Review Article

Regulation of Traditional and Alternative Medicines: The Case of the Gambia.

Abstract

The regulation of a profession comes in many forms; statutory and non-statutory. Statutory regulation refers to professions that must be registered with a professional regulatory body by law. Non-statutory regulations are normally voluntary and are another term for common law.

However, in Africa, non-statutory regulations are difficult to be implemented by professional bodies. Statutory bodies are created by an act of parliament, while non-statutory bodies are not. Statutory bodies have legal powers and have binding effects, while non-statutory bodies do not have any legal powers and are only advisory.

Aim: This paper examines the legal framework of traditional and alternative medicine in the Gambia and the risk and benefits associated with regulated and unregulated professions.

Method: The author reviews the healthcare legal laws in the Gambia that have a direct and indirect link with traditional and alternative medicines. Also, literature searches were conducted to examine the benefits and risks associated with regulated and unregulated professions using Google engine tools.

Result: about herbal and homeopathic medicinal products; there exists a law that regulates them. However, no law regulates the practice and practitioners of traditional and alternative medicine in the Gambia. Also, several risks and benefits are associated with the regulated and unregulated profession.

Conclusion: Due to the many risks and benefits associated with the regulated and unregulated profession, there is a need for legislation to help regulate the practice of traditional and alternative medicine.

Keywords: regulated, unregulated, risk, benefits, legislation, traditional and alternative medicine, Gambia.

Introduction

The Practice of traditional medicine of the people of the Gambia cannot be separated from them. It is a way of life. Traditional medicine has been in existence before the development of modern medicine. Modern Medicine has received recognition due to many factors. One is effective legislative regulation that has built public trust in the profession.

In India, China, and other countries with effective legislative regulation in the profession of traditional and alternative medicine, there is a growing demand and public trust in the profession. The case is different in the Gambia.

Several pieces of legislation regulate the Gambian Healthcare sector, including the Medical and Dental Practitioners Act[**1**] CAP. 37.01; Nurses and Midwives Act[**2**]; CAP. 38.01; Medical Services Act[**3**]; CAP. 39.01; Medicines Act[**4**]; CAP. 40.01; Medicines and Related Products[**5**],2014; Medicines and Related Products Regulations[**6**], 2019 ("Regulations"); Public Health Act[**7**], CAP 40. 02; and Food Act[**8**], CAP 40. 07.

Here, I will briefly present what legislations may directly or indirectly influence the practice of traditional and alternative medicine and point out areas that lack regulation or standardization. I will look at this from two areas; *professional and product regulation.*

Professional Regulation

The first law I reviewed was the Medical and Dental Practitioners Act[**1**]. Its object is to make provision for the establishment of a Medical and Dental Council, for the Registration of Medical and Dental Practitioners, for the discipline of persons registered under the Act, and for connected matters[**1**].

Section 2 of the Act [1] defines a 'Medical Practitioner' as '*a person qualified to practice the profession of medicine and is registered in accordance with the provisions of this Act'.*

Similarly, a 'Dental Practitioner', under the Medical and Dental Practitioners Act[**1**], means '*a person who is qualified to practice the profession of dentistry and is registered in accordance with the provisions of this Act'.*

The most important section that proves that the Act does not regulate traditional, complementary, and alternative medicine practice is enshrined in section 41(1) of the Medical and Dental Practitioners Act[**1**]. It states that: '*The provisions of this Act do not apply to a person who is recognized by the community in which he or she lives and practices as a person who practices a customary system of therapeutics'.*

Any person recognized by the community who practices a customary system of therapy is regarded as a traditional healer. Therapeutics are treatments used to

alleviate or prevent a particular disease. Customary systems of therapeutics consist of diverse traditional practices, herbal medicine, complementary, as well as other alternative therapeutics such as Ayurveda, homeopathy, naturopathy, and many more.

African traditional medicine practices are diverse and are engraved in the customs of the people who live there. The customs of the people are recognized by the Constitution[**9**]. In the Gambia, Section 7(e) of the Constitution of the Republic emphasizes customary law as part of the laws of the Gambia. Customary law is concerned with members of the communities to whom it applies. In this regard, the customs of the people in the communities also include the practice of traditional medicine. Hence, the practice of traditional medicine could be argued to be a constitutional right based on the customs and common law recognition as part of the laws of the Gambia[**9**].

Furthermore, Section 31 of the Constitution grants the right to culture promotion. It states that every person shall be entitled to enjoy, practice, profess, maintain, and promote any culture, language, tradition, or religion, subject to the terms of this constitution and to the condition that the rights protected by this section do not impinge on the rights and freedoms of others or the national interest, especially on the interest of national unity. The practice of traditional medicine is a way of life for the people of Gambia and it could be argued that it is part of their culture[**9**].

Section 2 of the Interpretation section of the Evidence Act 1994 of the Gambia defines customs as a rule which, in a particular area, has, through long usage, obtained the force of law[**10**]. Section 13 of this act further emphasizes the admissibility[**10**] of customs as evidence in a Court of competent jurisdiction in the Gambia. It states that a custom may be adopted as part of the law governing a particular set of circumstances if it can be proved to exist by evidence[**10**].

However, Section 41(2) of the Medical and Dental Practitioners Act highlights that the provision of subsection 1 of this section does not authorize any person to perform any customary system of therapy which is dangerous to life or health[**1**]. This implies that the Medical and Dental Practitioners Act provides no grounds to regulate customary therapeutics and gives no leeway for traditional healers to engage in any practices that will endanger the public.

