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RESEARCH ARTICLE

The Environmental Conservation, Legal and Ethical Issues concerning Herbal Products in Nigeria

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Abstract
It has been widely reported that there have been rising cases of communicable and non-communicable disease, given the poor level of unhealthy lifestyle and disease outbreak from poor scientific laboratory management. It must be noted that Nigeria has also had its fair share of the rising cases of most infectious diseases. However, in quest of most persons affected by various communicable diseases in Nigeria, it has led finding a better solace and cures to these communicable diseases, by resulting to taking phytomedicine or herbal product. It suffices to state that the growing demand for herbal medicine in Nigeria in the cure or treatment of communicable diseases results from its natural, medicinal, and therapeutic effects. However, the increasing demand for the herbal product has resulted in indiscriminate plant harvest and various individuals not being skilled in the art of herbal medicine production to indulge in manufacturing a poor, harmful and low-quality herbal product. It must be noted that although the international community set out ethical guidelines concerning the the conservation of plant material and manufacturing of herbal medicine. It is in this regard that this study tends to examine the international legal framework concerning environmental conservation of plant material and, local legal and ethical framework concerning the production of herbal products in Nigeria.

Keywords: Environment; Conservation; Legal; Ethical; Phytomedicine; Herbal; Products; Nigeria

Introduction

It is no news that there several communicable and non-communicable diseases that are ravaging the entire global environment. Some of these communicable and non-communicable diseases include but cannot be limited to Covid19, joint, cancers, tuberculosis, sickle cell, diabetes, high blood pressure, bone disease, also sickle cell, and diabetes. It has been said that most communicable and non-communicable diseases stem from an unhealthy lifestyle, natural disasters (such as environmental pollution) (Aidonojie et al., 2020; Ukhurebor and Aidonojie, 2021) an outbreak of infection from poor laboratory management. However, it must be noted that Nigeria also has its fair share of these communicable diseases ravaging the world. This is concerning the fact that there have been reported high cases of communicable and non-communicable diseases. In the quest to eradicate and treat some of these communicable diseases, it has led to several persons or individuals relying on the herbal product (Also known as phytomedicine product) as a supplement and treatment of some of these diseases. It suffices to state that herbal medicine product is derived from various plant parts, such as; leaves, the barks of plant, roots, and tubers (Calixto, 2000; Keller, 1991). Herbal medicinal or supplement products have been proven to have numerous health benefits (Jiang, 2005; Ernst, 1998). They are very effective in treating communicable and non-communicable diseases, given the fact that it is derived from a natural substance that enhances the quality and standard of healthy living (Mahady, 2001).

It suffices to opine that given the increased rate of communicable and non-communicable diseases and the high demand for an herbal product, it has led to led to an indiscriminate plant harvesting and sporadic increase in the production and manufacturing of herbal or phytomedicine products (Gutierrez, 2014; Kaya, 2012; Riget, et al, 2016; Falkner, 2016; Ladychenko et al, 2019; Anderson and

Bows, 2008). However, the increased production of herbal products is not a major problem, but the unchecked increase of indiscriminate plant harvest and fake manufacturing of the herbal product in Nigeria.

It is concerning the above that this study tends to examine various international legal framework concerning preservation and conservation of plant. Furthermore, the study will also examine laws in Nigeria as they relate to the manufacturing of herbal or phytomedicine products. The study will x-ray and highlight some ethical guidelines and legal issues concerning herbal or phytomedicine. The study will further conclude and suggest some possible legal remedy to that will aid in regulating the production and use of herbal products in Nigeria.

International Regulatory Framework of Environmental Conservation of Herbal Materials

As a result of a change in the average weather condition, extreme events have progressively impacted biodiversity (which also include plant materials for manufacturing herbal products) globally. While the effect may differ across continental lines, the general effect is that it alters the ecosystem and exposes the plant and animal species to hazards. Due to the disproportionate annual rainfall, intense flood, and wide fire in the ecosystem, many biological plant and animal species have been forced into extinction or to relocate and secure an adaptable environment for their continuous existence. The gradual extinction of some endangered species is more worrisome, mainly in the Savannah or African region, hence the need for a regulatory framework.

Herbal products use as food supplements, and treatment of communicable and non-communicable diseases are often manufactured from plants material. Although there is no international regulatory framework directly regulating herbal product, however, it suffices to state that indirectly the Convention on International Trade in Endangered Species of Wild Fauna and Flora tends to have an effect on the manufacturing of nutraceutical and phytomedicine products. This is concerning the fact that the convention tends to place restrictions on some rare plant species by protecting and conserving them from indiscriminate harvesting and use without due permission from the appropriate body (Ukhurebor and Aidonojie, 2021; Aidonojie et al, 2020).

