

## REGULATORY STATUS OF TRADITIONAL MEDICINES IN AFRICA REGION

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### ABSTRACT

Although modern medicine is well developed in most of the world, large sections of the population in developing countries still rely on the traditional practitioners, medicinal plants and herbal medicines for their primary care. Moreover during the past decades, public interest in natural therapies has increased greatly in industrialized countries, with expanding use of medicinal plants and herbal medicines.

The many and various forms of traditional medicinal products have evolved against widely different ethnological, cultural, climatic, geographical, and even philosophical backgrounds. The evaluation of these products and ensuring their safety and efficacy through registration and regulation present important challenges.

The purpose of this document is to share national experiences in formulating policies on traditional medicinal products and in introducing measures for their registration and regulation, and to facilitate information exchange on these subjects among Member States.

**KEYWORDS:** Traditional Medicines, Ayurveda, Africa, Herbal & WHO.

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### INTRODUCTION

Herbal medicine also called botanical medicine or phytomedicines refers to using a plant's seeds, berries, roots, leaves, bark, or flowers or whole plant for medicinal purposes. Herbalism has a long tradition of use outside of conventional medicine.

Herbal medicine is used to treat many conditions, such as asthma, eczema, premenstrual syndrome, rheumatoid arthritis, migraine, menopausal symptoms, chronic fatigue, and irritable bowel syndrome, among others. Herbal supplements are best taken under the guidance of a trained health care provider.<sup>1</sup>

Literature produced in Ancient Egypt, China, India, and Europe<sup>2</sup> were based on the wisdom accumulated by herbalists, apothecaries and physicians,<sup>3</sup> these were the first books that were published in both China and Europe. In Western Europe herbals flourished for two centuries that is between 1470–1670.<sup>4</sup>

The late 17th century marked the rise of modern chemistry, toxicology and pharmacology and decreased use of medicinal value of the classical herbal, as reference manuals for botanical study and plant identification herbals were supplanted by Floras systematic accounts of the plants found growing in a

particular region, with scientifically accurate botanical descriptions, classification, and illustrations.<sup>5</sup>

Herbals have seen a modest revival in the western world since the last decades of the 20th century, as herbalism and related disciplines (such as homeopathy and aromatherapy) became popular forms of complementary and alternative medicine. As a result of improvements in analysis and quality control along with advances in clinical research which reveals the value of herbal medicine in the treating and preventing disease. Because of this awareness a major percentage of the medicinal spending which were prior spent on allopathic drugs have siphoned to traditional medicines.<sup>6</sup>

This has worked as the catalyst for the manufacturer of herbal drugs to look for prospective markets and thus thrusting the Medical agencies to streamline their regulatory policies to cater to the ever increasing influx.

### Regulation and Registration of Herbal Medicines

The legal situation regarding herbal preparations varies from country to country. In some, phytomedicines are well-established, whereas in others they are regarded as food and therapeutic claims are not allowed. Developing countries, however, often have a great number of traditionally used herbal medicines and much folk-

knowledge about them, but have hardly any legislative criteria to establish these traditionally used herbal medicines as part of the drug legislation. For the classification of herbal or traditional medicinal products, factors applied in regulatory systems include: description in a pharmacopoeia monograph, prescription status, claim of a therapeutic effect, scheduled or regulated ingredients or substances, or periods of use.

In most parts of Africa, herbal products sold in public places lack scientific evidence for safety, efficacy and quality. In response to lack of scientific awareness WHO developed generic guidelines on various aspects of the development of herbal medicines including generic regulations and law, consequently the situation is changing.

These guidelines have been expressly developed in order to facilitate the registration, marketing and distribution of traditional medicines of assured quality in the WHO African region.

This document is particularly relevant to those countries that have already put in place mechanisms for the registration of traditional medicines. Use of this classification system should assist the work of national drug regulatory authorities when undertaking the assessment of the documentation submitted with the applications for registration of herbal medicines<sup>7</sup>.