The second law up for review is the Nurses and Midwives Act CAP. 38.01. Section 27 gives recognition to Traditional birth attendants[**2**]. It states that the 'Council' in the Nurses and Midwives Act may train and recognize a person as a traditional birth attendant who shall perform such duties as the Council may prescribe. Hence, traditional birth attendants can make themselves available to be accepted by the council.

Thirdly, the Medical Services Act CAP[**3**]. 39.01. Section 2 defines a 'health facility' "*as a Government health Centre, policy clinic, dispensary, or any other health facility belonging to the government and not forming part of, or attached to a hospital"*. It further emphasizes that 'Private Health' institution means "*any hospital, polyclinic, dispensary or any other health facility not owned by the government*".

My concern is that in the future it is likely that this Act will propose to also regulate the facilities of traditional healers due to its ambiguous nature. It will be prudent for future legislation in traditional medicine to clarify this.

Herbal and alternative therapies regulation

The first law for analysis is the Public Health Act[**7**], CAP 40. 02, which makes provision for public and environmental health, and connected matters. However, this Act does not also regulate herbal and alternative therapies.

Secondly, the Food Act[**8**], CAP 40. 07, controls the production, manufacture, sale, distribution, importation, and exportation of foods and makes provisions for connected matters. Section 2 defines an 'additive' as:

> *"a substance not normally consumed as food by itself and not normally used as a typical ingredient of food, whether or not it has nutritive value, whose intentional addition to food for a technological purpose, in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of the food, result, or may reasonably expected to result, directly or indirectly, in its byproduct becoming a component of or otherwise affecting the characteristic of the food".*
>
> This section could mean that herbal manufacturers or complementary and nutritional supplement practitioners who use additives for product formulation could be regulated by this Act.

Furthermore, by an 'Advertisement' the Act means 'a representation, written, pictorial, visual, and otherwise, for the purpose of promoting directly, or indirectly, the sale or the disposal of any food or any substance represented as food'[**8**].

'Food' means:

(a) "*an article or a substance, or drink whether processed, semi processed or raw, intended for human consumption including a part of the article or substance used, ingredients of the article or substance used or intended or destine to be used as a part or an ingredient of the article or substance;*
(b) an article or a substance of no nutritional value which is used or intended for human consumption; or
(c) *Chewing gum and any other product of similar nature used."*

Medicines and Related Products Act, 2014.

Finally, the third most important law is the Medicines and Related Products [**5**]Act, 2014. This is a specific law that regulates and provides standards for the registration of the products.

This law became very necessary due to the *lacunae* in the Medicines Act[**4**], cap 40.01 passed in 1984, and the Medicines Regulations 1986. For instance, one of the major weaknesses of the 1984 Act was that it combines the regulation of the practice of pharmacy and the regulation of the business of pharmaceuticals (products), to be managed by a Board grossly inadequate to regulate the practice of Pharmacy[**4**].

In the regulation of herbal and alternative therapies, the Medicines Act cap 40.01 did not make provisions for the registration of alternative therapies. Also, concerning herbal therapies, the Act provided *lacunae* for herbal medicinal product registrations[**4**].

Explicitly[**4**], the Second Schedule, Regulation 6 (6), of the Act states that "*any herbs cultivated in the Gambia and used as traditional medicine are exempted from regulation".*

Regulation 6 (7) also states that "*any preparation not containing active ingredients in excess of one millionth part of the preparation's own weight"* does not need to be registered or exempted from registration as an herbal medicinal product.

Hence, to cure these ambiguities[**4**], there was a need for a new law to effectively regulate herbal and alternative therapies. Thus, section 66 of the Medicines and Related Act 2014 repealed[**5**] the Medicines Act 1984 [cap 40.01] [**4**].

Immediately after the passage of the new law, in 2014, the Ministry of Health and Social Welfare issued a Prohibition order[**11**] on the advertisement of traditional medicine practices in The Gambia as it violet the Ministry of Health and Social Welfare and Traditional Medicines Regulations 2014.

I herein examine in detail some specific sections of the Act[**5**] with specific reference to herbal and alternative therapies regulations. This Act however does not regulate the practitioners but their products.

Section 2 of the interpretation[**5**] of the Medicines and Related Products Act, 2014, defines

"herbal medicinal product" to *includes plant–derived materials preparations with therapeutic or any other human or animal health benefits which contain raw or*

processed ingredients from one or more plants and materials of organic or animal origin;

"homeopathic medicine" *includes a substance that be attenuated to render it stronger as the potency increases and at some time that the original substance is diluted, and a substance that can cause certain symptoms in a healthy person and can be used to relieve those symptoms any other person suffering from those symptoms;*

"homeopathy" means "*an alternative system of medicine based on the concept that diseases can be cured when a patient is treated with minute quantities of a substance that produces symptoms of the disease on a healthy person";*

"manufacture" "*includes the operations involved in the production, preparation, processing, compounding, formulating, filling, refining transformation, packing, packaging, re-packaging and labeling of products regulated under this Act";*