Article III, IV, and V of the Convention on International Trade in Endangered Species of Wild Fauna and Flora stipulate that in importing or exporting of any wild fauna and flora (which include medicinal plants) red listed in appendix I, II, and III of the convention, there must be prior approval from the exporting state upon satisfying the following conditions;

i. The scientific authority of the exporting state must have confirmed that exporting such species will not threaten and endanger the existence of the species
ii. That the species obtained was not in contravention of the exporting state laws protecting fauna and flora
iii. The exporting state is satisfied that the species obtained will be shipped in a facility that will reduce the risk of damage to the species so obtained
iv. That import permit has been obtained from the appropriate authority

Given the above, it suffices to state that if any plant that is suitable in manufacturing nutraceutical and phytomedicine products is red listed in appendix I, II, and III to the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the appropriate procedure stipulated in Article III, IV, and V of the convention must be duly complied with.

Furthermore, it suffices to state that the preservation and conservation of rear germ of agricultural produce which could also be useful in herbal production is also a major concern of the international community (Ali et al, 2020; Elmer and White, 2018). In this regard, the international community has sorted the need to, through a legal framework, ensure the development of sustainable means in ensuring the sustainable conservation and preservation of rear agricultural produce. In this regard, the International Plant Protection Convention (IPPC) came into in 1997 to address the need for international cooperation in protecting and controlling pests (which may include; animal or pathogenic agents injurious to plants, or any strain, species, or biotype of a plant) that may affect the viability of plants product and causes the spread of plants diseases or pest across borders. Furthermore, the essence of the IPPC, as stated in the preamble, is to implement recognized international principles that sort to protect humans, plants, animals, and the environment. In this regard, Article I of the IPPC provide that the signatory state should endeavor to adopt an effective action to prevent, curtail and control the spread of pests or disease of plants products and plant. Also, State takes proactive administrative, legal, and technical step in implementing the provision of the IPPC. Concerning the provision of Article of the IPPC, Article IV further places the following responsibilities on the national institute of plant protection as follows;

i. Ensuring effective surveillance of plants under cultivations to ensure they are free from pests and diseases
ii. Conducting of risk analysis as it concern pest or disease of plant products and plant
iii. Detection, report, and controlling of an outbreak pest or diseases of plants and plants products
iv. Facilitating the protection, surveillance, and maintenance of endangered areas free of pest or disease of plants

Furthermore, by Article IV(3)(b) of the IPPC, it provides thus;

Each contracting state shall facilitate and make provision, to the best of its ability as regard investigation and research in the field of plant protection

Also, article VIII(1)(C) of IPPC also provides that the contracting states to the convention shall liaise with one another to the extent of being practicable in providing biological and technical information necessary for risk analysis of pest or diseases affecting the plant. The purport of this provision suggests the fact that materials source from biological material in curing, managing, and controlling plant pests or diseases could be said to have been contemplated by Article IV(3)(b) and VIII(1)(C) of IPPC. In this, it suffices to state that the international community is well informed concerning the conservation and preservation of plant material necessary for human use such as in the production of herbal material.

Ethical Guidelines concerning Manufacturing of Herbal Product in Nigeria

At the international level, there are no international treaties or conventions concerning the regulation of herbal products. However, the world health organization, an ambit of the United Nations, had set quality standards concerning the ingredient and content of herbal or phytomedicine products. In this regard, the World Health Organisation guidelines concerning the processing of herbal products identify some ethical guidelines to be observed in the production of herbal products. Some of the guidelines are as follow;

The World Health Organisation guidelines concerning good agricultural and collection practices for medicinal plants specify some ethical and medical guidelines. The guideline provides that a good agricultural collection practice for the production of herbal drugs should accede to the following ethical and medical guidelines, which include; sorting of the medicinal plant, cleaning, and washing, leaching, cutting and sectioning, drying of the medicinal plants to reduce damage by microbial infestation except in circumstances where the medicinal plant is needed freshly, fermentation and fumigation.

Concerning good quality manufacturing practices of herbal products, the World Health Organisation came up with a guideline on Quality Manufacturing practices of Herbal or Nutraceutical and Phytomedicine products. The guideline stipulates that herbal products are prepared or manufactured from the medicinal plant if the extracted medicinal material has been subjected to the following treatment and preparation; proper extraction, purification, fractionation, distillation, fermentation, fractionation, concentration, and subjecting the said material to biological or physicochemical treatment.

