

A Critical Review of the WHO Global Report on Traditional and Complementary Medicine 2019: Implications for harmonization of Traditional and Complementary Medicine regulation in Africa.

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A mini thesis submitted in partial fulfilment of the degree M.Sc. in
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Regulation

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Harmonization



Abstract

A Review of the WHO Global Report on Traditional and Complementary Medicine 2019: Implications for harmonization of TCM regulation in Africa.

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Background: A broad range of Traditional and Complementary Medicine (TCM) practices and products is available and accessible to the population in many countries in Africa, and worldwide. Therefore, an effective and harmonized medicines regulatory system is required for TCM. The World Health Organization (WHO, 2019) global report on TCM highlighted the progress that was globally achieved in the regulation of TCM by countries that have implemented and adopted TCM services over the past two decades. Within the African continent, the African Medicines Regulatory Harmonization (AMRH) Initiative aims to strengthen regulatory capacity, encourage harmonization of regulatory requirements, and expedite access to good quality, safe, and effective medicines. However, several studies have shown a limited capacity to regulate TCM and medical products in general, hence the need to assess.

Aim: This study assessed the status of TCM regulation in some African countries and deduced how the current status can advance the harmonization efforts in Africa.

Method: A desk research on the status of African countries in adopting and implementing the WHO, 2019 TCM indicators was conducted, and a qualitative descriptive approach was used to analyze the data.

Results: A total of 28 African countries responded to the (WHO, 2019) global report.

The results showed remarkable progress on some WHO indicators such as the National policy and the National Office for TCM. For the primary WHO indicators that are fundamental to achieving harmonization such as the regulation and monitoring of the manufacturing of herbal medicine, results showed less than 50% of implementation by African countries.

Conclusion: The study provided a summarized snapshot of the status and progress towards the desired harmonized TCM regulation in Africa. The African countries demonstrated a will to regulate TCM as reported by 28 out of 28 countries having a National Policy on TCM. However, only a few countries have achieved some other WHO indicators, and less than half of the responding countries implemented the key indicators such as the regulation of herbal medicine as well as indicators relating to funding of TCM programs. More progress in implementing WHO indicators is needed to achieve harmonization of TCM regulation in African countries.

Declaration

I, Martin Mukeshimana, hereby declare that this mini thesis titled, 'A Review of the WHO Global Report on Traditional and Complementary Medicine 2019: Implications for Harmonization of TCM regulation in Africa', I am submitting in partial fulfilment of the degree M.Sc. in Pharmacy Administration and Policy regulation, is entirely my work. I have cited and acknowledged all sources I used to complete my work and it has not been submitted to any other learning institution.

Martin Kamuhanda Mukeshimana

Signature



Date: August 2022

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May the Almighty God immensely bless you.



List of Abbreviations

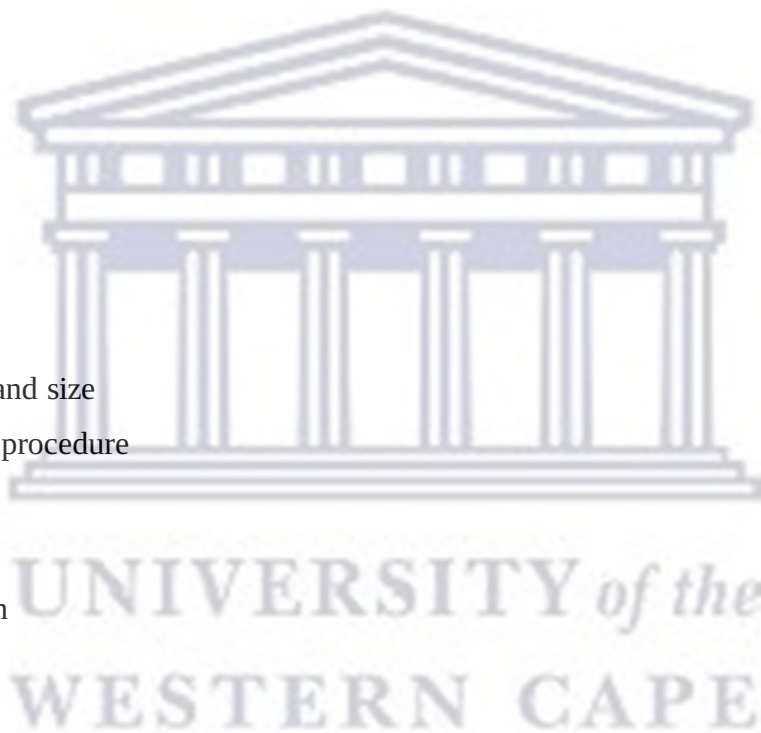
AMA	African Medicine Agency
AMRH	African Medicine Regulatory Harmonization
AUDA	African Union Development Agency
EAC	East African Community
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
ICH	International Council for Harmonization
IPR	Intellectual Property Rights
NEML	National Essential Medicine List
NEPAD	New Partnership for Africa's Development
NMRA	National Medicine Regulatory Authority
OCEAC	Organization for Coordination for Fight against Endemic Diseases in Central Africa
R&D	Research and Development
SADC	Southern African Development Community
SDG	Sustainable Development Goal
TCM	Traditional and Complementary Medicine
UHC	Universal Health Coverage
WAHO	West African Health Organization
WHO	World Health Organization



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Table of Contents

Title page	i
Keywords	ii
Abstract	iii
Declaration	iv
Acknowledgment	v
List of Abbreviation	vi
Chapter 1:	
1.1. Introduction and problem statement	8
1.2. Aim	10
1.3. Specific Objectives	10
Chapter 2:	
2. Literature Review	11
Chapter 3:	
3. Methodology	20
3.1. Study design	20
3.2. Sample population and size	20
3.4. Data collection and procedure	21
3.5. Data analysis	21
Chapter 4:	
4. Results and discussion	23
4.1. Results	23
4.2. Discussion	27
Chapter 5:	
5.1. Conclusion	30
5.2. Recommendations	31
5.3. Limitations	31
7. References	32
8. Appendices	37



CHAPTER ONE

This chapter outlined a general overview of the study, which is a review of the WHO, 2019 Global Report on Traditional and Complementary Medicine; it further outlined the WHO indicators, stated the problem and the purpose of this study. The aim and objectives of the study are presented in this chapter as well.

1.1. Introduction and problem statement:

Traditional and Complementary Medicine (TCM) is a concept entailing both: (1) Traditional Medicine as the knowledge and healthcare practices that are based on cultural beliefs and practices transmitted from one generation to another; and (2) Complementary Medicine as the health care practices that are borrowed from somewhere else rather than being native or conventional (WHO, 2019). This study explored the World Health Organization (WHO) global report on TCM 2019, a report that combined the information obtained from three WHO surveys on TCM: 1999-2005; 2005-2012; 2012-2018. In these surveys, WHO Member States divided in six regions, namely, WHO African region; WHO Region of the Americas; WHO Eastern Mediterranean Region; WHO European region; WHO South-East Asia Region and WHO Eastern Pacific Region, provided information vis a vis WHO TCM indicators, by responding to various questionnaires provided (WHO, 2019). The surveys were conducted in response to a worldwide resurgence of TCM use since more than three decades back, as WHO strategies to help countries develop laws and policies to improve and strengthen the role of TCM in the global health care of the countries (WHO, 2019). Such a resurgence and a widespread use of TCM call for more control on quality, safety, and efficacy standards among others (Ndomondo-Sigonda et al., 2021).

The progress made by countries in adopting and implementing TCM was measured by countries responses to the WHO indicators. Those indicators were categorized in (1) the National framework for traditional and complementary medicine: National policy on TCM; National or state level law or regulations on TCM; National program on TCM; National office on TCM; National expert committee on TCM; National research institute on TCM; Government and public research funding for TCM and National plan for integrating TCM into national health service delivery, (2) the Regulatory status of herbal medicines: Regulation of herbal medicines; Regulatory category given to herbal medicines; Regulatory claims made about herbal medicines; Pharmacopeias and monographs; Manufacturing of herbal medicines; Safety assessment of herbal medicines; Registration systems for herbal medicines; National essential medicine list; Market surveillance system for safety for herbal medicines and Marketing and sale of herbal medicines, (3) the Practice, providers, education and health insurance: TCM practices, Type of TCM practices used in Member States, TCM providers- practice settings and licensing; Education of TCM providers, Type of TCM providers, Health insurance and TCM and Consumer education project or program for self-health care using TCM, and (4) the Challenges and the needs for WHO support: Main difficulties faced by Member States and where WHO support is needed.