"medical device" *"means an instrument, apparatus, implement, a medical equipment, machine, contrivance, implant, in vitro reagent or any other similar or related article, including a component, part or an accessory which is recognized in the official natural formulary or pharmacopoeia or a supplement to them, or intended for use in the diagnosis of a disease or any other condition, or in the cure, mitigation, treatment or prevention of disease in humans and animals, or intended to affect the structure or a function of the body of the human being or other animal and which does not achieve any of its principal intended purposes through chemical action within the body of the human being or any other animal and which is not dependent on being metabolized for the achievement of any of its principal intended purposes";*

"medical treatment centre" *"means a health institution for the treatment of out-patients and which is under the immediate supervision of an attendant recognised by the Agency";*

"medicines" *"includes a substances or mixture of substances prepared, sold or represented for use- (a) in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, (b) restoring, correcting or modifying organic functions in man or animal", (c) nutritional supplements, or (d) herbal medicines;*

"package" *"means in relation to a product regulated under this Act, a box, packet or any other article in which one or more primary containers of products regulated under this Act is or are to be enclosed in one or more other boxes, packets or articles in question, the collective number of them";*

"premises" *"includes land, buildings, structures, basements, and vessels, and in relation to a building, includes a part of a building and the cartilage, forecourt, yard or place of storage used in connection with the building or part of the building, and in relation to a vessel, includes a ship, boat, an aircraft, a carriage or receptacle of any kind whether open or closed";*

"regulations" means "*regulations made under this Act; "related product" means an article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal";*

"retail" means *"professional services that include the supply or sale of medicines or related products to a patient or final consumer for personal non-business use from premises by the holder of a retail license issued under this Part";*

"sell or sale" includes *"sell or sale by wholesale or retail, import, offer advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange supply or dispose of to a person whether for a consideration or otherwise";*

"selling" includes "*offering for sale, exposing for sale and having in possession for sale or distribution; "substance" means a natural or artificial substance whether in solid or liquid form or in the form of a gas, vapour or radiation";*

"supply outlet" means *"premises licensed under this Act where medicines are supplied";* and

"unfit product" means *"a product regulated under this Act which violates a provision of this Act".*

Section 4 of the Act states that

"the Agency shall be the regulatory body for the products regulated under this Act, and shall in particular- (a) regulate all matters relating to efficacy, quality and safety of medicines and related products; (b) regulate in accordance with this Act, the importation, manufacture, labeling, marking or identification, storage, promotion, sale and distribution of medicines and or any related product, materials or substances used in the manufacture of products regulated under this act; (c) ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored globally, are analyzed and acted upon; (d) ensure that, clinical trials on medicines and related products, and herbal medicines are being conducted in accordance with prescribed standards; (e) foster co-operation between the Agency and other institutions or organizations and other stakeholders; (f) approve and register medicines and related products regulated under this Act, manufactured within or imported into, and intended for use in The Gambia as mentioned in Schedules I, II, and III; (g) examine, grant, issue, suspend, cancel and revoke certificates and licenses or permits issued under this Act; (h) appoint inspectors and order inspection of any premises; (i) promote the rational use of medicines and herbal medicines; (j) establish and maintain the Gambia National Formulary and Pharmacopoeia; (k) provide the public with unbiased information on products regulated under this Act; (l) Control of advertisements of

medicines and related products (m) prescribe standards of quality in respect of products regulated under this Act, Manufactured or intended to be manufactured or imported into or exported from the Gambia; (n) maintain registers pertaining to regulation of medicines and related products prescribed under Schedule I, II and III under the regulations; (o) be responsible for its human resource management and development; (p) promote, monitor and ensure successful implementation of the provisions of this Act relating to medicines and related products; (q) attend to and where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act; (r) carry out such other functions as may be conferred upon the Agency by any written law or as are incidental to the performance of its functions under this Act; (s) do such acts or take such measures as are, in the opinion of the Agency, necessary or expedient for the 12 prevention of health hazards to consumers which may result from the consumption or use of low or bad quality medicines and related products regulated under this Act;

Section 5 of the Act[**5**] deals with the governing board and this time there is a representation for the herbal practitioners association in (1) (j).

With regards to alternative therapies, Section 27 provides the roadmap[**5**] for the registration of homeopathic medicines; and states that:

(1) *A person shall not manufacture, prepare, supply, sell, distribute, export or import a homeopathic medicine unless the homeopathic medicine has been registered with the Agency.*

(2) The Agency may by regulations, prescribe particulars to be provided for the registration of homeopathic medicines under subsection (1).

Regulations for Herbal and Alternative Medicinal Products Registration

After the passage of the Medicines and Related Products Act, 2014, it took almost 6 years for a regulation as specified in the Act to be drafted for herbal medicine registration[**6**]. I am sure this was orchestrated due to the many unsubstantiated advertisements in the media space by practitioners.

The regulation of herbal medicinal products in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

The regulation[**6**] can be found in Part VI of the Act, Registration of Medicines and Related Products, Sections 25, 26, and 30 mandate that all medicines manufactured, prepared, imported, exported, distributed, sold, supplied, or exhibited for sale have been registered by the Agency. This means that all herbal products locally manufacture for commercial purposes and imported alternative and nutritional therapies must conform to this law. The Medicines and Related Products

Regulations, 2019 ("Regulations") details the legal requirements. This is found in document number and version MCA-GL-106, version 3, and came to force on 15th April 2020.