### **Specific Objectives**

The specific objectives of the guidelines are as follows:

1. To propose a classification scheme for traditional medicines;
2. To propose general minimum regulatory requirement for the registration of traditional medicines.
3. To formulate proposals for facilitating the introduction of safe and effective traditional medicines of consistent quality into the African market.

### **Classification of traditional medicines**

Four categories of traditional medicines, based on their mode of preparation, the indication, and the extent of the development of the medicine relative to the traditional remedy used, are thus distinguished as set out below.

#### **Category 1**

Category 1 traditional medicines are medicines that have been prepared by traditional health practitioners for the treatment of individual patients; they have the following characteristics:

- Prepared in an extemporaneous manner and according to traditional methods;
- Safety and efficacy are justified by a long period of use;

#### **Category 2**

A category 2 traditional medicine is one that is widely used in the community but has a commercial possibility. It is characterized as follows;

- Traditionally used in a given locality and very well known by the local population, both in terms of composition and treatment;
- The formulation is well known and its preparation is according to traditional methods;
- Safety and efficacy are justified by a long period of use

#### **Category 3**

A category 3 traditional medicine is one that has been developed through scientific research. It has the following characteristics:

- It has been developed by research based on ethno-medical use;
- The formulation, dosage, dosage forms and therapeutic use are based on research data;
- Safety and efficacy are based on research data derived from standard scientific and clinical investigations.

#### **Category 4**

Category 4 traditional medicines are imported traditional medicines, and as such are distinguished by the following;

- It originate from a foreign country, either within or outside the WHO African region;
- It should meet the definition of a traditional medicine;
- It should be registered in the originating country;
- It should meet the requirement for the regulation of traditional medicines of the country into which it is being imported<sup>7</sup>.

### **Registration Requirement in Africa Region**

Where herbal medicines and related products are neither registered nor controlled by regulatory bodies, a special licensing system is needed which would enable health authorities to screen the constituents, demand proof of quality before marketing, ensure correct and safe use, and also to oblige licence holders to report suspected adverse reactions within a post-marketing surveillance system<sup>8</sup>.

### **SOUTH AFRICA**

South Africa regulates general traditional healers, herbalists, chiropractors, homeopaths, osteopaths, and naturopaths under the Associated Health Service Professions Act of 1982, as amended<sup>9</sup>. This Act sets up a registration and licensing scheme for various professions. Registration entitles medical providers to practise for gain and call themselves members of that profession. Practice for gain by a non registered person is an offence

punishable by a fine and/or imprisonment of up to one year.

To qualify as a traditional healer, one has to serve an apprenticeship of between one and five years and must be well known within the community one serves and amongst other traditional healers. Qualified traditional healers register with the Traditional Healers' Organization and are given a book to certify that they are qualified healers. The qualifications are valid in Africa, Asia, Latin America, Europe, and Australia<sup>10</sup>. However, Section 41 of the Associated Health Service Professions Act of 1982 states that the provisions of the Act shall not be read to "derogate from the right which a medicine man or herbalist contemplated in the Code of Zulu Law may have to practise his profession". The South African law also imposes restrictions on the professional nomenclature that can be adopted by traditional healers. Use of the title "Medical Practitioner", or a title suggesting that its holder is qualified as an allopathic medical practitioner, is prohibited.

#### **Legal Status**

The trade in crude indigenous herbal products is completely unregulated. However, once a health-related claim is made for a finished product, it has to go through the full drug evaluation procedure in the Medicines Control Council (MCC) before marketing<sup>11</sup>.

Specific regulations for registration and control of new "traditional" herbal medicines do not exist. Old medicines including some well-known herbal medicines, such as Senna or Aloes, are already registered by the MCC, according to internationally accepted standards of efficacy and safety. Pharmaceutical standards need to be consistent with those of the United States Pharmacopoeia (USP) or the British Pharmacopoeia (BP)<sup>12</sup>.