Although all the WHO indicators constitute the necessary tools to assess the status and the progress made by

countries to adopt and implement TCM, some of them are primary, and their adoption, implementation drive the others. Like any other health indicators, TCM programs need funding to progress, hence (1) TCM funding, budget allocation, and TCM insurance coverage are among the key indicators. The (2) education and training of TCM providers: any profession requires ethical standards, knowledge and skills that need training and education, TCM as a profession, is not an exception and in order to successfully implement other indicators such as the TCM research, herbal medicine manufacturing and quality control, a country needs people with expertise, hence education and training of TCM providers is among the key indicators. The (3) national policy, program or laws and regulation for TCM: this is a key indicator as it shows the country or decision makers willingness to undertake TCM regulation and establish guidelines to follow in the process.

One of the six WHO regions, the African region, a continent with the highest burden of disease, the highest hit with HIV/AIDS, malaria, and a rising burden of non-communicable diseases such as diabetes and hypertension, yet a continent with the lowest health care spending and the lowest access to essential medicines was the focus of this study. Many African countries reported the use of one or many forms of TCM. Equally, few other available studies that were conducted in African countries found a high use of TCM among the population despite some study limitations such as the non-disclosure of TCM use by patients out of fear of being stigmatized following the African colonial past where African traditional medicine was seen as inferior to the western medicine or completely banned (James et al., 2018; Ezekweli-Ofilu & Ogbonna, 2022).

Furthermore, in many African countries, TCM practitioners, mostly known as traditional healers or traditional doctors outnumber by far the western medicine doctors (Abdullahi, 2011). This high TCM demand goes parallel with the market growth of TCM products across Africa and other WHO regions, which in turn increase concerns about safety, quality, and efficacy of TCM. Most African countries do not have adequate mechanisms to control and regulate conventional medicines entering their markets, let alone TCM. As a result, counterfeits and substandard conventional medicines have increased across African countries (Okereke et al., 2021). As little is known about substandard TCM products, a closer look into WHO indicators such as the herbal medicine regulation and registration and manufacturing of TCM products, needs research such as the current study to find out the status of their adoption and implementation by African countries.

The few available studies were conducted in isolated countries, with no collaborative initiatives in the sub-African regions despite the existing African trade blocs and incentives for intracontinental free trade (Olayungbo & Iqbal, 2021). Furthermore, the studies focused on few indicators and only highlighted the difficulties encountered by the countries to adopt and implement some indicators such as the lack of a regulatory framework, the lack of funding, the lack of education on TCM and the lack of herbal medicine research data, adding very little knowledge to the status of African countries towards TCM regulation. This research not only explored more indicators in detail but also highlighted the TCM status of many more African countries that contributed to the WHO global report 2019.

Bodeker and Kronenberg (2002) remarked that for a maximal TCM contribution to global national health, the

political, economic, social, and cultural aspects of TCM must be emphasized. Most of the current studies on TCM are clinically oriented. However, the lack of research data as well as the absence of scientific evidence for TCM use constitute the African countries' major challenges and a block to other TCM contexts. This study took a closer look in the WHO indicators on TCM and assessed if other incentives to TCM regulation such as TCM and job opportunities, TCM and the environment, TCM and culture-conservation and advancement, and TCM and Intellectual Property Rights (IPR) have been considered throughout the African countries' responses to the WHO indicators.

In addition, the third WHO survey focused only on the following TCM practices: Traditional Chinese Medicine, Acupuncture, Ayurvedic Medicine, Osteopathy, Chiropractic, Unani Medicine, Herbal Medicine, Homeopathy, Indigenous Traditional Medicine, and Naturopathy. Apart from Herbal Medicine present in all the six WHO regions and the African Indigenous Traditional Medicine, all other practices evaluated in this study, originated from outside Africa. The rest of the practices originated from countries such as China, India, Germany, and North America. Some of these countries possess useful tools for GMP such as the homeopathic, ayurveda, unani pharmacopias that may be useful in African countries adopting these practices.

1.2. Aim:

This study aims to review the reported status of TCM regulation in selected African countries and to find similarities that drive progress towards the harmonization of TCM regulation in Africa.

1.3. Specific objectives:

- Assess the extent to which African countries members of WHO regions have achieved harmonization and regulation of TCM.
- Identify what are the WHO indicators African countries implemented in common and deduct if those indicators can drive the TCM regulation and harmonization.
- Highlight the challenges African countries, encounter in terms of harmonization and regulation of TCM.

CHAPTER TWO

Through the WHO indicators, this chapter presents a broad overview of the published works available in the literature concerning TCM practices, products, and providers focusing on African countries, with a general view of the rest of the WHO regions. Benefits, challenges, and factors underlying TCM harmonization have also been highlighted.

2. Literature review:

The TCM resurgence is becoming a global phenomenon, which has increased the need for TCM regulation and harmonization. Not only are various types of TCM found around the world, but like conventional medicines and devices, TCM products are being traded across countries. The need for TCM regulation and harmonization is also broadly supported by TCM professionals and stakeholders (Care et al., 2021). However, among the challenges African countries reported to encounter include the lack of research data, lack of financial support for TCM research, lack of education and training for TCM providers, and lack of appropriate mechanisms to control, regulate and monitor the safety of herbal medicine (WHO, 2019).

As it is for conventional medicines, harmonization has many advantages ranging from standardization and sharing of needed information for research, Good Manufacturing Practices (GMP), and Good Clinical Practices (GCP) for medical products and practices quality, safety, and efficacy (Chung et al., 2021), to the globalization of the market, of the products and practices (Reggi, 2017). Equally, TCM harmonization would minimize the concerns about safety, quality, and efficacy; facilitate and reduce research cost, speed up and improve regulation as well as sharing of information leading to regulation, expand the market to the international level and increase incentives for research and development (Lin et al., 2021).

For a better understanding of the status of TCM regulation in Africa, it is worthy to investigate the status of the regulatory harmonization of conventional medicine in Africa. Since the inception of the International Council for Harmonization (ICH) in 1990, the International Council for Harmonization (ICH) on conventional drugs and devices, several regulatory authorities around the world, mostly in the developed world, refer to ICH guidelines for medicines safety, efficacy, and quality such that the products available on the market are standardized (Molzon et al., 2011). However, it was only in 2009 that the African Medicines Regulatory Harmonization (AMRH) was established and had among other objectives to guide laws and policies to help establish National Medicine Regulatory Authorities (NMRAs) in Africa (AUDA-NEPAD, 2009).

The AMRH also has a mandate to help put in place the African Medicine Agency (AMA) which will in turn help decrease the technical barriers and improve pharmaceutical trade between African countries (Ndomondo-Sigonda et al., 2018). AMRH encourages African countries to work towards meeting indicators such as clinical trials, import and export, information management systems, inspection of good manufacturing practices/good

distribution practices, licensing, quality laboratory, pharmacovigilance, post-marketing surveillance, registration/market, and authorization for harmonization for conventional medicines (AMRH Consortium, 2019). However, this AMRH call has still not yielded enough results although many African countries have now established NMRAs, only a few are fully functioning due to various reasons including, insufficient financial, technical, and human resource support (Ncube et al., 2021). This indicates that the state of regulation and harmonization of conventional medicine in Africa is still to be desired, let alone TCM, hence the necessity for this study to review the WHO global report and establish to what extent African countries have implemented TCM.

Despite the expected collaboration to facilitate medicines circulation in the African sub-regions, drawn from the existing regional community organizations such as the East African Community (EAC); Southern African Development Community (SADC); Organization of Coordination for the Fight against Endemic Diseases in Central Africa (OCEAC); West African Health organization (WAHO); Economic Community for West African States (ECOAS); Arab Maghreb Union (AMU); and Intergovernmental Authority on Development (IGAD), Jones et al. (2022) found that these regional organizations are still playing the role of advocacy to the governments, to speed up harmonization of conventional medicine regulation. Nevertheless, citing the example of EAC and SADC where harmonization is being achieved between countries in those regions, Ncube et al. (2021) predicted that with continuous efforts, these organizations can reach active collaboration that is necessary to achieve regional, then continental medicine regulatory harmonization.

In evaluating the progress made by countries in adopting and implementing TCM or conventional medicine, some indicators need to be considered. Many indicators have been set by WHO for TCM and categorized into the national framework for traditional and complementary medicine, the regulatory status of herbal medicines, the practice, providers, education, and health insurance and the challenges and the needs for WHO support (WHO, 2019). The national framework for traditional and complementary medicine includes all plans of action by governments and other stakeholders seeking to regulate TCM. Many African countries have engaged in establishing leadership and frameworks for TCM, and the existence of national policy and national programs indicates a plan of action and willingness (Lin et al., 2021).

