

A Facile Study concerning the Legal Issues and Challenges of Herbal Medicine in Nigeria

Paul Atagamen Aidonojie¹, Esther Chetachukwu Aidonojie²,
Oaihimire Idemudia Edetalehn³, Oluwaseye Oluwayomi
Ikubanni⁵, Alade Adeniyi Oyebade⁵

^{1,3} *Edo State University, Uzairue, Nigeria*

² *Nnamdi Azikiwe University, Awka, Nigeria*

^{4,5} *Joseph Ayo Babalola University, Nigeria*

Abstract

It is apt to state that there have been an increase and the threat of contagious communicable and non-communicable diseases within most countries and Nigeria in particular. The causes of the outbreak are a result of an unhealthy lifestyle and poor scientific laboratory management. However, in search for finding a cure, has resulted in most people relying on herbal products. In this regard, the increasing demand for the herbal products has resulted in unskilled individuals indulging in the production of herbal products. It is concerning this pharmaceutical abnormality that this study tends to utilize a hybrid method of study in ascertaining

the dangers, guidelines, and legal regulations concerning poorly processed and manufactured herbal products. In this regard, the study, therefore, employs the use of a hybrid method of research to ascertain if there is compliance with international ethics and guidelines concerning herbal medicine production. An online questionnaire was sent to 313 respondents residing in Nigeria. The study, therefore, found that most individual indulging in herbal medicine production does not observe the international and national ethical guidelines concerning the manufacturing of herbal medicine. The study therefore concluded and recommended that there is a need for the Nigerian Government to through an effective legal framework and regulatory body address scientific and legal issues as it concerns the whole process involved in the production of herbal products.

Keywords

Legal, Ethical, Herbal, Products, Nigeria

I. Introduction

It has been globally reported that there have been widespread contagious communicable and non-communicable diseases ravaging virtually all countries within the global environment¹.

¹ Aidonojie, P.A., & Francis, E.C. (2022). Legal Issues Concerning Food Poisoning in Nigeria: The need for Judicial and Statutory Response. *Jurnal Media Hukum*, 29(1), 65-78; Aidonojie P. A., Anani O. A., Agbale P. O., Olomukoro J. O. and Adetunji C. O., (2020). "Environmental Law in Nigeria: A Review on its Antecedence, Application, Judicial Unfairness and Prospects", *Archive of Science & Technology*, Vol. 1(2), 212 – 221;

However, it suffices to state that the causes of most infectious and non-infectious diseases majorly stem from an unhealthy lifestyle, infectious disease outbreaks emanating from most scientific labs², and the consequences of natural disasters³.

Concerning the above, it suffices to state that, in Nigeria, there have been reported cases of infectious and non-infectious diseases such as Covid-19, tuberculosis, cholera, HIV, sickle cell, high blood pressure, diabetes, and high blood⁴. In this regard, it is apt to state that the expensive nature of health care delivery in Nigeria has resulted in individuals struck with infectious and non-infectious diseases finding solace in herbal medicinal products⁵. Although, herbal medicine product has been proven to be very potent in treating most infectious and non-infectious disease, given their natural endowment⁶. However, the upsurge in demand for herbal products has resulted in poorly processed and

Ukhurebor K. E. and Aidonojie P. A., (2021), The influence of climate change on food innovation technology: review on topical developments and legal framework, *Agric & Food Security*, Vol. 10(50), 1-11 <https://doi.org/10.1186/s40066-021-00327-4z>

² Admckenzie A., Sokpo E., and Ager A., (2014), Bridging the Policy Implementation Gap in Federal Health Systems: Lessons from the Nigerian Experience, *Journal of Public Health in African*, Vol. 5(3), 381-397;

³ Mahady G. B., (2001), Global harmonization of herbal health claims, *Journal of Nutrition*, Vol. 131(3), 1120S–1123S.

⁴ Abkeller K., (1991), Legal requirements for the use of phytopharmaceutical drugs in the Federal Republic of Germany, *Journal of Ethnopharmacol*, Vol. 32 (3), 225–229

⁵ Acalixto J. B., (2000), Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phytotherapeutic agents), *Brazilian Journal of medical & biological Research*, Vol. 33(2), 179–189

⁶ Jiang W. Y., (2005), Therapeutic wisdom in traditional Chinese medicine: a perspective from modern science, *Trends Pharmacol. Science*, Vol. 26(11), 558–563.

manufactured herbal medicinal products by most individuals who possess little or no knowledge concerning herbal medicine⁷.

It suffices to state that though there are no international legal frameworks concerning the regulation of herbal products, however, there are international guidelines and a few related national legislations that indirectly provide for issues concerning herbal products in Nigeria. However, despite the few relevant laws concerning the processing and manufacturing of herbal products in Nigeria there seems to be an increase or an upsurge of fake and poorly processed herbal products in Nigeria.

It is concerning the above, that this study tends to embark on a facile study concerning the dangers and consequences of fake and poorly processed and manufactured herbal medicinal products. Furthermore, the study will also investigate the causes or reason for the increased rate of poorly processed herbal drugs and to what extent the laws tend to regulate and curtail the incidence of poorly manufactured herbal products.

II. Method

Concerning the subject matter of the study, the researchers adopt a hybrid method of research that involves a doctrinal and non-doctrinal method of research. Concerning the doctrinal research method, it will enable the researcher to examine and analyse various national, international, and ethical guidelines concerning the production of phytomedicine products in Nigeria. Furthermore, the doctrinal method will also aid the researchers to

⁷ Aernst E., (1998), Harmless herbs? A review of the recent literature, *America Journal of Medicine*, Vol. 104, 170–178.

review or appraise some literature such as; textbooks, internet articles, journal articles, and relevant materials to this study.