The scope of the regulation applies to finished herbal medicinal products as defined in this guideline whether manufactured in the country or imported into The Gambia. However, it does not apply to traditional herbal remedies prepared for individual patients[**6**]. This means that locally prepared remedies for patients in herbal or alternative clinics are not mandated to be registered. It should be within the premises for the patients and not for commercial advertisement or mass production.

The new regulation[**6**] aims to provide a roadmap to a prospective applicant on how to go about with regards to the registrations of herbal medicinal products in The Gambia, for variations of registered herbal medicinal products, and renewals of registrations. It should be emphasized that the registration, variation, and renewal of registration of herbal medicinal products should be approved by the Agency[**5**] before importation into the country, except for those used as samples for this application. The Agency intends to provide effective regulation and standardization for herbal and alternative therapies in the Gambia to meet international standards of quality, safety, and efficacy; and are manufactured and controlled to consistently meet acceptable standards.

Methods

First, the author reviews the healthcare laws in the Gambia that have a direct and indirect link with traditional and alternative medicines in a non-systematic way.

Healthcare legislation reviewed is the following: The Medical and Dental Practitioners Act, CAP. 37.01; Nurses and Midwives Act; CAP. 38.01; Medical Services Act; CAP. 39.01; Medicines Act; CAP. 40.01; Medicines and Related Products, 2014; Medicines and Related Products Regulations, 2019 ("Regulations"); Public Health Act, CAP 40. 02; and Food Act, CAP 40. 07.

Finally, literature searches were conducted to examine the benefits and risks associated with regulated and unregulated professions using Google engine tools with keywords such as risk and benefits of regulated and unregulated traditional and alternative medicine. The benefits aspect also examine extensively the economic or business aspect of traditional and alternative medicines.

Findings

With regards to professional registration, there is no specific law that regulates the practitioners and provides recognition for them in the primary

healthcare team in the Gambia. However, practitioners can practice their trade based on the common law and customary law as embedded in the Constitution.

However, the Medicines and Related Products Act, 2014, is the specific law that regulates the herbal medicinal and homeopathic products in the Gambia under the Medicines Control Agency(MCA).

Finally, the economic prospect of a regulated profession such as traditional and alternative medicine are uncountable. Unregulated traditional and alternative medicine also pose danger to the public.

Discussion

Two aspects of the regulatory issues were raised in this paper concerning herbal and alternatives profession; *Professional* and *medicinal products* in the Gambia.

Professional Regulation

With regards to professional registration, there is no specific law that regulates the practitioners and provides recognition for their trade in the primary healthcare team in the Gambia. This was evident in the new Medicines and Related Products Act, 2014[**5**].

Section 2 of the interpretation[**5**] defines "health practitioner" to include *a nurse, midwife, physician assistant, and any other person approved by the Agency*.

The phrase "*any other person approved by the Agency"* is ambiguous[**5**]. Probably, the Agency is also waiting for specific legislation on traditional and alternative medicine in the Gambia to regulate and recognized the practitioners officially into the healthcare system before taking further action to recognize them. This notwithstanding, no law also proscribes their trade in the Gambia. Practitioners can practice their trade based on the common law and customary law embedded in the Constitution as long as they do not endanger public health.

However, it is prudent to know that traditional or natural therapies are not always beneficial nor are they always benign. Hence, practitioners should be well trained and regulated to adhere to standards in their profession. Though, there is a national association called the National Traditional Healers Association of The Gambia (TRAHASS), a recognized national body of traditional healers. The association is financial and human resources constraints to carry out its mandates. The association is constrained to provide a non-statutory regulation of its members due to a lack of government support.

Members are faced with strong opposition from mainstream practitioners who paint a negative picture of them to the general public. They regard them as uneducated practitioners in the medical profession. There is also no tertiary or professional program in traditional and complementary medicine to train these practitioners.

Hence, they are unable to set standards in the profession to help provide a non-statutory regulation for traditional and complementary practices in the Gambia. It is clear from the various healthcare Acts in the Gambia, that they have no *locus* to regulate the practitioners.

Due to the several *lacunae* in the healthcare legislation, it has created a platform where every practitioner does whatever they believe works for them. There is no uniformity in their practice.

This is a recipe for healthcare disaster in the Gambia. Besides, traditional medicine is highly regarded and favored by the public due to its popularity, accessibility, and affordability, more than 80% of the people continue to rely on it for their healthcare needs. Besides, the average ratio of traditional health practitioners to the population of medical doctors in Africa is 1:25,000 to 1:200, respectively according to the World Health Organization[**12**]. This should tell you how their services are assessed and the need for legislation and regulation.

Risk of unregulated Profession

Even in countries where regulation exists, the risk of traditional practices has been reported in the media space. What would therefore be the case for countries without legislation and regulation? For instance, in one old study[**13**] babies of women delivered in an "unorthodox health center" had a significantly higher incidence of birth asphyxia than babies born in a hospital. The birth asphyxia death rate in this study was 20.8%. Another study[**14**], documented several other adverse outcomes arising from the delivery practices of Traditional Birth Attendants (TBAs).

Chibwana et al[**15**], the study also reported poisoning due to traditional medicine. A previous study by[**16**], also reported adverse outcomes emanating from treatment by traditional bonesetters (TBS). The same study from Nigeria reported that of the 225 limb amputations performed over ten years, 63.2% were the result of trauma that had been inappropriately treated by traditional practitioners. Others [**17**], have documented permanent eye injuries following the use of traditional medicine for eye problems.