Some African countries have an established framework on TCM for many years. For instance, Benin and Burkina Faso have a national policy or a national committee to deal with TCM since the early 1970s, but the advancement and progress to TCM regulation has been at a very slow pace in both countries and different in each, despite that they are neighboring and belong to one organization WAHO (Dori et al., 2019). In Cameroon, the national framework on TCM has existed since 1981 and has been amended from time to time, but until 2020, there were no laws controlling the practice of TCM (Nsagha et al., 2020). Other examples include Burundi with an association of traditional practitioners and an integrative medicine unit; Ghana with tertiary education on traditional medicine and South Africa with a council to regulate traditional medicine (Ampomah et al., 2020). Moreover, in many other African countries like the Ivory Coast, the Democratic

Republic of Congo, Ethiopia, Mozambique, Namibia, Uganda, and Tanzania, the existing NMRAs established laws to regulate TCM (Ndomondo-Sigonda et al., 2017). This is an indication that many countries in the WHO African region have positively responded to the WHO call to start regulating TCM.

However, many African countries were found to have close to no budget set aside for TCM, and in the WHO global report, 86% of the African countries reported the lack of funding for TCM research as a challenge. Research funding as well as funding other TCM programs, is among the driving TCM indicators, and the failure to achieve it, negatively impacts the advancement of other indicators. As found by Asante et al, (2020), in many African countries, the spending on global health programs is low compared to developed countries. With the high burden of diseases present in these countries, and unlike China, Korea and Vietnam, no African country has fully integrated TCM into their national health system, and the little health spending is understandably directed to the mainstream/conventional medicines, and TCM programs are left behind (Kasilo, 2022).

Regarding the regulatory status of herbal medicine, even though herbal medicine is still the first recourse for many people to resolve their health problems in many African countries, it is still largely unregulated. Especially in the rural and remote areas with poor to no infrastructures such as roads, clinics, and hospitals, TCM is the only available and accessible health setting. Countries such as Ghana, Zambia, Tanzania, Kenya, Nigeria, and South Africa among others, have an established policy for herbal medicine regulation, some have manufacturing plants for herbal medicine and many herbal products sold in pharmacies or other outlets with or without claims, however, in those countries and several others in Africa, many herbal medicines are still sold in different forms in the streets, uncategorized, without a proper control of safety or market surveillance and many TCM practitioners are unregulated (Ozioma, & Nwamaka Chinwe, 2019).

Such an uncontrolled market in herbal medicine exposes consumers to many unwanted, sometimes serious side effects, infections caused by contaminated herbs, as well as a possibility of herb-drug interaction for people on prescribed medication. For example, Kira et al. (2021) found a high microbial contamination in the herbs used by unregulated practitioners in Tanzania. Some of the plants used in herbal medicine can be naturally toxic or contain adulteration with heavy metal or radioactive material, requiring GMP, adherence to monograph and pharmacopoeia, indicators that are not necessarily observed in many instances in African countries (Mensah et al., 2019).

Nevertheless, the potential of herbal medicine to help fight and decrease the burden of diseases in Africa is being demonstrated by few data that are becoming available. Okaiyeto and Oguntibeju (2021), found several medicinal plants with antibacterial, antifungal, antiviral, anti-plasmodial and anticancer activities in many African subregions, Cameroon, Tunisia, South Africa, Nigeria, Ethiopia, Kenya, Zimbabwe, Algeria, Ghana, Morocco, Congo, Tanzania, Niger, Gabon, Burkina Faso, Senegal, Uganda, Togo, Cote d'Ivoire, and Sudan, indicating that more studies like this may discover even more potential herbs to solve many unmet medical needs.

The WHO indicator on education and training of TCM providers is among the key indicators to drive others, and countries such as India, China, Japan, Thailand, and the Republic of Korea have an advanced integration of TCM in their health systems, and their success story is enhanced by the advanced education and training of TCM providers at colleges and university levels (Lin et al., 2021). Equally, some African countries such as Ghana, Madagascar, Sierra Leon, South Africa, and Tanzania that provide training and education at college and university level, show better performance on other indicators such as the registration of herbal medicine on their NEML, regulation and licensing of TCM providers and their practice settings, even though TCM projects are still underfunded in those countries (Innocent, 2016).

Many African countries are unable to access essential and lifesaving conventional medicines, due to poorly funded regulatory programs, poor policies, and lack of regulatory harmonization among others (Barton et al., 2019), which implies a worse situation for TCM. Similarly, many scholars such as Akarowhe, (2018), Zhou et al. (2019) and Giuliani et al. (2021) concluded that the lack of research and information as well as the difficulty conducting randomized studies, lack of pharmacological and clinical data, lack of funding for TCM projects, lack of education and scientific awareness, esoteric and secret practices, cultural and religious interference as well as ethical consideration and mismanagement of the environment will continue to hinder efforts and constitute a stumbling block toward regulation and harmonization of TCM. In addition, the continuous lack of codification of indigenous medicine, practices, and devices has been and will continue to slow down the advancement of indigenous medicine in Africa. While many African practices and disease diagnosis processes such as divinity, spirituality, ancestral consultation, as well as advanced practices such as sky consultation for weather prediction and management are the same in most parts of Africa, no common name is given to such practices making it difficult to be attributed to the African origin. The same applies to diagnostic devices such as bone throwing, utilized in many African countries (Masango, 2019).

Another challenge to the integration of TCM into National health systems, some studies have noted skepticism and mistrust by conventional medicine practitioners. Abdalla et al., (2020) found that a high number of patients do not disclose their use of TCM products to their healthcare providers and cited various reasons including the healthcare provider-patient relationship. Other reasons for nondisclosure according to Foley et al., (2018) include lack of inquiry from medical providers, fear of provider disapproval, perception of disclosure as unimportant, and belief that TCM is safe. Bahall and Legall (2017) found that many healthcare providers have little knowledge of TCM, and some consider TCM as non-scientific based and may discourage their patients who use it, a communication challenge between the health providers.

Another point of skepticism against TCM was developed through the years and was influenced by colonialism and Western cultures that have been imposed on many African countries and still constitute a big stumbling block to the recognition and regulation of traditional medicine practices (Abdullahi, 2011). Colonialists found traditional medicine health systems in many African countries and brutally changed and prohibited them. As it was concluded by Tilley (2016), colonial rule pushed traditional medicine practitioners to barely survive.

Consulting, and visiting a traditional medicine practitioner became 'bad' and unreligious. This legacy has continued in many African countries and contributes immensely to the underdevelopment of African traditional indigenous medicine; thus, the openness, confidence, and trust of traditional medicine practitioners and the population are still lacking. Until today, the practical environment is still not conducive enough for traditional medicine practitioners to freely see their patients and openly contribute to the well-being of the people in their societies. Mbatha et al. (2012) gave an example where sick certificates issued by traditional medicine practitioners in South Africa are not recognized and accepted by employers at work citing the old attitudes towards the profession that is often confused with African rituals. Another example of South Africa, applicable to some extent to many African countries is that colonial and western legacy towards traditional medicine in South Africa has made traditional medicine keep a very low profile.

According to the (WHO, 2019) report, the economic stand of TCM in terms of money has not been fully established in the many WHO member states due to the complexity and the unregulated market. However, considering the global growth of TCM, the sale and services thereof significantly contribute to economic development. Few African WHO member states reported their herbal medicine sale in monetary value even though all African countries reported having one or another way of herbal medicine sale outlet. In the most recent report, Mali received \$117 612, and Cote d'Ivoire received \$1 300 000, from herbal medicine sales (WHO, 2018).

Consumers benefit immensely from TCM services and many TCM products have been available on the market since the start of the resurgence of TCM around the world and people especially those living with chronic conditions use the products as alternatives or complementary to their conventional medicine regimens. Despite these facts and realities, it is still difficult to show the exact value of the services for the decision-makers to consider. For example, Hughes et al. (2015) concluded that the economic evaluation of TCM used by some communities in South Africa for chronic non-communicable diseases could make a difference and give decision-makers more options to choose from in reducing the burden of diseases, especially in rural and poor communities.

Furthermore, the WHO global report indicated the number of TCM practitioners that amounts to thousands in some countries suggesting that TCM constitutes an industry that creates several jobs for the communities. Unregulated and uncontrolled harvesting of medicinal plants has been and is still a source of income for many people in rural areas in many African countries. The availability of medicinal plants in the forms of roots, leaves, whole plants, powders, solutions for crushing plants and many more is well documented and found on sale on several streets in many countries (Ndhlala et al., 2011). Though it may define a large industry financially sustaining a good number of people, it is still difficult or impossible to accurately quantify its exact value in monetary terms until proper regulation is done.