At present, there is no possibility for an abridged application procedure, and there is neither a list of therapeutic indication claims suitable for treatment with traditional medicines, nor a national herbal medicines formulary of a pharmacopoeia<sup>12</sup>.

Traditional medicines are included in the drug policy section of the government's Reconstruction and Development Programme. The Traditional Medicines Programme (TRAMED) at the Department of Pharmacology, University of Cape Town, participated in formulating an outline proposal for the registration and control of traditional medicines in 1994. The aims of TRAMED are promotion of the use of safe, effective and high quality "essential" traditional medicines, promotion of the documentation of traditional medicines and their scientific validation, contributing to primary health care through the provision of appropriate information to traditional healers and health professionals, support of

industrial development in this sector by local industry, and contributing to the training of traditional healers<sup>13</sup>.

#### **Republic of Benin**

The Republic of Benin established a national policy in 2002, a law or regulation Concerning TM/CAM was adopted in 2001, and a national programme on TM/CAM was put in place in 1999. ATM/CAM office has existed since 1997 under the Ministry of Health. The expert committee was established later in 2001. No national research institute exists for the study of TM/CAM and herbal medicines. Benin does not regulate herbal medicines; herbal medicines are classified only as over the counter medicines and for self medication and can be sold with medical, health, Nutrient content, and structure/function claims. No national pharmacopoeia or national monograph exists, although both are currently being developed. In the meantime, nothing is used. There are no regulatory requirements for manufacturing or safety assessment of herbal medicines. There is no system of registration and herbal medicines are not included on the essential drug list. No post marketing surveillance exists, though a system is being established. Herbal medicines are sold either as over the counter drugs in pharmacies, or without regulation<sup>14</sup>.

#### **Ghana**

The Traditional Medicine Practice Act 595 was drafted by traditional medical practitioners, placed before the Parliament in 1999, and passed on 23 February 2000. The Act establishes a council to regulate the practice of traditional medicine, register practitioners and license them to practice and to regulate the preparation and sale of herbal medicines.

The Act defines traditional medicine as "practice based on beliefs and ideas recognized by the community to provide health care by using herbs and other naturally occurring substances" and herbal medicines as "any finished labeled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant materials or the combination of them whether in crude state or plant preparation"<sup>15</sup>.

#### **Guinea**

In Guinea, Ordinance 189 PRG of 18 September 1984<sup>16</sup> states that the profession of physician can only be practiced by persons with a Guinean diploma of Doctor of Medicine, a foreign diploma granting equivalent status, or a foreign diploma that entitles its holder to practice medicine in his or her country of origin. Various activities that constitute the unlawful practice of medicine are set out in Section 9. However, traditional medicine seems relatively unaffected by this ordinance. Guinea has official, applied, legislative/regulatory texts governing the practice of traditional medicine. There is a

licensing process and a registry of traditional health practitioners as well as local and national inter-sectoral councils for traditional medicine. Local officials are allowed to authorize the practice of traditional medicine in their administrative and/or health subdivisions, and some traditional medicine practitioners are involved in Guinea's primary health care programme<sup>17</sup>.

#### **Kenya**

Traditional medicine started being incorporated into Kenya's national health policy framework in the late 1970s. Kenya's Development Plan 1989–1993<sup>18</sup> recognized traditional medicine and made a commitment to promoting the welfare of traditional medicine practitioners. The Ministry of Health and provincial authorities require the registration of traditional medicine practitioners. In 1999, Kenya's patent law was revised to include protection for traditional medicines.

#### **Mali**

The Department of Traditional Medicine is mandated to inventory medicinal plants and their indications, verify the therapeutic and toxic effects of the recorded plants, undertake studies to improve and standardize the forms of presentation of traditional medicines, train researchers in the fields of traditional medicine and traditional pharmacopoeia, involve traditional medicine practitioners in the politics of primary health care, write technical notices related to traditional medicine, and set up expert advisory missions for national and international institutions interested in traditional medicine in Mali.