Finally, traditional healers' refusal to refer cases to mainstream facilities to seek standard medical treatment leads to a disaster[**18**]. For instance, one study[**18**] in Benin found frequent injuries emanating from traditional treatment administered for childhood convulsions. An older study also found that of eighty-nine patients with

tuberculosis, 37% reported having consulted a traditional healer before seeking medical attention[**19**].

I emphasized that the government of The Gambia should take interest in regulating traditional and complementary medicine practitioners. This is to prevent harm. Besides, this is grounded on the doctrine of natural medicine; do no harm. Moreover, the Gambia government must protect the well-being of the citizenry regardless of whether the citizenry is subjectively content with the treatment that they are receiving. This was the court decision in *Dent v. West Virginia 129 U.S. 114, 122 (1889)* though it has a persuasive effect in law[**20**]. The court reasoned that:

"[t]he power of the state to provide for the general welfare of its people authorizes it to prescribe all such regulations as, in its judgment, will secure or tend to secure them against the consequences of ignorance and incapacity.'

Countries such as China and India are benefiting from traditional therapies due to effective regulation. Ghana has over 55 government Hospitals with herbal medicine departments with trained Medical Phythotherapists. The economy of Ghana and the healthcare space is benefitting from effective regulation of traditional and complementary therapies.

In the private health space, herbal hospitals are competing with mainstream hospitals. Some of these herbal hospitals in Ghana have huge and nice edifices with modern medical types of equipment with educated practitioners.

Effective regulation also increases education of practitioners; investment in research and development to validate claims on the safety, efficacy, and quality of traditional medicines; documentation of inventories of effective traditional medicine practices; the development of national formularies on traditional medicines with evidence of safety, efficacy, and quality; large-scale cultivation and conservation of medicinal plants, development of local production of traditional medicines, and the protection of intellectual property rights[**12**].

Also, in the present situation in the Gambia without statutory provisions for practitioners, establishing standards may be difficult. For instance, some commentators held the view that self-regulation is meant for personal interest and not for the public good and that organizations that engaged in self-regulation have a challenge in enforcement.

Hence, when government regulates, it is to further the public good. The law can get around this by prescribing what traditional practitioners cannot do (rather than entering into the difficult task of trying to define what they can do) and by requiring them to refer patients whom they are unable to treat.

We have seen how government regulations have impacted the standards in mainstream medical practice, and the legal profession. We have seen the relevance

of regulation in countries with traditional medical practice. They have national licensing standards; educational requirements and standards in the practice. Licensing of practitioners provides public confidence in any profession.

For instance, the Nigerian Medical and Dental Practitioners Act[**21**] of 1988 regulates alternative medicine practitioners but prohibits practitioners from performing surgery or prescribing drugs. Additionally, the Malawi Medical Practitioners[**22**] and Dentists Act of 1987 prohibits traditional practitioners from performing any act which is dangerous to life.

Also, the Ugandan[**23**] Traditional and Alternative Medicine Practice Act, 2019; Traditional Medicine Practice Act 575, of Ghana[**24**]; Traditional and Alternative Medicine Act, 2002, of Tanzania[**25**]; Traditional Health Practitioners Act, 2007, of South Africa[**26**]; Allied Health Professions Act, 63 of 1982[**27**]; Burkina Faso, order N°2013 -552-MS/CAB of June 21, 2013[**28**]; Benin 2001-036 decree of February[**29**] 15, 2001; Natural Therapeutic Practitioners Act of 1976[**30**], Lesotho; Law No. 11–001/AU of 26 March 2011 on the Public Health Code in its Title III: Exercise and Organization of Traditional Medicine, particularly in Articles 262–279, of Comoros[**31**]; The Ayurvedic and Other Traditional Medicines Act of 1989, of Mauritius[**32**]; Traditional Medical Practitioners Act (27:14) of 1996, of Zimbabwe[**33**], are some African countries with legislation to regulate the practice[**34**].

Herbal Medicinal and Alternative therapies regulation

Before 2014, these remedies were not regulated[**4**]. The passage of the Medicines and Related Products, 2014, and subsequent Medicines and Related Products Regulations, 2019 have paved the way for effective regulation of herbal and alternative therapies in the Gambia[**5**].

Another unique nature of this Act[**5**] is that it defines "herbal medicinal product" *to includes plant–derived materials preparations with therapeutic or any other human or animal health benefits which contain raw or processed ingredients from one or more plants and materials of organic or animal origin*.

Alternative therapies with specific reference to homeopathy were also integrated[**5**]. It defines "homeopathic medicine" [**5**] to *includes a substance that be attenuated to render it stronger as the potency increases and at some time that the original substance is diluted, and a substance that can cause certain symptoms in a healthy person and can be used to relieve those symptoms any other person suffering from those symptoms;* and "homeopathy" *means an alternative system of medicine based on the concept that diseases can be cured when a patient is treated with minute quantities of a substance that produces symptoms of the disease on a healthy person.*"

It captured both homeopathy and homeopathic medicine[**5**] though they mean the same. I presumed the drafters did not want to leave room for a further legal tussle.

Evidence on an herbal medicine product

The Regulation further detailed on providing evidence of claimed indication and stated that for instance, when one claims that the product is effective, the information of proof of efficacy should include any of the following[**5**]:

- Individual experiences recorded in reports from registered medical practitioner; or
- Experiences from herbal practitioners; or
- Experiences from treated patients.