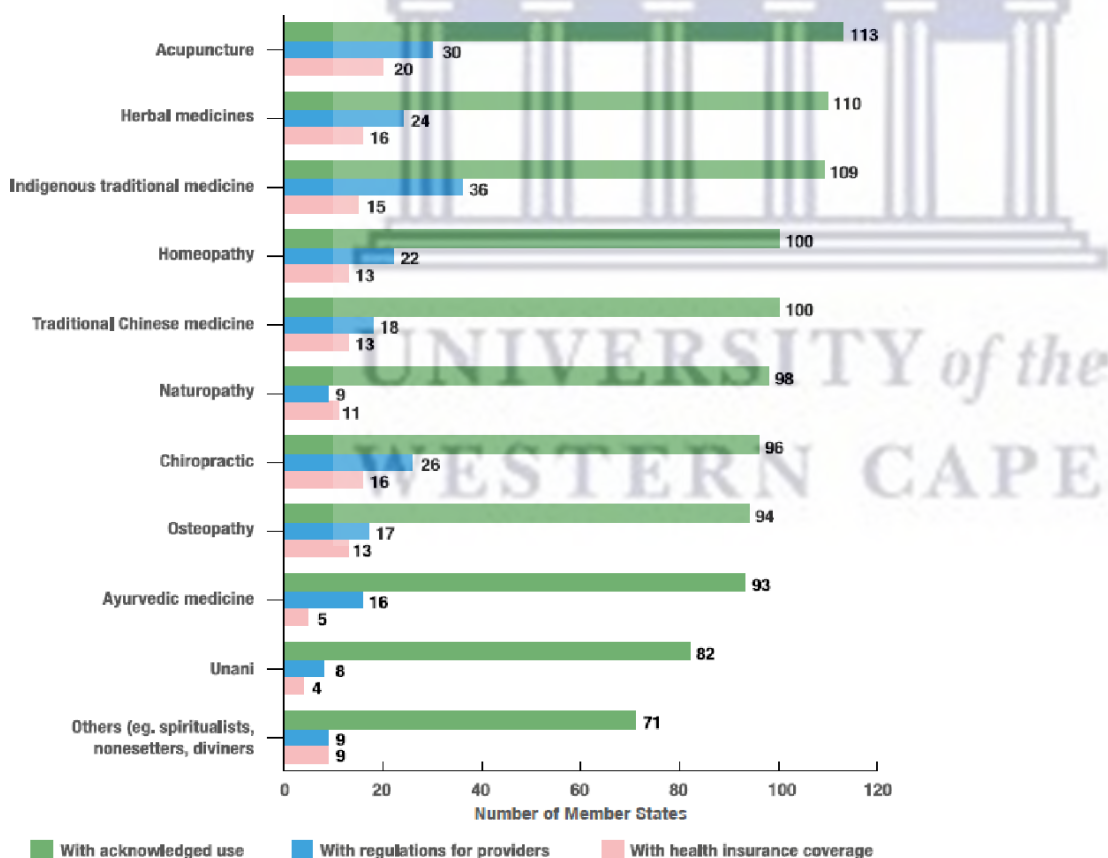
In her book 'Traditional and Complementary Medicines: Are they Ethical for Humans, Animals, and the

Environment?’, Chatfield et al. (2018) attracted attention to a vicious cycle that can result from the current increased ill health that implies depletion of the environment for solutions, and this environmental depletion comes back with increased ill-health citing pollution, waste management, climate changes, endangering plant, and animal species among others, a challenge that calls for TCM regulation.

The innumerable diversity of TCM constitutes another incentive for regulation. Even though WHO global report has only focused on nine major types of TCM (figure 2.1 below) and the most available in the literature, there are many other non-conventional practices in Africa and around the world. Many TCM disciplines have in common a holistic approach, with emphasis on the patient’s body and mind, as well as a salutogenic approach, whereby health-promoting factors such as immune systems are supported rather than a focus on the disease itself (Roberti di Sarsina et al., 2012).

Figure 2.1: Typology of TCM practices as reported by WHO.

Source: WHO (2019: 55)



The nine practices are Acupuncture, Ayurveda, Chiropractic, Herbal Medicine, Homeopathy, Naturopathy, Osteopathy, Traditional Chinese Medicine, and Unani Tibb Medicine. Other types other than these nine were categorized as 'Others' (WHO, 2019).

Acupuncture

Originating from China and spread around the world centuries earlier, Acupuncture is one of the oldest Chinese Traditional Medicine available worldwide. It is based on the philosophy that blood and qi (Energy), go from one point to another, through structures called meridians. The needling of the points (acupoints) influences the functions of organs or sites represented by those acupoints through the meridians by stagnant blood or qi dispersion (Dorsher, 2017). Acupressure is a form of acupuncture using pressure, usually with hands on the points (pressure points) on the meridians. Other forms of acupuncture are practiced in other countries such as Shiatsu in Japan.

Ayurveda

Ayurveda Medicine is the oldest body and mind holistic medicine known to man. Native to India, Ayurveda is based on five elements and three doshas. Each element is defined as a set of aspects in the body such as Space (Ether) for communication, consciousness, and intelligence in the cells; Air for touch, sensation, and nonphysical movement of thoughts; Fire for digestion of food and emotion transformation; Water for body fluids, sense of taste and certain emotions; Earth for solid body parts and sense of smell. The three doshas (energy) are Kapha for bones, tendons, and water supply; Pitta for digestion, thinking and temperature and Vata for any body part that moves such as muscles, heart, and eyes (Raj et al., 2011).

Chiropractic

A more than a century-old North American Medicine, Chiropractic, a “science of healing without drugs” according to its father, Daniel David Palmer, is a musculoskeletal therapeutic approach to treating muscular, neurological, articular, and bone conditions using skilled manipulation of the affected areas such as the spine. When a subluxation happens in the body, specifically in the vertebra of the spine, the energy or influx from the brain struggles to reach its destination, resulting in a delayed or unwanted response. A realignment of the vertebra (Chiropractic) corrects the pathway of the brain command resulting in the regaining of body function (Ernst, 2008).

Herbal Medicine

Oldest Medicine worldwide and across all cultures, the use of Medicinal plants or Herbal Medicine dates from the existence of humans. It has inspired many modern medicines as a source of many medicinal compounds available in modern medicine today. Herbal Medicine or a traditional philosophy behind a safe and effective use of herbal medicine as the use of whole plants as opposed to extracts (Modern medicine drugs). For

example, the use of meadowsweet as a whole plant will not cause unwanted effects that can cause the salicylic acid contained in it because of the presence of other plant components (Yuan et al., 2016). The outcome of herbal treatment is to restore the body's natural balance. Herbs are also used to prevent diseases by boosting the body's immune system. Furthermore, the majority of TCM disciplines except for the 'drug-free' such as body manipulation techniques, are sourced from Herbal Medicines for their plant-based products.

Homeopathy

Originating from Germany, homeopathy's philosophy, illness is defined in body, mind, and spirit. The body manifests symptoms of illness but it is not the origin of the illness. Upon death, the physical body remains, but it is no longer curable. The origin of illness lies in an imbalance of the vital force. The symptoms expressed by the body, mind, and spirit are the manifestation of that imbalance. By matching the symptoms of illness with the appropriate homeopathic remedy, the vital force returns to balance. The symptoms disappear along with the person's healing. Homeopathy is based on four principles with the first one being the cornerstone, *Similia Similibus Curentur* or *Likes Cure Likes*: a substance that can produce disease in a healthy person is used to elicit a healing response in someone presenting with a similar disease. The second principle is Homeopathy as 'The Single Individualized Remedy' where each person's clinical presentation requires specific remedies that may differ from one individual to another even when the two present the same illness. The third principle, Homeopathy is the *Minimum Dose* where the smallest doses are utilized and the fourth principle, Homeopathy is *The Potentized Remedy*, a principle of multiple dilutions, high potency remedy containing just nothing quantifiable of the original substance before dilution (Sehon & Stanley, 2009).

Naturopathy

Like Homeopathy, Naturopathy originated from Germany and its philosophy prioritizes the most natural, least invasive, and least toxic therapies to treat illness, and promotes wellness by viewing the body as an integrated whole. The principles of Naturopathy are, *Do No Harm* (*Primum non nocere*): Naturopathic physicians choose the most non-invasive and least toxic treatments necessary for each patient, *The Healing Power of Nature* (*Vis medicatrix naturae*): Naturopathic doctors recognize the body's inherent ability to heal itself, *Identify and Treat the Causes* (*Tolle causam*): Naturopathic doctors identify, address and remove the underlying causes of disease, *Doctor as Teacher* (*Docere*): Educating and supporting patients on personal health management is an important role for naturopathic doctors (Wardle et al., 2013). They empower patients to take responsibility for their health. They also acknowledge the therapeutic value inherent in the doctor-patient relationship, *Treat the Whole Person* (*Tolle totum*): This is a holistic concept that recognizes the body as an integrated whole. Naturopathic doctors treat the patient, not the disease. A naturopathic assessment addresses the nutritional status, lifestyle, family history, physical, mental, emotional, genetic, environmental, and social factors in a person's life, *Prevention* (*Praevenic*): Naturopathic doctors promote a focus on overall health, wellness, and disease prevention.