It must be noted that the World Health Organisation Guidelines on Quality Production of Herbal Dosage Forms further ensure that for there to be a good production of herbal dosage forms, it must aim at ensuring that medicinal plant material is suitable for the production of the final product and dosage forms of the herbal products.

The above serves as a guild line and ethical issues as stipulated by the World Health Organisation concerning the production of herbal medicine. However, the primary regulatory frame was left for countries where the activities are taking place to intervene and regulate the same in accordance with their laws.

Regulation of Nutraceutical and Phytomedicine under the Nigeria Law

Although the words herbal or phytomedicine are not expressly mentioned in any of the laws in Nigeria, however, they are often grouped into drugs which could be pharmaceutical and herbal drugs or supplements. This is concerning the fact that section 31, which is the interpretative section of the National Agency for Food and Drug Administration and Control Act, describe drug to include “any substance of vegetable, animal or any preparation or admixture that is manufactured to diagnose, mitigate, treat or prevent disease, abnormal physical state, and disorder state in man or animal. Given this description of what constitute drugs, to a large extent or by interpretation, it includes herbal or phytomedicine product, given the fact that they are mainly extracted from a plant for the purpose of serving as a supplement and medicine in the treatment of communicable and non-communicable disease.

Given the above, it suffices that in Nigeria, there are several laws that could serve as a means of regulating the production and use of herbal products, and they are examined as follows;

Nigeria Drug Products Advertisement Regulation

However, it must be noted that Article 2 of the Nigeria Drug Products Advertisement Regulation under the schedule to the Subsidiary Legislation of the National Agency for Food and Drug Administration and Control Act stipulate that before any drug (which may include herbal or phytomedicine product) can be advertised in Nigeria, there must be the issuance of pre-clearance and approval by the National Agency for Food and Drug Administration and Control. Article 1 of the regulation stipulated that whether a product is locally manufactured or imported into Nigeria, pre-clearance, and approval by the agency is a prerequisite for any advertisement and selling of such medicinal product.

It must be noted that Articles 11 and 16 of the Nigeria Drug Products Advertisement Regulation required that in

advertising any drugs product (may likely include herbal product) for sale, appropriate caution with regard to the usage of the product must be stated. Furthermore, it stipulates that a proper advertisement or labeling of a product should effectively and reasonably provide vital information concerning the safety, effectiveness, contra-indication, and side effect that may be adverse when consumed. To ensure effective compliance, Article 14 of the Nigeria Drug Products Advertisement regulation further require an individual or owner of a drug product (which is likely to include herbal product) to ensure their product has a proper prescription contained in a label which shall include the following information;

i. The name of the products and their brand name
ii. The content or ingredient of the product
iii. Indicating what the product is used for
iv. A proper description of the dosage
v. Duration of use of the product
vi. Mode of storage
vii. Manufacturing date
viii. Expiration date
ix. Adequate caution and warning concerning the product side effect

However, despite the above provision of Article 14 of the Nigeria Drug Product Advertisement Regulation, Article 12 of the regulation further caution manufacturers or owners of a product not to state in any advertisement or imply that their product is "safe," "possess special status" or "guarantee its efficacy." However, any claims as to the effectiveness, less toxic and safety of a product by a producer must be adequately substantiated. In substantiating any claims of less toxic nature and safety of a product, section 18 and 19 of the Nigeria Drug Product Advertisement Regulation require the owner or producer of a drug product (which include herbal products) to substantiate their claims by furnishing an accurate and proper interpretation of their research findings and any claims from scientific literature substantiating the safety, efficacy and adverse effect of the product.

Concerning the above provision articles 11, 12, 14, 16, 18, and 19 of the regulation, it must be noted that the regulation is required to adhere strictly. This is concerning the fact that, by Article 12 of the regulation, it is considered as an offence if producers provide misleading or false information concerning the efficacy, safety, and effectiveness of their product, or unsubstantiated claim or an impression that their product is safer and better than other related product. This position of the law has been aptly recognized in the case of George Abi V. Central Bank of Nigeria & Ors (2012) 3 NWLR (Pt. 1286), 1 at 38 and 48, the court although, it is the duty of a medical officer to inform a patient concerning the side effect of drugs or supplement and the risk therein. However, the court further stated that if a medical officer has exacted his professional knowledge skill and follows the prescription of the product, the medical officer will not be held liable for any resultant side effect. The purport of this decision of the court is that in this circumstance, it is the owner of the product that will be held liable for not adequately stating possible side effects the product may cause to an individual.

Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act

This Act regulates any fake or counterfeit drugs or food that has not been properly processed. In this regard, it suffices to state that, given the provision of Article 11, 12, 14, 16, 18, and 19 of the Nigeria Drug Product Advertisement Regulation, a drug (which include an herbal product or phytomedicine product) is considered fake, where there is misleading or false information concerning the safety and effectiveness of the product. This is concerning the fact that section 12 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act defined "fake drug" to include;

1. Any drug product container which is so designed to mislead the general public
2. A product that does not specify the following

i. An appropriate direction of the product use,
ii. Sufficient warning of the product use
iii. Method of use
iv. Dosage of the product to be taken
v. Production and expiry date

3. A product that is not registered in accordance with the drugs, food, and other related product Act in Nigeria

Concerning the above-cited provisions of section 12 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, a product that possesses or fall any of the condition stated therein is considered fake. Section 1 of the Fake Drugs Act prohibits the manufacturing, importation, possession, or sell, aid, and abets anyone in the manufacturing, importation, and selling of any product which falls within the specification of the Act. Section 3 and 8 of the Fake Drugs Act empower the state task force to confiscate the said fake drugs and materials used in the production of the fake products. Furthermore, the section also imposed penalties of N 500,000 or imprisonment not less than five years if anyone is found guilty.

National Drug Formulary and Essential Drugs List Act

It suffices to state that in Nigeria, the production or importation of drugs must contain or fall within the range of the list of drugs permitted by law. This is concerning the fact that section 1 of the National Drug Formulary and Essential Drugs List Act specifically stipulates the list of formulary and essential drugs permissible for production

and importation in Nigeria. And by section 2 of the Act, anyone found wanting of production, selling, advertising, and importing any drugs (which may likely include herbal products) not contained in the list has committed an offence. Although section 3 of the Act further provide if an individual is interested in manufacturing or importing any drugs not contained in the list provided for in the first schedule to the Act, such individual must apply to the minister In charge of health matter for approval upon satisfying the minister on the following ground;

i. That the product made or imported for treating uncommon disease (just like the ebola and Covid19 cases)
ii. That the common drug or product listed in the first schedule to National Drug Formulary and Essential Drugs List Act is not responsive enough to treat the disease
iii. That the drug is of great relevance and more responsive to those listed in the schedule to the Act

If the above condition has been satisfied, the minister of health may grant approval for the production or importation of such product. However, it seems by section 7 of the Act, an individual or firm may recommend to the National Drug Formulary and Essential Drug List Review Committee any product or formulation considered relevant treating communicable and non-communicable disease but not included in the list.

Also, in Nigeria, there are several health agencies responsible for the administration of the various laws that regulate drugs, foods, and supplement products, some of which are;

1. The National Agency for Drug Administration and Control Agency
2. The above laws are National Drug Formulary and Essential Drug List Review Committee
3. National Drug Law Enforcement Agency
4. National Primary Health Care Development Agency
5. Consumer Protection Council

The above agencies are saddled with the responsibility of regulating and implementing the various laws that regulate the importation, manufacturing, sales, or distribution of drugs, food, and supplement products (Olomojobi, 2019; Mckenzie et al., 2014). The agencies must also be required to conduct scientific tests on the product and the standard of facilities and factories in ascertaining if it is of quality standard and safe for the public to consume (Obioha et al., 2010; Omonona, 2015).

Legal Issues or Challenges Concerning Nutraceutical and Phytomedicine Products

Herbal products have been proven to be very effective as a supplement and treatment of communicable and non-communicable diseases. However, despite the numerous benefit of herbal product, there are still some legal issues or challenges inherent in the regulatory framework, and they are considered as follows;

1.Lack Direct National Legislation Regulating Herbal Product

Although, it may be argued that, given section 3 of the Act that it create a lily way for the importation or production of the herbal or phytomedicine products, however, it suffices to opine that given the condition stated therein before a minister could grant approval for the production or importation of drugs did not mention herbal drugs, but rather pharmaceutical drugs. Furthermore, it suffices to state that a perusal of the first schedule to the Nigeria National Drug Formulary and Essential Drugs List Act reveals that herbal or phytomedicine is not directly mentioned in the Act.

In this regard, the lack of a regulatory framework indirectly regulating herbal or phytomedicine products within Nigerians may lead to quack and fake manufacturing of an herbal medicinal product.