Clinical evidence[**5**] will be required in cases where traditional use has not been documented by scientific literature validated by clinical trials. The recommended dosage of the product needs to be consistent with the evidence used to make the claim. The evidence must relate to the whole product or the same active constituent(s) with a similar dosage regimen, dose form, and route of administration to the product for which a claimed indication is being made. This also means that hearsay evidence from clients that have been documented is allowed for justification and it could be presented by either a medical practitioner or herbal practitioner.

Justification for Product Safety

The Regulation also emphasizes the requirement for herbal medicinal product safety. Manufacturers are supposed to submit to the Agency result of Physical/chemical identification tests; Microbial tests; Heavy Metals (i.e., arsenic (inorganic), cadmium, lead, and mercury; Pesticide Residues, and Foreign matter[**5**].

Also, the manufacturer has to submit to the agency document attesting to long-term use without evidence of safety problems should form the basis of the risk assessment. It should be supported also by proof of long-term use by different communities including folklore, anthropological studies, etc. However, the regulation further state that if there is no documentation on long-term usage of the product or there are safety doubts, toxicity data should be submitted.

Finally[**5**], the applicant has to provide a report on pharmaco-toxicological data including pharmacological activity, acute, sub-acute, chronic, and sub-chronic tests submitted from laboratories or research institutions recognized by the Agency.

Many opportunities are associated with legislative regulation. For instance, the global market for traditional therapies stood at more than US$ 60 billion in 2000[**12**], and is steadily growing.

The Gambia, is a nation of tea lovers specially *attaya*(green tea), black tea, coffee, and loose tea; a market report[**35**], found that the tea market was equal to 18.40 million USD (calculated in retail prices) in 2015. Until 2025, the tea market in the Gambia is forecast to reach 48.18 million USD (in retail prices), thus increasing at a compound annual growth rate (CAGR) of 9.01% per annum for the period 2020-2025. This is a decrease, compared to the growth of about 11.46% per year, registered in 2015-2019.

The average consumption per capita in value terms reached 9.61 USD per capita (in retail prices) in 2015. In the next five years, it grew at a CAGR of 8.16% per annum. In the medium term (by 2025), the indicator is forecast to slow down its growth and increase at a CAGR of 5.92% per annum[**35**].

In this report[**36**], the coffee alone instant market in Gambia was equal to 2.80 million USD (calculated in retail prices) in 2015. Until 2025, the coffee market in the Gambia is forecast to reach 11.51 million USD (in retail prices), thus increasing at a CAGR of 12.80% per annum for the period 2020-2025. This is a decrease, compared to the growth of about 18.39% per year, registered in 2015-2019.

The average consumption per capita in value terms reached 1.48 USD per capita (in retail prices) in 2015. In the next five years, it grew at a CAGR of 14.23% per annum. In the medium term (by 2025), the indicator is forecast to slow down its growth and increase at a CAGR of 9.67% per annum[**36**].

Also, Statista[**37**] reports that the Gambia tea revenue amounts to US$39.83m in 2023. The market is expected to grow annually by 4.71% (CAGR 2023-2025). The interesting thing is that in global comparison, most of the tea revenue[**37**] is generated in China (US$111,800.00m in 2023).

This could either be a negative or positive market outlook for the Gambia, as they contribute to the tea market outlook of China. I believe that legislation and strict regulation of the traditional and complementary medicine industry have a chance to benefit the Gambian economy.

The same report also revealed that by 2025, 16% of spending and 1% of volume consumption in the Tea segment will be attributable to out-of-home consumption (e.g., in bars and restaurants) in the Gambia[**37**].

On the international front, Fortune Business Insight[**38**] reported that the global herbal medicine market size was valued at USD 151.91 billion in 2021 and the market is projected to grow from USD 165.66 billion in 2022 to USD 347.50 billion by 2029, exhibiting a CAGR of 11.16% during the forecast period.

Also, The Grand View Research[**39**] also reports that the global complementary and alternative medicine market size was valued at USD 117,210.3 million in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 25.1% from 2023 to 2030.

The interesting thing is that India's export of AYUSH(Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy) and value-added products of medicinal plants during 2015-2016 was $358.60 million[**40**].

In Africa for instance, where legislation and regulation exist, Andel et al[**41**] found that an estimated 951 tons of crude herbal medicine were sold at Ghana's herbal markets in 2010, with a total value of around US$ 7.8 million. Most of these plants sold at the market were mostly used for women's health, in rituals, as aphrodisiacs, and against sexually transmitted diseases.

Also, in Benin, one study by Quiroz et al[**42**] reported that the domestic medicinal plant market in Benin has economic significance. About 655 metric tons worth 2.7 million USD is sold yearly and traditional spiritual beliefs are the major driving force behind the trade in herbal medicine[**42**]. Gabon on the other hand; has just 27 medicinal plant products giving the economy US$ 1.5 million annually.

In Nigeria[**43**], is reported that the current market value of traditional medicinal plants stands at about N200 billion, and could hit N1 trillion by 2025. In South Africa[**44**], it has been reported that the trade in traditional medicines in South Africa is estimated to be worth R2.9 billion per year, representing 5.6% of the National Health budget. The report further established that raw materials amount to R520 million per year (in 2006 prices). An additional R2.6 billion value is estimated to be added through the prescription of traditional plant medicines by traditional healers[**44**].