Osteopathy

Originated from North America, Osteopathy is an alternative therapy where practitioners apply hands to tissues, muscles, and bones to correct body elements. Body manipulation allows the body to adjust and regain its normal function. Like many other TCM disciplines, Osteopathy sees diseases as consequences or manifestations of an abnormal function of cells caused by an abnormal structure of the body, itself resulting from an abnormal environment (Evans, 2013). The osteopath stands between the cause of the disease and its manifestation helping the body to regain its normal function for acute disease and to better adapt to chronic conditions.

Traditional Chinese Medicine

Yin and Yang are the basis of Traditional Chinese Medicine. It is the concept that opposing forces (Qi) are complimentary, essential, and need to exist in balance and harmony for optimal health. Traditional Chinese Medicine products are used to balance those opposing forces by increasing or decreasing either way according to the diagnosis. Traditional Chinese Medicine is among the oldest philosophies of medicine and together with Acupuncture and Herbal Medicine among the most widely used forms of TCM in the world. In the main principle and philosophy of Yin and Yang, equilibrium between body and mind forces as explained by Jaeger, (2013), neurological and physical elements of the body are described.

Unani medicine

A combination of Greek and Arabic principles of medicine, Unani Tibb's medicine philosophy is that the well-being of the body is achieved when the seven principles are in harmony. The principles include arkan, or elements, Minaj, or temperament, akhlat, or bodily humor, aaza, or organs and systems, arwah, or vital spirit, quwa, or faculties or powers, and afaal, or functions. Interacting with each other, these seven natural components maintain the balance in the natural constitution of the human body. Everyone's constitution has a self-regulating capacity or power, called tabiyat. The outcome of the Unani Tibb treatment is to have the seven principles in equilibrium. These principles are taken into consideration for a Tibb physician to diagnose and treat patients who appear to be different and require different treatment (Hoosen, 2017). Tibb physicians must determine Temperaments when treating patients as Sanguineous, Phlegmatic, Bilious, and Melancholic.

CHAPTER THREE

This chapter presents and details different methods, techniques, and procedures that were used to collect and analyze data that are needed to meet the aim of this study which consists of evaluating the status and progress made towards the harmonization and regulation of TCM in Africa and the challenges that the harmonization of TCM might be encountering in African countries.

3. Methodology:

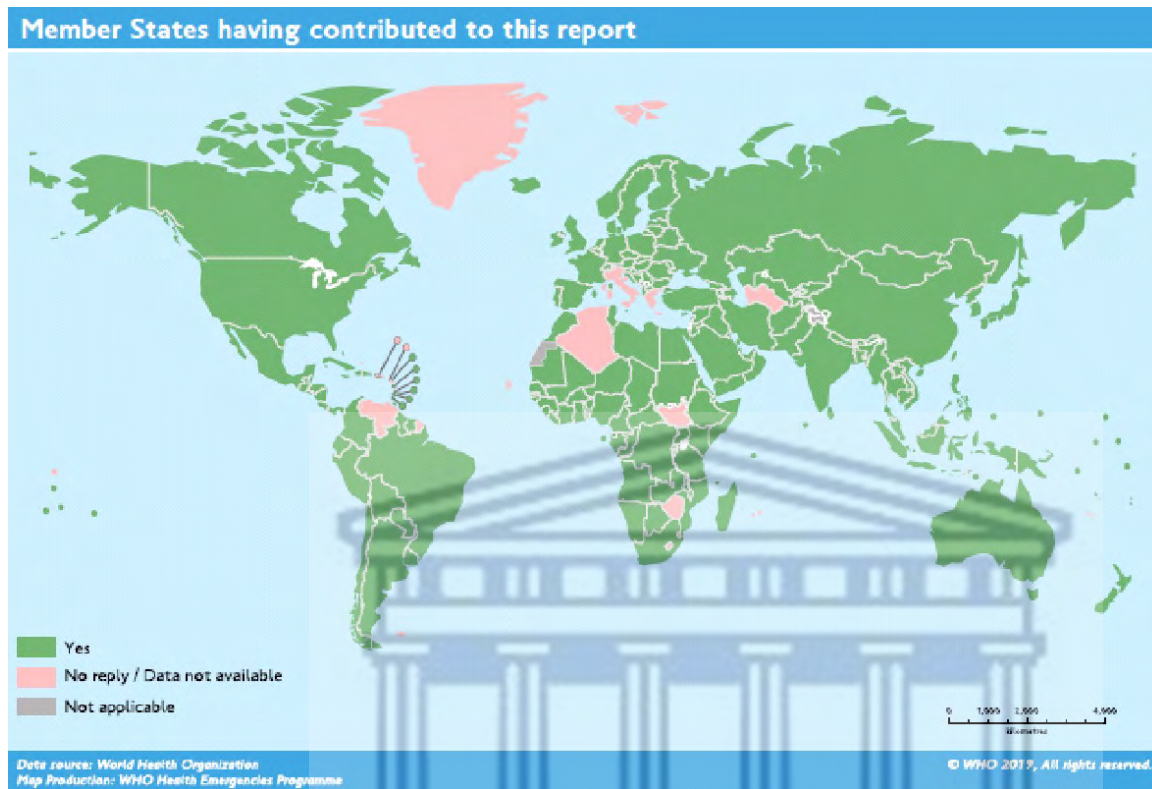
3.1. Study design:

Since this study aimed at evaluating secondary data that was provided in the WHO global report of 2019 on TCM, desk research on the status of African countries in adopting and implementing the WHO, TCM indicators was conducted. To find similarities that drive progress towards the harmonization of TCM regulation in Africa, the aim of the study, from the secondary data collected, the researcher wants to assess to 'what extent' African countries have implemented TCM, and according to Kim et al, (2017), a qualitative descriptive design best answers such a question, hence a descriptive approach was used in this study.

3.2. Sample population and size:

The sample population that was used in the WHO global report consists of 179 countries (see Figure 2.2 below) which were classified into 6 regions, namely WHO African Region, WHO Region of the Americas, WHO Eastern Mediterranean Region, WHO European Region, WHO South-East Asia Region and WHO Western Pacific Region. However, since this study focused on African countries, only a sample of 28 countries was used. Concerning the data sampling method, the study adopted purposive sampling which consists of deliberately selecting the sample that can provide important information that cannot be obtained from other cases or respondents (Taherdoost, 2016). Thus, this sampling strategy was important as it allowed the researcher to only focus on African countries, while exploring the implementation and harmonization of TCM, from 179 WHO Member States to 48 WHO African countries. These 48 African WHO Member states were further narrowed to only 28 African countries that responded to the third (2012-2018) WHO survey. It also allowed the researcher to exclude other African countries counted into other WHO regions, namely Morocco, Somalia, Sudan, and Tunisia, counted in the WHO Eastern Mediterranean Region.

Figure 2.2: List of countries that participated in the WHO global report of 2019.
Source: WHO (2019:11)



3.3. Data collection procedures:

The first step consisted of reading the (WHO, 2019) global report to understand and locate any information that might correspond to the aim of this research. Thirty WHO TCM indicators were identified, and categorized into general indicators (1), herbal medicine regulation (2), herbal medicine safety indicators (3) and indicators on TCM practices and providers (4). The indicators were then numbered from 1 to 30. The extent to which African countries have adopted and implemented those indicators, was measured in the second step, by recording the figures provided by each country's responses to different WHO indicators. The responses were tabled, with symbols: √ for 'Yes'; x for 'No' and 0 where no information was provided. The African countries' responses were summarized in Table II.1; Table II.2a; Table II.2b and Table II.3.

3.4. Data analysis:

The answers given by each country to each WHO indicator and collected in the tables were analyzed. Neergaard et al. (2009) stated that when a researcher needs to stay closer to the data and as opposed to other qualitative approaches, the qualitative description allows to retain the original information as given by the respondent. For this study, the researcher analyzed the information as summarized in the tables and deduced the reflection of

what the countries themselves put forward as to the adoption and implementation of WHO TCM indicators. As described by Bradshaw et al. (2017), a “straight description” of the data in the qualitative descriptive research allows the researcher to analyze the quantifiable data available in the study. In this research, the straight description allowed the researcher to analyze the quantifiable data such as the number of indicators African countries have adopted /implemented individually and in common and was able to assess and deduct how those indicators can be the drivers for TCM regulation and harmonization in Africa.



CHAPTER FOUR

In this chapter, the summary of the findings from the reviewed WHO TCM report are presented, analyzed, and discussed in the context of the aim and objectives of this study.

4. Results and Discussion

4.1. Results

Table I: A list of categorized TCM indicators presented by WHO to countries through questionnaires.

