data collection Tool:

Data Collection Tool				
		YES	NO	Comments
1	Existence of national policy and legislation of traditional medicine			
2	Existence of national traditional medicine committee			
3	Availability of support of traditional medicines through public funds			
4	Medical insurance reimbursement on traditional medicines			
5	State of professional traditional practitioners recognition			
6	State of professional traditional practitioners regulation			
7	Voluntary self-regulatory body of traditional medicine practitioners			
8	State of professional education for traditional practitioners			
9	State of formal education and training regulation on traditional medicine			
10	Entitlement of conventional medical practitioners to practise traditional medicine as part of their conventional practice			
11	Established traditional medicine registration system			
12	Conservation of medicinal plants			
13	Availability of regulation on traditional medicine			

14	Existence of local production of traditional medicines			
15	Traditional medicines in National Essential Drug List			
16	Existence of national pharmacopoeia			
17	Post-marketing surveillance system in place			
18	Legal recognition of traditional medicine			
19	There is an authority (institutions/agencies/autonomous bodies) responsible for the regulation of herbal products.			

8. <u>References:</u>

These have been included in the overall bibliography