Herbal and Homeopathic Products Regulation in the Gambia: A Commentary on the Medicines and Related Products Act, 2014

ABSTRACT

In 1984, the Medicines Act, cap 40.01 was passed to regulate medicines in the Gambia. If one reviews the said law, one will see the many *lacunae* in the Medicines Act, cap 40.01, and the Medicines Regulations 1986.

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

Explicitly, 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.

The National Assembly of the Gambia thus passed a new law, The Medicines, and Related Products Act, 2014, to cure these ambiguities to effectively regulate herbal and alternative products. Thus, section 66 of the Medicines and Related Products Act 2014 repealed the Medicines Act 1984 [cap 40.01].

In this commentary, I examine the role of the new Act on herbal and alternative medicinal products in the Gambia.

Keywords: The Gambia, Herbal, Homeopathy, regulation, standards

INTRODUCTION

The Medicines and Related Products Act, 2014[1] is a specific law that regulates and provides standards for the registration of medicinal products. This law became very necessary due to the *lacunae* in the Medicines Act, cap 40.01[2] passed in 1984, and the Medicines Regulations 1986.

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Hence, to cure these ambiguities, there was a need for a new law to effectively regulate herbal and alternative therapies. Thus, section 66 [1] of the Medicines and Related Act 2014 repealed the Medicines Act 1984 [cap 40.01].

Immediately after the passage of the new law, in 2014, the Ministry of Health and Social Welfare issued a Prohibition order[3] on the advertisement of traditional medicine practices in The Gambia as it violates the Ministry of Health and Social Welfare and Traditional Medicines Regulations 2014.

The research question for discussion is whether the Medicines and Related Products Act, 2014 also regulates herbal and alternative medicinal products in the Gambia.

Methods

I review the Medicines and Related Act 2014 and The Medicines and Related Products Regulations, 2019 to examine their legal effect on herbal and alternative therapies products in the Gambia context. I further, conclude with my concerns about the Act.

Results and Discussion

In tackling the legal research question: I examined in detail some specific sections of the Act with specific reference to herbal and alternative therapies regulations. This Act however does not regulate the practitioners but their products.

Section 2 [1] of the interpretation 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 is 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;*
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> "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[1]

"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 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 [1] provides the roadmap 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. I am sure this was orchestrated due to the many unsubstantiated advertisements in the media space by practitioners. It could also be triggered by the Memorandum of Understanding (MOU) between the Indian government and the Gambia to promote homeopathy and other Indian traditional medicines in the Gambia[4].

The regulation 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[1]

This means that all herbal products locally manufactured 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 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 Scope and Aims

The scope of the regulation [5] 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. 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 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 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.

Herbal Medicinal and Alternative therapies regulation

Another unique nature of this Act 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. It defines "homeopathic medicine" 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 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[5] 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:

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

Clinical evidence 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 could be presented by either a medical practitioner or herbal practitioner.

Justification for Product Safety

The Regulation[5] 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.

Also, the manufacturer[5] 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, 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[5].

Concerns

My concern is that though the Act and Regulation 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

The Medicines and Related Products, 2014 regulates the quality and safety of medicines and related products and for connected matters.

Part VI of the Act, Registration of Medicines and Related Products, Sections 25, 26, and 30 requires that all medicines manufactured, prepared, imported, exported, distributed, sold, supplied, or exhibited for sale have to be registered by the Agency.

For herbal and alternative medicinal products: The Medicines and Related Products Regulations, 2019 ("Regulations") provides the legal requirements. I recommend that the Medicines Control Agency publicize the Act to create awareness.

References

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