Number	TCM WHO Indicator
Regulatory framework Indicators	
1	National Policy on TCM
2	National plan for TCM
3	National office for TCM
4	Expert Committee for TCM
5	Funding for TCM
6	National Research Institute
7	Insurance coverage of TCM
8	Integration of TCM in healthcare system
9	TCM laws and regulations
Herbal medicine safety and regulation	
10	Classification of herbal medicine
11	Claims made about herbal medicine
12	Use of Pharmacopeia
13	Use of Monographs
14	Registration of herbal medicines
15	Herbal medicines in the NEML
16	Safety of TCM products inspection
17	Post-market surveillance system
18	GMP
19	TCM products sold in pharmacies
20	TCM products sold outside pharmacies
21	TCM products sold as herbal medicines
22	TCM products sold as supplements
Providers, practices indicators	
23	Training- Education of TCM providers
24	Practice requires license or certificate
25	Presence of imported practices
26	Presence of statistics of people using TCM
27	Health insurance on TCM
28	TCM practice in public sector
29	TCM practice in private sector
30	TCM practice from home

Table II. 1: African countries responses to WHO framework indicators.

African Countries	Regulatory framework indicators (1-9)								
	1	2	3	4	5	6	7	8	9
Benin	√	√	0	X	√	√	0	√	√
Burkina Faso	√	X	X	X	X	√	X	√	√
Burundi	√	√	√	0	X	√	0	X	√
Cameroon	√	√	√	√	0	√	0	√	√
Cent Afri Rep	√	√	√	√	X	√	X	√	√
Chad	√	√	√	√	X	√	X	√	√
Comoros	√	√	√	X	X	√	0	X	√
Congo	√	√	√	X	X	X	X	√	√
Côte d'Ivoire	√	√	√	√	X	X	X	X	√
DR Congo	√	√	√	√	X	√	0	√	√
Eq-Guinea	√	√	√	X	X	√	0	X	√
Eritrea	√	√	√	X	X	X	X	X	√
Ethiopia	√	√	√	X	X	√	X	X	√
Gabon	√	√	0	X	X	X	X	X	√
Gambia	√	√	√	√	X	X	0	X	√
Ghana	√	√	√	√	√	√	X	√	√
Guinea-Bis	√	√	√	X	X	X	X	X	√
Liberia	√	√	√	X	X	X	X	X	√
Madagascar	√	√	√	√	√	√	0	X	√
Mali	√	√	√	√	√	√	0	√	√
Mozambique	√	√	√	√	√	√	0	√	√
Namibia	√	√	X	X	X	√	X	X	√
Niger	√	√	X	X	X	X	X	X	√
SaoTom Princ	√	√	X	X	X	X	X	X	√
Senegal	√	√	√	√	X	X	X	X	√
South Africa	√	√	√	√	√	√	√	X	√
Uganda	√	√	√	X	X	X	X	X	√
Tanzania	√	√	√	X	X	√	X	X	√
Total (√)	28 of 28	27 of 28	22 of 28	16 of 28	6 of 28	17 of 28	1 of 28	10 of 28	28 of 28

1. National policy, 2. National plan, 3. National office, 4. Expert committee, 5. TCM funding, 6. National research institute, 7. Insurance coverage, 8. Integration of TCM in the healthcare system, 9. TCM laws and regulation (√= present, 0 = non- present, X= not specified by the report).

Table II.2a. Herbal medicine regulatory indicators.

African countries	Herbal medicine regulation (10-15)					
	10	11	12	13	14	15
Benin	√	√	X	√	√	X
Burkina Faso	√	√	√	√	√	√
Burundi	√	√	X	X	√	X
Cameroon	√	√	X	√	√	√
Cen Afri Rep	√	X	X	X	X	0
Chad	√	X	√	X	X	0
Comoros	√	X	X	X	X	X
Congo	√	X	X	X	X	X
Côte d'Ivoire	√	X	√	√	√	X
DR Congo	√	√	√	√	√	√
Eq Guinea	√	0	0	√	√	0
Eritrea	X	√	X	X	X	X
Ethiopia	√	√	X	X	√	X
Gabon	X	X	X	X	X	X

Gambia	X	X	X	X	X	X
Ghana	√	√	√	√	√	√
Guinea-Bissau	√	√	X	X	X	X
Liberia	X	X	X	X	√	X
Madagascar	√	√	√	√	√	√
Mali	√	√	√	√	√	√
Mozambique	X	X	√	√	X	X
Namibia	X	X	X	X	X	X
Niger	√	√	X	X	X	√
Sao Tome Pr.	X	X	X	X	X	X
Senegal	√	√	√	X	√	X
South Africa	√	√	√	√	X	X
Uganda	√	X	X	X	X	X
Tanzania	√	X	X	√	√	X
Total (√)	21 OF 28	14 OF 28	10 OF 28	12 OF 28	14 OF 28	7 OF 28

10. Classification of herbal medicine, 11. Claims made about herbal medicine, 12. Use of pharmacopeia, 13. Use of monograph, 14. Registration of herbal medicine, 15. Inclusion of herbal medicine in the NEML. (√= present, 0 = non- present, X= not specified by the report).

Table II.2b. Herbal medicine safety indicators

African Countries	Herbal medicine safety indicators (16-22)						
	16	17	18	19	20	21	22
Benin	√	√	√	√	√	√	X
Burkina Faso	√	√	√	√	√	√	X
Burundi	0	0	0	√	√	√	X
Cameroon	√	√	√	√	√	√	√
Cent Afr Rep	√	0	0	√	√	√	X
Chad	X	X	X	X	X	√	X
Comoros	X	X	X	√	√	√	X
Congo	X	X	X	X	√	√	X
Côte d'Ivoire	√	√	√	√	√	√	X
DR Congo	√	X	√	√	√	√	√
Eq Guinea	X	X	X	X	√	√	X
Eritrea	X	X	X	X	X	√	X
Ethiopia	X	X	X	√	√	√	X
Gabon	X	X	X	X	√	√	X
Gambia	X	X	X	X	√	√	X
Ghana	√	√	√	√	√	√	√
Guinea-Bis	X	X	X	X	√	√	X
Liberia	X	X	X	√	√	√	X
Madagascar	√	√	√	√	√	√	√
Mali	√	√	√	√	√	√	√
Mozambique	√	√	√	√	√	√	√
Namibia	X	X	X	√	√	√	X
Niger	X	X	X	√	√	√	√
Sao Tome Pr	X	X	X	√	√	√	X
Senegal	√	√	√	√	√	√	√
South Africa	√	X	√	√	√	√	√
Uganda	√	√	√	√	√	√	X
Tanzania	√	X	√	√	√	√	X
Total (√)	14/28	10/28	13/28	21/28	26/28	28/28	9/28

16. TCM safety inspection, 17. Post market surveillance system, 18.GMP, 19. TCM products sold in the pharmacy, 20. TCM products sold outside pharmacy, 21. TCM products sold as herbal medicine, 22. TCM products sold as supplements. (√= present, 0 = non- present, X= not

specified by the report)

Table II.3: TCM provider and practice indicators

African Countries	Providers, practices indicators (23-30)							
	23	24	25	26	27	28	29	30
Benin	X	√	√	√	X	0	√	0
Burkin Faso	X	√	√	√	√	X	√	X
Burundi	X	X	√	X	X	X	√	√
Cameroon	X	√	√	√	0	X	√	X
Cent Af Rep	X	√	√	X	X	0	√	0
Chad	X	X	√	√	X	√	√	X
Comoros	X	X	√	X	X	X	√	X
Congo	X	X	√	√	X	√	√	X
Côte d'Ivoire	√	X	√	√	X	X	√	X
DR Congo	X	√	√	X	X	√	√	X
Eq Guinea	X	√	0	√	X	0	0	0
Eritrea	X	√	0	X	X	0	0	X
Ethiopia	X	√	X	√	X	X	√	X
Gabon	X	√	√	√	X	X	X	√
Gambia	X	√	√	X	X	X	√	X
Ghana	√	√	√	√	√	√	√	√
Guinea-Bis	X	0	X	X	X	X	X	√
Liberia	X	√	√	√	X	√	√	X
Madagascar	√	√	√	√	√	√	√	√
Mali	√	√	√	√	√	√	√	√
Mozambique	√	√	√	√	X	X	√	X
Namibia	X	X	√	X	X	X	√	X
Niger	X	0	0	X	X	X	√	X
Sao Tom Pr.	X	X	√	X	X	X	√	X
Senegal	X	X	√	X	X	√	√	X
South Africa	√	√	√	√	√	X	√	√
Uganda	X	0	√	√	X	X	√	X
Tanzania	√	√	√	X	X	X	√	X
Total (√)	6/28	17/28	23/28	16/28	5/28	8/28	24/28	7/28

23. Training, education of TCM providers, 24. License, certificate required, 25. Presence of imported practice, 26. Statistics of people using TCM, 27. Health insurance on TCM practices, 28. TCM practice in public sector, 29. TCM practice in private sector, 30. TCM practice from home. (√= present, 0 = non- present, X= not specified by the report)

4.2. Discussion

For the TCM regulatory framework indicators, the findings show that all African countries were able to implement a national policy for TCM and have established laws and regulations towards TCM. Furthermore, all countries except Burkina Faso have a national plan, while 22 out of 28 countries (78%) have established a national office. An expert committee and a national research institute have been implemented in 16 and 17 out of 28 countries (57% and 60%) respectively. However, only 1 country, South Africa, 6 out of 28 and 10 out of 28 countries respectively adopted/implemented insurance coverage, TCM funding and the integration of TCM in their health systems. These findings are in line with the literature, that many African countries have responded to the WHO's call to start TCM regulation and established laws, plans and policies.