An order issued by the Minister of Public Health and Social Affairs on 16 May 1980<sup>19, 20</sup> established a Scientific and Technical Committee to work in conjunction with the National Research Institute of Medicine and Traditional Medicine. The Committee, whose functions are defined in relation to the overall health care needs of the country, has drawn up draft regulations on the practice of traditional medicine.

#### **Mauritius**

The Ayurvedic and Other Traditional Medicines Act of 1989<sup>21</sup> governs traditional medicine in Mauritius. In this Act, traditional medicine is defined as "the practice of systems of therapeutics according to homeopathy, Ayurvedic, and Chinese methods". The central provisions of the legislation include the establishment of a regulatory body, the Traditional Medicine Board, and a registration system that requires practitioners to obtain a diploma in traditional medicine.

The registration system for traditional Chinese medicine practitioners requires applicants to hold a diploma in traditional medicine. Under Section 24, non-registered persons are not entitled to practise any act of traditional

medicine for gain, unless exempted from registration. However, no exemptions are listed in the Act. Unregistered persons are also prohibited from presenting themselves as registered practitioners. The Minister responsible for health has the power to make regulations, set out the basic qualifications required for studying traditional medicine, and establish the terms and conditions under which it may be practiced. The Minister also has the power to impose restrictions on the practice of any aspect of traditional medicine.

#### **Mozambique**

Mozambique does not have official legislative/regulatory texts governing the practice of traditional medicine, any licensing process for traditional health practitioners, or procedures for the official approval of traditional medical practices and remedies<sup>17</sup>. However, in 1991, a proposal was put forward for a three-year programme to establish a foundation for collaboration between the National Health Service and the practitioners of traditional medicine in Mozambique. The proposal suggested that traditional medicine practitioners constitute a separate, parallel, and self-regulating health service that collaborates with the Mozambique Government in the realization of specific public health goals. In this regard, the three-year programme would do the following:

- Establish workshops to train traditional medicine practitioners in the treatment of priority diseases;
- Establish a research-derived information base about traditional beliefs and practices;
- Educate Government health workers at all levels in traditional beliefs and practices;
- Coordinate research in traditional medicines, although, due to a tight budget, this research would not be funded by the Government itself.

Collaborative programmes with traditional medicine practitioners also take place under the umbrella of the Department of Health. In addition, there are a number of programmes sponsored by non-governmental organizations, most of which collaborate with either district or provincial health authorities<sup>22</sup>.

#### **Namibia**

The Official National Primary Health Care/Community-based Health Care Guidelines were launched in 1992.

The Council will be given the task of supervising and controlling the practice of traditional medicine practitioners, fostering research into traditional medicines, and making loans or grants available to traditional health practitioners. Traditional medicine practitioners in Namibia, many of whom come from other African countries, are not currently registered and operate without any guidelines from the Ministry of Health and Social Services.

### **Nigeria**

The Traditional Medicine Council of Nigeria Act looks after the functions of the Council which includes facilitating the practice and development of traditional medicine; establishing guidelines for the regulation of traditional medical practice to protect the population from quackery, fraud, and incompetence; liaising with state boards of traditional medicine to ensure adherence to the policies and guidelines outlined in the Federal Traditional Medicine Board Act; establishing model traditional medicine clinics, herbal farms, botanical gardens, and traditional medicine manufacturing units in the geopolitical zones of the country; and collaborating with organizations with similar objectives within and outside Nigeria. The Nigeria Medical Council is contemplating integrating homeopathy into the country's health care delivery system<sup>23</sup>.

### **Senegal**

Traditional medicine was officially recognized by the Government of Senegal in 1985<sup>24</sup>(55). Senegal has a registry of traditional health practitioners<sup>17</sup>. The Health Ministry advocates the promotion and rehabilitation of traditional medicine and traditional pharmacopoeia. There are official strategies and activities to encourage collaboration between traditional and allopathic medical practitioners.