The traditional medicine industry in South Africa value does not enter into formal trade and therefore is an addition to the Gross Domestic Product (GDP). The most intriguing thing is that the medicinal plant trade in South Africa is equal to 5.6% of the National Health budget, equal to the whole Mpumalanga Health budget, or equal to the KZN Provincial Hospital budget[**44**].

Additionally, in Tanzania, a study[**45**] found that more than 61 000 kilograms of nonpowdered medicines valued at US$344,882 are traded in informal herbal medicine markets. Morocco, on the other hand, annual revenues generated from the

export of medicinal plants were US$55.9 million in 2015[**46**] and US$174, 227,384 in Egypt[**41**].

It is interesting how North African countries make a huge amount of monies from herbal medicinal products as compared to West African Countries. For instance, [**47**] reported that the Gambia exported just $559 in Tea, making it the 171st largest exporter of Tea in the world. In the same year, Tea was the 239th most exported product in Gambia. The main destination of Tea exports from the Gambia is Switzerland ($365), China ($108), and Spain ($86).

The fastest-growing export markets for Tea[**47**] in the Gambia between 2019 and 2020 were Switzerland ($365), Spain ($86), and China ($31).

In terms of import[**47**]: that same year, Gambia imported $23.9M in Tea, becoming the 60th largest importer of Tea in the world. In the same year, Tea was the 14th most imported product in Gambia. Gambia imports Tea primarily from: China ($21.8M), Sri Lanka ($1.19M), India ($581k), Egypt ($108k), and Senegal ($53.9k). The fastest-growing import markets in Tea for the Gambia between 2019 and 2020 were Sri Lanka ($135k), Singapore ($33.2k), and the Netherlands ($12.8k) [**47**].

The Gambia is unable to export its herbal medicinal teas outside to generate foreign exchange. The recent regulation on herbal and alternative therapies provides a stringent mechanism for standardization and if implemented well, I believe it could improve the overdependence on foreign herbal medicinal products. The Gambia herbal market could see more investment and export to rake in foreign exchange.

Concerns

My concern is that though the Act[**5**] and Regulation[**6**] have been implemented it lacks public awareness. One characteristic of law is that it has to be publicized and accessible. The public and even the traditional healers are not aware of this new development in their profession to help develop products to improve the economy.

Another issue is the stringent mechanism could affect the indigenous healers who would to go into mass production as they would be met with a huge cost of production and this will create room for foreign products to penetrate the Gambia healthcare system generating more funds for foreigners as they would have the funds and the capacity to conduct all the tests as specified in the Regulation.

Conclusion and Recommendations

From the forgoing analysis, I make a case for legislative regulation of practitioners of traditional and complementary medicines in the Gambia, and I urge the government

to take a keen interest in the affairs of traditional and complementary practices for public safety.

Finally, I hold the view that Laws regulating traditional practitioners could contribute to a drastic change in the way traditional medicine is practiced in the Gambia and help improve the economy.

This is because no specific law regulates them in the Gambia and this is evident in Section 41(2) of the Dental and Medical Practitioners Act which notes that besides the prohibition of any customary system of therapy which is dangerous to life or health, the Act explicitly does not regulate traditional, complementary, and alternative medicine practices professionals.

This notwithstanding, sections 41(1) and 41(2) of the same Act, in combination, mean that people who are recognized by communities as a practitioner can practice as long as they are not dangerous to life and health.

The Nurses and Midwives Act, CAP. 38.01, with Section 27 which refers to the professional council, also does not regulate traditional and alternative medicine professionals.

On the other hand, the good news is that with regards to the practitioners' activities such as herbal and alternative medicinal products, the Medicines and Related Products, 2014, and The Medicines and Related Products Regulations, 2019 ("Regulations") detail the legal requirements.

I, therefore, call on policymakers to take the necessary steps to formulate legislation to regulate the professionals of traditional, complementary, and alternative medicines in the Gambia.

I, further, support the WHO call for regulation and also encourage member states to integrate, as appropriate, traditional and complementary and alternative medicine (CAM)' into their national healthcare systems.

References

1. The Medical and Dental Practitioners Act, CAP. 37.01
2. Nurses and Midwives Act; CAP. 38.01
3. Medical Services Act; CAP. 39.01
4. Medicines Act; CAP. 40.01

5. Medicines and Related Products, 2014

6. The Medicines and Related Products Regulations, 2019

7. Public Health Act, CAP 40. 02

8. Food Act, CAP 40. 07.

9. The Constitution of the Republic of the Gambia, 1997

10. Evidence Act 1994

11. Prohibition order on the advertisement of traditional medicine practices in The Gambia(2014) https://thepoint.gm/africa/gambia/article/prohibition-order-on-the-advertisement-of-traditional-medicine-practices-in-the-gambia

12. WHO Calls On African Governments to Formally Recognize Traditional Medicine(2022) https://www.afro.who.int/news/who-calls-african-governments-formally-recognize-traditional-medicine

13. Etuk SJ, Etuk IS. Relative risk of birth asphyxia in babies of booked women who deliver in unorthodox health facilities in Calabar, Nigeria. Acta Trop. 2001 May 25;79(2):143-7. doi: 10.1016/s0001-706x(01)00070-5. PMID: 11369307.