The literature further showed that only a few African countries have funds set aside for TCM and as found in this study, only 20% of the respondents have a budget for TCM. The integration of TCM in the national health system is another important indicator of TCM regulation and the literature showed that countries that have integrated TCM, have been found to perform on more other TCM regulatory indicators, but only 35% of the African countries adopted/implemented the integration of TCM into their health system, suggesting a lesser adoption/implement of other TCM indicators.

Furthermore, for the national research institute and national committee, the findings provided in the report indicated that even for the few that are present, they are in universities providing degrees in health sciences or medicine. Examples of these include 'the African Pharmacopoeia and Traditional Medical Research Centre' which is at the University of Bangui in the Central African Republic, the Research Unit in Pharmacopoeia and Traditional Medicine of the University of N'Djamena in Chad, and the Centre for Research on Pharmacopoeia and Traditional Medicine of the University of Burundi (WHO, 2019). This is an indication of limited funding for those institutions where in most cases they must rely on university budgets that are themselves limited in many cases.

In the second category of indicators on the regulation of herbal medicines, the results show that 21 out of 28 African countries (75%) have herbal medicine classification. 14 out of 28 countries (50%) reported registering herbal medicine and herbal medicines are sold with claims. Only 12 and 10 out of 28 countries (42% and 35%) use monographs and pharmacopoeias respectively and only 7 countries (25%) have included herbal medicine on their NEML. The mechanisms in place to classify herbal medicine are in line with many African countries having national plans, laws, and regulations for TCM, and half of the respondents have their herbal medicine registered and sold with claims. However, countries underperformed on indicators for safety control, such as the use of monographs and pharmacopoeia. This is in line with the literature that showed that in many African countries, herbal medicines are sold uncontrolled in open markets in the streets, and only a few countries have included herbal medicines on their NEML. Even where efforts to register herbal medicines are remarkable, the inclusion on the NEML is still slow. For example, Burkina Faso registered 13 herbal medicines but only 4 were added to the NEML in 2012 while in Cameroon only 3 of the 41 registered herbal medicines were registered in the NEML (WHO, 2019).

This also explains how low TCM project funding blocks the implementation of other indicators.

Moreover, for the following indicators, the GMP of herbal medicines (i.e. the use of accepted medicinal plant species, the procedures followed and material or instruments used when manufacturing and storing products, cleaning and sanitation methods used); the post-market surveillance system or inspection for the safety of herbal medicines after they have been used or sold; places where providers are allowed to sell TCM products and how these are to be sold; results show that only 14 out of 28 countries (50%) inspect on TCM safety, 10 out of 28 countries (35%) perform a post-marketing surveillance, 13 out of 28 countries (46%) observe GMP in their TCM manufacturing, and 9 out of 28 countries (32%) herbal medicines are sold as supplements. The literature has shown that many side effects, herb-drug interactions, herbal medicine contamination and adulterations are among the problems consumers are exposed to. All countries (100%) reported the sale of medicines as herbal medicines mostly in natural forms such as dried, crushed herbs, roots, fruits, and other parts of plants. These findings explain that situation, as only a few African countries inspect the manufacturing, and the post-market surveillance and demonstrate that the herbal medicine manufacturing into other forms such as tablets, capsules, and tinctures is still low.

The category of herbal medicine sold as supplements implies manufacturing or the sale of imported TCM supplements. Only 9 countries implemented the indicator, implying that in many cases, herbal medicines are not categorized as prescription or non-prescription medication and no claims or information such as medical, or nutritional claims are given to the consumers. However, the fact that in 21 out of 28 countries (75%), herbal medicines are sold in the pharmacies. The majority of the TCM products sold in pharmacies or health shops are manufactured in different forms such as tablets, capsules, powders, and tinctures. In 26 out of 28 countries, sales are done in other outlets such as health shops.

In addition, the pharmacopoeia and monographs used in the African countries are borrowed from other countries and in many cases, the monographs used such as in Benin and Ivory Coast, are not legally binding. Only very few countries such as Ghana and DRC responded to have and use their own pharmacopoeia, others use mostly African Union, European, Brazilian, United States, and British pharmacopoeias. Most of these pharmacopoeias are used in African TCM for herbal medicine from outside of Africa.

Countries which use pharmacopoeia and monographs show better performance in implementing WHO indicators. The progress and development of herbal medicine require reference to pharmacopoeia (Fitzgerald et al. 2020). As for the monographs, the WHO monographs on selected medicinal plants are used especially where the monographs are legally binding (WHO, 2006).

The TCM practitioners and providers need education or training for their profession. The TCM professionals need a license, a degree, or a certificate to practice TCM. Other incentives to regulate TCM include the increase of imported TCM practices, need of record-keeping of people using TCM, the health insurance of TCM, the settings in which TCM providers can practice or deliver their services. The results show that 23 out of 28 countries (82%) reported to have imported TCM practices, 16 out of 28 countries (57%) have statistics of

people using TCM, 5 out of 28 countries (17%) insure TCM services, 8 out of 28 countries (28%) practice in public sector, 24 out of 28 countries (85%) practice in private sector and 7 out 28 (25%) practice at home. Despite all the incentives and many more, the results show that only 6 out of 28 (21%) have training/education system for TCM providers; 17 out of 28 countries (60%) of the countries require license or certificate for TCM providers to practice.

The only 6 countries that adopted and implemented training and education is in line with the literature that showed that only few African countries provide TCM education or training. Worthy to note that among the respondents, Ghana and Madagascar are the only countries that offer training on African traditional medicine at the university level. Even among the countries that responded to have training and education towards TCM, some such as South Africa offer training on imported disciplines such as Homeopathy, Chiropractic, and Osteopathy through some South African Universities, but not on Indigenous African Traditional Medicine. As one of the key indicators, the failure to implement it, negatively impacts on the advancement of other indicators. This is the case for insurance of TCM practices implemented by only 5 countries.

Only 57% of the countries that participated in the WHO global report, reported on the statistics or record keeping of the TCM users, however, in the same report, 88% of African countries reported the use of TCM. This discrepancy shows that countries were unable to precisely provide the correct statistics of TCM users, speaking to difficulties such countries may encounter to properly plan and establish programs appropriate to TCM regulation and make it difficult for the decisionmakers to provide educated decisions such as TCM funding. For countries that reported on their statistics, a good number of people use TCM products or services. Countries such as Gabon, Benin and Congo reported the highest number of users (80-99%). In few countries (28%) TCM practices are integrated, and the services are delivered from the public settings as opposed to 85% in private, this is in line with the literature findings and explains why TCM practices funding from the public sector is still low.

CHAPTER FIVE

5. Conclusion, Recommendations, and Limitations

5.1. Conclusion:

For the aim of the study, to review the reported status of TCM regulation in selected African countries and find similarities that drive progress towards the harmonization of TCM regulation in Africa, the study found remarkable performance in adopting and implementing some of the WHO indicators on TCM regulatory framework, herbal medicine safety regulation, and TCM providers and practices. The similarities that drive progress towards harmonization are highlighted by the adoption/implementation by 75% to 100% of the countries (21 to 28 out of 28 countries) of 33% (10 out of 30) WHO indicators namely: Regulatory framework (1): national policy, national plan, national office and TCM laws and regulation; Herbal medicine safety regulation (2): classification of herbal medicine, TCM products sold in pharmacies, TCM products sold outside pharmacies, and TCM products sold as herbal medicine and TCM providers and practices (3): presence of imported practices and TCM practices in private sector. The number of indicators adopted/implemented by majority of countries is still low. A lot must be done, and African countries must speed up the adoption and implementation of more WHO indicators.

The study assessed the extent to which individual countries have performed against the indicators and found that the level of progress differs from country to country and for different indicators leading to the conclusion that the WHO African region is still far behind in achieving TCM harmonization. Very little progress was made for the funding, insurance coverage of TCM, and health insurance of TCM practices indicators, only 1 to 6 out of 28 countries indicated the adoption/implementation of those indicators, meaning that the funding of TCM programs is still a problem and a challenge to TCM progress in African countries. Equally, countries have poorly adopted/implemented the training and education of TCM providers, the inclusion of herbal medicine on the NEML, herbal medicine manufacturing and TCM practices in the public sector. Only 5 to 9 out of 28 countries performed on those indicators. These are among the driving indicators and failing to adopt/implement them block the progress of other indicators.