### **Swaziland**

In Swaziland, the Control of Natural Therapeutic Practitioners Regulations of 1978<sup>25</sup> limits the definition of "natural therapeutic practitioner" to persons practicing chiropractic, homeopathy, naturopathy, or electropathy. The prohibitions on professional practice are similar to those in force in Lesotho. Some traditional medicine practitioners are involved with Swaziland's primary health care programme<sup>25</sup>.

### **Togo**

Togo's law on health practitioners holds exemptions in favour of providers of traditional medicine. In the first paragraph of Section 68 of the Criminal Code of 1980<sup>26</sup>(67), the definition of the illegal practice of medicine very closely reflects Article L 372 of the French Code of Public Health. However, the second paragraph of Section 68, states the following: "The above provisions do not apply to medical practitioners who practice according to traditional methods". Togo has a registry of traditional health practitioners. Some traditional medicine practitioners are involved with Togo's primary health care programme<sup>17</sup>.

### **Uganda**

The Government of Uganda has expressed interest in recognizing traditional health systems and has set up, under the Ministry of Health, the Natural

Chemotherapeutics Research Laboratory to study the therapeutic potential of natural products<sup>27</sup>. The intention is eventually to include in the National Health Service those products deemed efficacious. Research is conducted jointly with traditional medicine practitioners. The Government of Uganda is in the process of developing a health policy emphasizing primary health care. The Health Review Commission<sup>28</sup> recommended that the Ministry of Health work closely with traditional medicine practitioners to achieve the objectives of health for all by the year 2000. The Commission specifically recommended including traditional health practitioners as members of community health teams and welcoming them to participate in primary health care.

### **United Republic of Tanzania**

The Medical Practitioners and Dentists Ordinance<sup>29</sup>, which was constituted before Tanzania's independence and is still in operation, hold exemplary status for traditional practitioners. Chapter 92.20 states the following:

"Nothing contained in this ordinance shall be construed to prohibit or prevent the practice of systems of therapeutics according to native methods by persons recognized by the community to which they belong to be duly trained in such practice. Provided that nothing in this section shall be construed to authorize any person to practise native systems of therapeutics except amongst the community to which he belongs, or the performance of an act on the part of any persons practicing any such system which is dangerous to life".

In an effort to promote and standardize traditional medicine, the Government established the Traditional Medicine Research Unit in 1974 as part of the University of Dar es Salaam and the Muhimbili Medical Centre<sup>30</sup>. Looking at the present situation and proposal of countries to streamline the regulation of herbal care, Regulatory bodies in guidance of WHO has established a regulatory requirement list which is the minimal requirement to be facilitated to the ministry of health or the respective regulatory bodies.

For the manufacturer of foreign countries to market herbal health care preparation in their countries. The cumulative requirement for the all above mentioned countries are tabulated in the **table 1 and 2**.

### **CONCLUSION**

The growth of the pharmaceutical industry and the unceasing development of new and more effective synthetic and biological medicinal products have not diminished the importance of medicinal plants in many societies. On the contrary, population growth in the developing world and increasing interest in the industrialized nations have greatly expanded the demand

for medicinal plants themselves and the products derived from them. Regulations in countries for the assessment of the quality, safety and efficacy of medicinal plants, and the work of WHO in supporting the preparation of model guidelines in this field, have been helpful in strengthening recognition of their role in health care. It is hoped that assessment of these traditional remedies could become the basis for a future classification of herbal medicines, as well as for evaluative studies on their efficacy and safety, and their potential use in national health care systems in different parts of the world. Thus emphasizing the new foreign or domestic players to provide their product and share the ever regulatory requirements. Demands of herbal health care sector are a win-win situation for this sector and consumer alike because it helps in providing the consumers a cheaper product (because of competition) with proven safety, efficacy at affordable prices.