14. E. Alabi(1990)Cultural Practices in Nigeria, Inter-African Comm. Traditional Practices Affecting Woman & Children 6 (1990); 0. Mabogunje, Ritual Hot Baths (Wankan-Jego) In Zaria, Nigeria, 9 Inter-African Comm. Traditional Practices Affecting Woman & Children.

15. Chibwana et al.,(2001) Childhood Poisoning at the Queen Elizabeth Hospital, Blantyre, Malawi, 78(6) E. AFR. MED. J. 292 ; M. Stewart et al., Findings in Fatal Cases of Poisonings Attributed to Traditional Remedies in South Africa 101(3) Forensic Sci. Int'l 177 (1999).

16. Garba & P. Deshi(1999) Traditional Bone Setting: a Risk Factor in Limb Amputation, 75 E. Aim. MED. J. 553;

17. M.H.Dashti-Rahmatabadi et al.,(2006) The analgesic effect of Carum copticum extract and morphine on phasic pain in mice, J. Ethnopharmacology, (published online before

print), available at www.sciencedirect.com (search under "analgesic effect of Carum copticum extract and morphine on phasic pain in mice.

18. D. Ayivi(1990) Accidents Linked to Traditional Treatment of Convulsions of Infants and Children in Benin, 85 Dev. Et Sante 25

19. J. Brouwer et al(1998) Traditional Healers and Pulmonary Tuberculosis in Malawi, 2 Int'l J. Tuberculosis & Lung Disease 231, 231

20. Dent v. West Virginia 129 U.S. 114, 122 (1889)

21. Nigerian Medical and Dental Practitioners Act of 1988

22. Malawi Medical Practitioners and Dentists Act of 1987

23. Ugandan Traditional and Alternative Medicine Practice Act, 2019

24. Traditional Medicine Practice Act 575, of Ghana

25. Traditional and Alternative Medicine Act, 2002, of Tanzania

26. Traditional Health Practitioners Act, 2007, of South Africa

27. Allied Health Professions Act, 63 of 1982

28. Burkina Faso, order N°2013 -552-MS/CAB of June 21, 2013

29. Benin 2001-036 decree of February 15, 2001

30. Natural Therapeutic Practitioners Act of 1976, Lesotho

31. Law No. 11–001/AU of 26 March 2011 on the Public Health Code in its Title III: Exercise and Organization of Traditional Medicine, particularly in Articles 262–279, of Comoros

32. The Ayurvedic and Other Traditional Medicines Act of 1989, of Mauritius

33. Traditional Medical Practitioners Act (27:14) of 1996, of Zimbabwe

34. Health Technology Assessment – Naturopathy(2021)https://worldnaturopathicfederation.org/project/health-technology-assessment-naturopathy/

35. Gambia: Tea Market and the Impact of COVID-19 on It in the Medium Term(2020) https://www.marketresearch.com/Williams-Marshall-Strategy-v4196/Gambia-Tea-Impact-COVID-Medium-13621504/

36. Gambia: Instant Coffee Market and the Impact of COVID-19 on It in the Medium Term(2020) https://www.marketresearch.com/Williams-Marshall-Strategy-v4196/Gambia-Instant-Coffee-Impact-COVID-13621471/.

37. Tea-Gambia(2022) https://www.statista.com/outlook/cmo/hot-drinks/tea/gambia

38. Herbal Medicine Market Share Analysis(2022)https://www.fortunebusinessinsights.com/herbal-medicine-market-106320

39. Complementary And Alternative Medicine Market Report, 2030. To be accessed at https://www.grandviewresearch.com/industry-analysis/complementary-alternative-medicine-market

40. India's share in global herbal medicinal market just 0.5%: Government(2016)https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indias-share-in-global-herbal-medicinal-market-just-0-5-government/articleshow/55498419.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

41. Van Andel T, Myren B, van Onselen S(2012). Ghana's herbal market. J Ethnopharmacol. 2Mar 27;140(2):368-78. doi: 10.1016/j.jep.2012.01.028. Epub 2012 Jan 28. PMID: 22306470.

42. Quiroz D, Towns A, Legba SI, Swier J, Brière S, Sosef M, van Andel T(2014). Quantifying the domestic market in herbal medicine in Benin, West Africa. J Ethnopharmacol. 2014 Feb 12;151(3):1100-1108. doi: 10.1016/j.jep.2013.12.019. Epub 2013 Dec 22. PMID: 24368155.

43. Experts Urge Nigeria To Harness $7trn Herbal Medicine Market(2022) https://von.gov.ng/experts-urge-nigeria-to-harness-7trn-herbal-medicine-market/.

44. Myles Manderi, Lungile Ntulii, Nicci Diederichsi, Khulile Mavundlai(2007)Economics of the Traditional Medicine Trade in South Africa. https://www.hst.org.za/publications/South%20African%20Health%20Reviews/18_SAHR_2006-2007_Section%2013.pdf

45. Posthouwer C(2015). Medicinal Plants of Kariakoo Market, Dar es Salaam, Tanzania [MSc dissertation] Leiden, Netherlands: Leiden University. [Google Scholar] [Ref list]

46. Market Insider(2015). Economic Importance of Moroccan Medicinal Plant Exports., http://www.intracen.org/blog/Economic-importance-of-Moroccan-medicinal-plant-exports/ [Ref list]

47. Tea in Gambia(2020)https://oec.world/en/profile/bilateral-product/tea/reporter/gmb