As for challenges, the lack of funding and financial support for TCM programs, lack of training and education of TCM providers, and the lack of proper regulation of herbal medicine are common in the African countries. The lack of funding and financial support for TCM programs creates a vicious cycle for TCM status in African countries. For example, the lack of funds causes the lack of training/education of TCM providers, which in turn negatively impacts on the advancement of other TCM indicators that need expertise to progress.

5.2. Recommendations:

TCM practices and products are as they have been and will continue to be part of health systems in many African countries, and it is critical for their harmonized recognition, integration, and regulation. Additionally, job creation, research and development, safety of TCM and consumer protection are among many incentives to TCM regulation. Governments, decision-makers, and all stakeholders must prioritize, and provide financial support to TCM programs as they do for conventional medicine. It is a positive note that many African countries have now their NMRA's mandated to work towards improving access to medicines. As they are striving to fully function, they should include TCM in their plans and consider it as one of the solutions to the chronic lack of access to medicine in Africa.

Equally, the efforts that are being made throughout African for free trade, as well as some collaboration among some regional blocks such as SADC and EAC in regulation and harmonization of conventional medicine, information exchange and movement of health products should be emphasized and enabled in all African subregions and include TCM on board. Without a collaborative and inclusive health systems, it will remain difficult for individual countries to make significant progress towards TCM regulation and eventual harmonization.

For any product, device, provider as well as technique, or practice to be registered in conventional medicine, it must be regulated after being scientifically tested and proved to be up to standard and the same should be applied to TCM. However, as the two health systems are different in their philosophies whereby TCM is commonly based on many years of use and acceptance while conventional medicine is scientific evidence-based, it will remain difficult for TCM to meet the requirements for regulation. A different appropriate approach should be applied to scientifically measure TCM for regulation and registration. Discussing this matter, (Kovic, 2016) found that the real problem lies in the epistemological framework of the two systems and tests should be done within the framework of the system, thus, for instance, TCM claims should be tested within the epistemological framework of TCM. Furthermore, and for that matter, countries should spare no efforts in setting apart an education proper to TCM.

5.3. Limitations:

Secondary data were used in this mini-thesis with the disadvantage of not having specific information available to the researcher. Furthermore, some countries have not responded to all the WHO surveys, and only 28 out of 48 WHO member states participated in the third survey, which made it difficult to follow up on information provided in the surveys they participated in, leading to limited information for this study.

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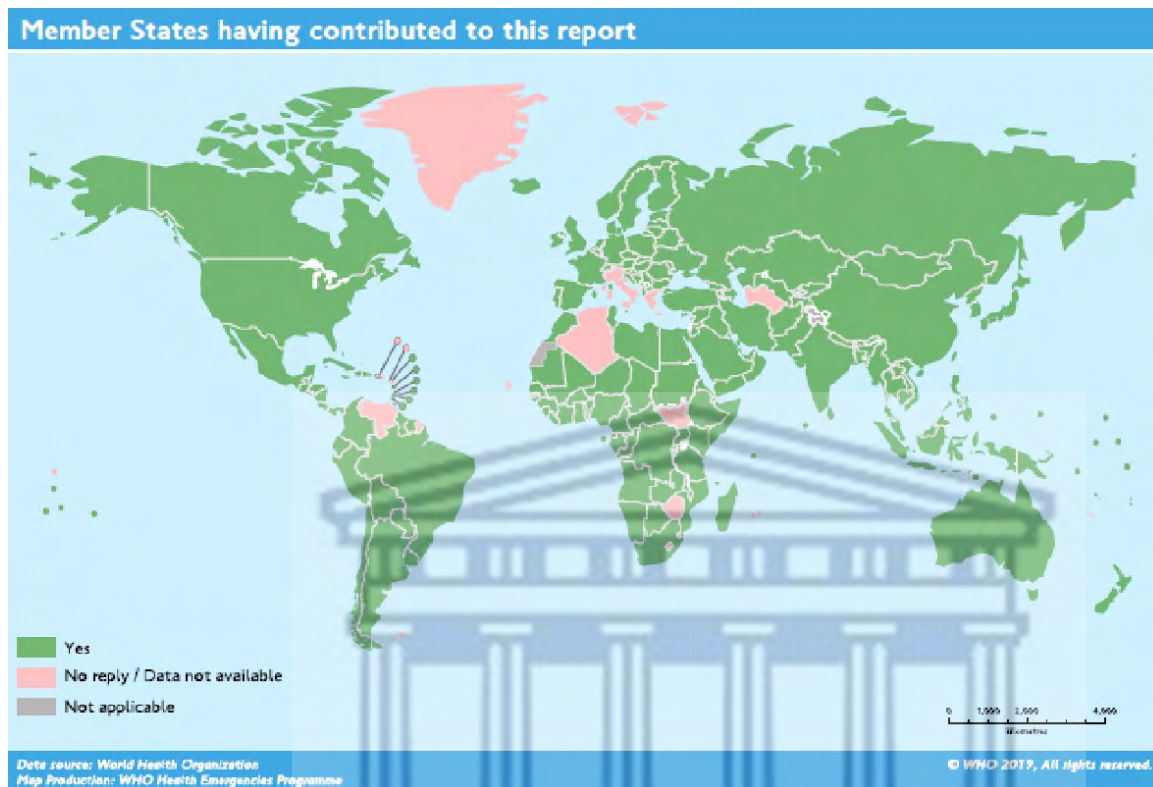
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Appendices

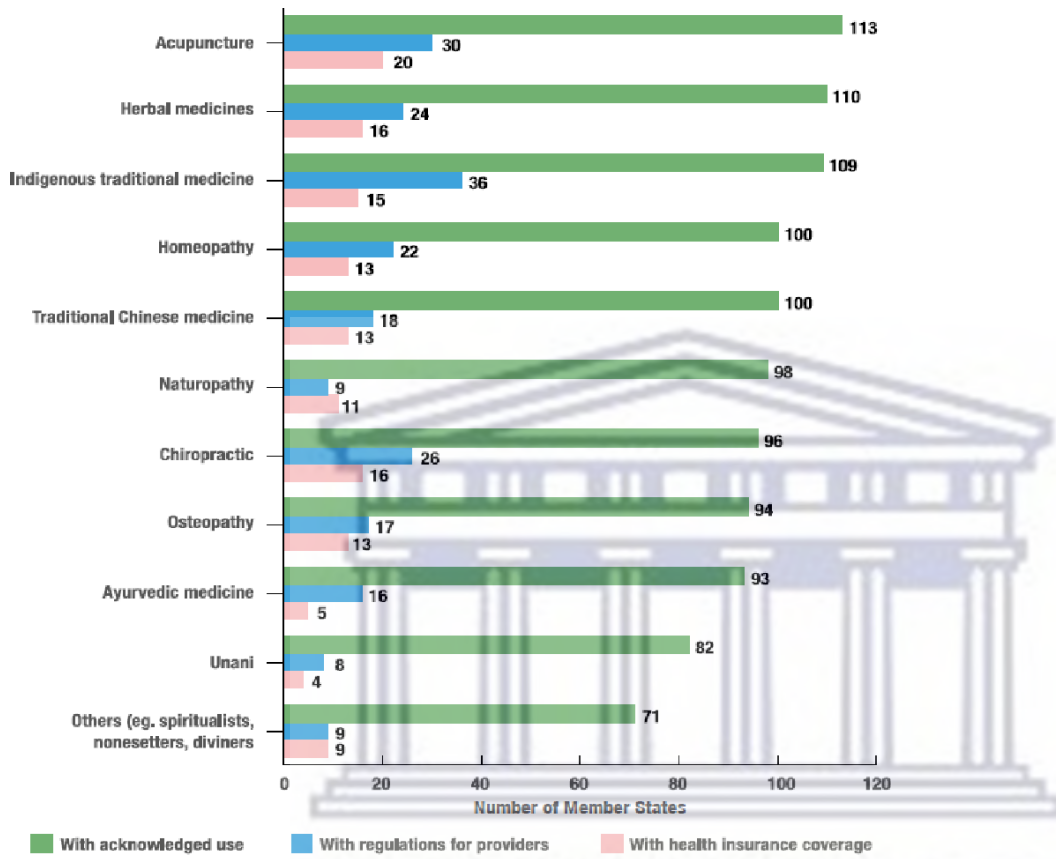
Countries that responded to the WHO global report 2019



Source: WHO (2019:11)

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Typology of TCM practices as reported by WHO



Source: WHO (2019:55)

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