#### Disclaimer

The authors do not claim anything; the purpose of this review article is solely educational. The requirements mentioned in the article are general requirements and should not be considered as guidelines for product registration or submission. Referring and abiding to respective country guidelines for submissions of product registration is highly recommended.

#### REFERENCES

- Herbal Medicine, <http://www.umm.edu/altmed/articles/herbal-medicine>, updated on 27/09/2009.
- Boulanger, The Islamic Contribution to Science, Mathematics and Technology, OISE Papers in STSE Education, Vol. 3, 2002.
- Culpeper, Complete Herbal: A Book of Natural Remedies of Ancient Ills. (The Wordsworth Collection Reference Library), Contemporary Publishing Company, 1995.
- Dwivedi G, Dwivedi S. History of Medicine: Sushruta – the Clinician– Teacher par Excellence, National Informatics Centre (Government of India), 2007.
- Greene EL. Landmarks of Botanical History- Part 1, ed. Egerton, Frank N. from 1909 edition, 1981.
- Grieve M. A Modern Herbal. Harmondsworth, England: Penguin Books. 1984.
- WHO Geneva Report Traditional Medicine Programme Department of Essential Drugs and Medicine Policy, held at Regional office for Africa Traditional Medicine Programme Division of Health Systems and Services Development Brazzaville, 2004.
- DeSmet PAGM. Should herbal medicine-like products be licensed as medicines? *British Medical Journal* 1995;310:1023-1024.
- Associated Health Service Professions Act, no. 63 of 1982, as amended by the Associated Health Service Professions Amendment Act, no. 108 of 1985 and the Associated Health Service Professions Amendment Act, no. 10 of 1990. South Africa.
- Hess S. Traditional Healers in SA, Health systems trust update, October 1998; 37:6-7.
- Gericke N. The Regulation and Control of Traditional Herbal Medicines. An international overview with recommendations for the development of a South African Approach, Traditional Medicines Programme at the University of Cape Town. Working draft document, December 1995.
- Felhaber T, Gericke N. TRAMED, Final Narrative Report: 1 June 1994 - 30 April 1996. Traditional Medicines Programme at the University of Cape Town, 1996.
- WHO Geneva Report, National policy on traditional medicine and regulation of herbal medicines Report of a WHO global survey, Geneva, 2005,
- Sanders AJGM, Towards the legalization of African folk therapy, *Medicine and the law*, 1989; 7:523-528.
- Le Grand A, Wondergem P. Herbal medicine and health promotion: a comparative study of herbal drugs in primary health care, Amsterdam, Royal Tropical Institute, 1990.
- Bodeker G. Planning for cost-effective traditional health services. In: Traditional medicine, better science, policy and services for health development: proceedings of a WHO international symposium, Awaji Island, Hyogo Prefecture, Japan, WHO Centre for Health Development, Kobe, 2001.
- Ordinance no. 189, The practice of the medical profession, Sections 1 and 2. *International digest of Health Legislation*, 1985, 36:21.
- Development plan, Kenya, 1989-1993.
- Koumare M. La médecine traditionnelle au Mali. Bamako, Institut National de Recherches sur la Pharmacopée et La Médecine Traditionnelle, 1980.
- Sall B. La médecine traditionnelle en République du Mali. *Revue juridique et politique, indépendance et coopération*, 1981, 35:117.
- Mauritius, An Act to provide for the practice and control of Ayurvedic and other traditional systems of therapeutics in Mauritius, *International digest of health legislation*, 1991, 42:424-426.
- Clarke E. Traditional medicine in Mozambique, *Health systems trust update*, 1998, 37:11.
- Information provided to WHO by the Ministry of Health and Social Services, Namibia, February 2000.
- Ajai O. The integration of traditional medicine into the Nigerian health care delivery system: legal implications and complications, *Medicine and the law*, 1990, 8:308.
- Liga, *Medicorum Homeopathica Internationalis*, ed. World homeopathy, Selva, Spain-1998.
- Baldé S, Sterck C. Traditional healers in Casamance, Senegal. *World health forum*, 1994; 15:390-392.
- Amooti-Kyomya S. Traditional health systems and the conventional system in Uganda, In: Islam A, Wiltshire R, eds. *Traditional health systems and public policy*. Ottawa, International Development Research Centre, 1994.
- Tanzania laws. Chapter 409, Section 37 and Chapter 416, Section 53. Tanzania, 1974.
- Swantz L. The medicine man among the Zamaro of Dar es Salaam. Uppsala, The Scandinavian Institute of African Studies in cooperation with Dar es Salaam University Press, 1990.
- The national traditional and birth attendants implementation policy. Dar es Salaam, Ministry of Health, United Republic of Tanzania, 1999.