2.National Legislation Restriction

Although, a perusal of the first schedule to the Nigeria National Drug Formulary and Essential Drugs List Act reveals that herbal or phytomedicine is not directly mentioned in the Act. Although, it may be argued by some individual that, given section 3 of the Act, it create a lily way for the importation or production of herbal products. However, it suffices to opine that even if reliance is placed on the various Nigeria legal framework as being relevant in regulating the herbal medicinal product, given the condition stated therein before a minister could grant approval for the production or importation of herbal or phytomedicine, this, in essence, could be very bureaucratic that may result to a bottleneck that may discourage potent and qualify manufacturer of herbal product.

3.The multiplicity of National Regulatory Legal Framework

There are several national regulatory frameworks (international guidelines, monographs, and national laws regulating the manufacturing and use of drugs which by implication could also be argued that it refers to herbal or phytomedicine products) concerning herbal or phytomedicine products. Given the multiplicity of regulatory frameworks existing side by side, it could render the whole process of regulating the manufacturing and use of herbal or phytomedicine products very complex. Furthermore, it may result in a conflict of laws; thus, a manufacturer may be faced and confused with the task of identifying the international and national regulatory framework that may be applicable in guiding the whole

process of manufacturing herbal or phytomedicine products. Furthermore, it suffices to state majority of the laws that are deemed to indirectly regulate the production of herbal could easily lead to a bureaucratic process of enforcement and compliance, given the multiplicity of the supposed regulatory framework. In essence, it could lead to the production of quack or fake herbal medicinal products.

4. The tort of Negligence (Doctrinal of Res Ipsa Loquitur)

In a civil proceeding, it is a principle of law that an individual who asserts must prove with his case relying on convincing evidence. In this regard, there are certain instances where a herbal or phytomedicine product which may have been term safe and effective, but an individual could trace the harm or damage suffered resulting from consuming or taking a herbal or phytomedicine product, such individual could rely on the doctrine of res ipsa loquitur which means "the fact speaks for itself." In this regard, in relying on res ipsa loquitur doctrine against the owner of a product that an individual links the harm suffered, the owner of the product is oftentimes legally amputated. In the case of George Abi V. Central Bank of Nigeria & Ors (2012) 3 NWLR (Pt. 1286), 1 at 32-33, the court stated that the doctrine of res ipsa loquitur is a rule in Tort law that requires an individual to prove a case without having to prove that the owner of a product negligence specific act or omission resulted to damage or harm he/she suffered. What such individuals need to show to the court is the result of the damage or harm suffered.

Given the above, the doctrine of res ipsa loquitur is a principle that majorly legally works against the owner of herbal or phytomedicine products no matter how careful a producer may envisage in producing their products. This concerns the fact that all the complainant needs to show to the court in claiming damage is the surrounding circumstances that led to damage or harm suffered in consuming the herbal or phytomedicine products.

Conclusion/Recommendation

In this study, it has been highlighted that there has been a high rate of communicable and non-communicable diseases ravaging the global environment. That Nigeria has also had its fair share of the communicable and non-communicable diseases affecting the international community. It was also stated that in the quest of finding an effective treatment concerning communicable and non-communicable diseases, it has led to the reliance on herbal products, given their natural potency and therapeutic effect in the treatment of communicable and non-communicable diseases.

However, it was also established that given the relevance of the herbal product, it has degenerated to a multiplicity of several unchecked and unregulated manufacture herbal products. Although it was identified that the World Health Organisation has set out ethical guild line concerning the processing and production of herbal products, however, countries are given the regulatory power to regulate the production of the herbal product within their territory.

It was also identified that, though there is several legislation concerning the regulation of pharmaceutical drugs, however, there seems to be legislative silence or missing link concerning the herbal product. This concerns the fact that there was no express provision that mentioned herbal products in the various Nigeria regulatory framework. In this regard, it has further resulted in some ethical and legal issues in the production of herbal products.

In this regard, it, therefore, recommended that given the relevance and importance of herbal products;

i. That there is a need for Nigeria to adopt a unified and effective legal framework that will adequately address scientific and legal issues as it concerns the whole process involved in the production of herbal products.
ii. Given the above, there is a need for the Nigerian law to be reviewed to adequately capture the regulations of the processing and production of herbal products
iii. Furthermore, it is recommended that there is need to set up an effective regulatory body that will be solely charged with the responsibility of administrative regulation of the ethical processing and production of herbal products

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