**ABBREVIATIONS**

WHO	:	World Health Organization	TRAMED	:	Traditional Medicines Programme
MCC	:	Medicines Control Council	TM/CAM	:	Traditional Medicines/Complementary Alternative Medicines
USP	:	United States Pharmacopoeia	PRG	:	People's Republic of Guinea
BP	:	British Pharmacopoeia			

**Table 1: Check List for General Requirement of Traditional Product Registration for Africa Region**

Country Name	Applicant Details	Product Details	Quality Documents of Raw Materials	Quality Documents of Finished Product	Stability Data of Finished Product			P'cological & Toxicological Data	Administrative Documents
					40°C/ 75% RH	25°C/ 60RH	30°C/ 65 RH		
Republic of South Africa	√	√	√	√	√	NA	√	√	
Republic of Benin	√	√	√	√	Optional	√	Optional	√	
Ghana	√	√	√	√	√	NA	√	√	
Kenya	√	√	√	√	√	NA	√	√	
Mali	√	√	√	√	Optional	√	Optional	√	
Mauritius	√	√	√	√	Optional	NA	√	√	
Nigeria	√	√	√	√	√	√	Optional	√	
Senegal	√	√	√	√	Optional	√	Optional	√	
Uganda	√	√	√	√	√	√	Optional	√	
Tanzania	√	√	√	√	√	NA	√	√	
Togo	√	√	√	√	Optional	√	Optional	√	

**Table 2: Supportive Requirements for Traditional Product Registration for Africa Region**

Technical Requirement	Descriptive Details
<b>Quality Documents of Raw Materials</b>	
Identification of plant	Definition, synonym, selected vernacular name, geological distribution, brief description of living plant
Part of the plant used and the condition of the plant material used	General appearance, organoleptic properties, microscopical characters, powdered plant material.
General identity tests	Chemical, biological or physical assay.
Purity tests	Microbiological and chemical, foreign organic matter, total ash value, acid insoluble ash and sulphated ash. Water soluble extracts, alcohol extractable substance, loss on drying, swelling index, pesticide residue.
<b>Quality Documents of Finished Product</b>	

Qualitative and Quantitative composition of the components (Active & Excipients)	
Description of the process of manufacture	
Specification of quality of finished products	
Method of Analysis	
Packaging details	Type of container & closures
<b>P'cological &amp; Toxicological Data</b>	
<b>Safety Requirements</b>	
Introduction	Latin name, species, local name and family
Biological Information (via literature search/ data bases)	Biomedical information, in case of no data available documented experiences should be used.
Toxicity studies	In case of absence of toxicity report, appropriate tests required like immunotoxicity, genotoxicity, carcinogenicity, and reproductive toxicity through long term to be done.
Posology	
Dosage form	
Adverse reactions, Contraindication, Warning & Precaution	
<b>Efficacy Requirements</b>	
Introduction	
Assessment of efficacy	
Active ingredients	
Evaluation of efficacy	
Guidelines for clinical evaluation of traditional medicines	