However, a non-doctrinal method of research also adopted in this study will enable the researcher to collate and analyse extensive data with the use of an online questionnaire survey. The essence or reason for adopting a non-doctrinal method of research is concerning the fact that it will aid the researcher to ascertain if there is an increase in infectious and non-infectious diseases in Nigeria and the current increase in phytomedicine production. Furthermore, it is also aimed at ascertaining if there is compliance with the relevant legal and ethical guidelines concerning phytomedicine production.

III. Dangers and Effects of Poorly Processed Herbal Medicine

It is a general idea of the most individual in Nigeria that herbal medicinal product is more potent and safer in the treatment of various degree of communicable and non-communicable diseases⁸. However, it suffices to opine that the assertion that herbal medicine is devoid of any side effects is misleading⁹. This is concerning the fact that an unduly processed and manufactured herbal medicine which does not adhere to the required guidelines and inspection of the necessary agencies regulating the manufacturing of drugs could cause devastating health damage that

⁸ Okoli RI, Aigbe O, Ohaju-Obodo JO, Mensah JK. Medicinal herbs used for managing some common ailments among Esan people of Edo State, Nigeria. *Pak. J. Nutr* 2007;6(5):490-496.

⁹ *Ibid*

could be life-threatening¹⁰. In this regard, in Nigeria, it suffices to reiterate that there have been several reported cases of herbal poisoning of most individuals by several literatures¹¹. The causes of most of these dangerous side effects of herbal drugs are stem from the fact that there is a high influx of inferior or fake herbal products by an unskilled and untrained individual.

However, some of the dangers and effects often cause to an individual by poorly processed and manufactured herbal medicine are discussed as follows:

1. Liver and Kidney Damage

It has been recounted by several literature that poorly manufacture Herbal medicines could also cause kidney and liver damage in most consumer¹². This is concerning the fact that most poorly manufacture herbal products contain chemicals or substances that are fatally toxic and harmful to the liver and kidney which are vital organs of an individual. The assertion that poorly processed and manufacture herbal product could be toxic and dangerous to the liver is concerning the fact that several studies have shown that most inferior herbal medicine is can elevate the plasma level of enzymes and therefore causing hypokalemia¹³.

Also, it is also a truism that an individual not skilled or possessing the knowledge concerning the proper manufacturing of

¹⁰ *Ibid*

¹¹ Oshikoya KA, Senbanjo IO, Njokanma OF, Soipe A. Use of complementary and alternative medicines for children with chronic health conditions in Lagos, Nigeria. BMC Complement Altern Med 2008;8:66. doi:10.1186/1472-6882-8-66.

¹² *Ibid*

¹³ *Ibid*

an herbal products, may also lack the knowledge concerning the appropriate prescription and dosage of such herbal products in the treatment of an ailment. In this regard, herbal medicine that does provide the appropriate prescription and dosage of treatment of an ailment could also be fatal to the kidney or liver.

Furthermore, apart from damage to the kidney and liver a poorly manufacture herbal product may cause, it may also lead to damage to other vital organs such as;

- a. Splenic enlargement
- b. Lung tumor
- c. Liver fibrosis
- d. Cellular toxicity or genotoxicity
- e. gastrointestinal discomfort
- f. Thyroid tumor
- g. Increased risk of urothelial cancer
- h. Cirrhosis and hepatic veno-occlusive disease

2. It can cause Death

Generally, the most plant is said to contain bioactive and chemical constituent that is intrinsically toxic (carcinogenic and mutagenic) to the human system. For example, *Momordica charantia* a well-known plant that could be used as a herbal mixture to treat or that serve as an anti-malaria and anti-diabetic is capable of causing deadly hypoglycemia in children and some adult individual¹⁴. Also, other plants that could be used for an herbal mixtures that could be toxic and poisonous include but are

¹⁴ Aidonojie, P. A., Oaihimore, I. E. and Agbale, O. P., (2022), The Legal and Ethical Issues concerning Diagnosing and Treatment of Patients by Pharmacists in Nigeria, *Euromentor Journal*, Vol. 13(2), PP. 113-138

not limited to; *Datura* spp., *Digitalis* spp., *Atropa belladonna*, *Pyrethrum*, and *Lantana Camara*

Concerning the above, although it can be said that most of the identified toxic and harmful plants could be useful as a pesticide and for hunting. However, it suffices to state that most individual who is not skilled or possesses the required knowledge of processing and manufacturing herbal drugs may endanger the lives of several persons when making use of such plants that are potentially toxic and harmful.

3. Destruction of Vital Human Cell

Most plants used in the processing and manufacturing of the herbal products are said to be cytotoxicity. Cytotoxicity is a process where a substance inhibits or causes an obstruction to cell attachment. It also involves a process of causing the proliferation of the cell, altering cells' growth, and ultimately causing death.

Furthermore, studies has shown that some herbal product such as *Ginkgo biloba* which is capable of invading tumor cell and inhibiting cell proliferation, also discovered of causing constrain to platelet-activating factor, therefore causing continuous bleeding¹⁵. In this regard, it suffices to state that in circumstances where an individual not skilled or possessing the knowledge of herbal medicine made use of plants that are cytotoxic to formulate herbal mixture it could be lethal to any individual who consumes such herbal product.

¹⁵ Abioha E. E., Ajala A. S., and Matobo T. A., (2010), Analysis of the Performance of Expanded Programme on Immunisation (EPI) for Four Killer Disease under the Military and Civilian Regimes in Nigeria, 1995-1999; 2000-2005, *Ethno Med Journal*, Vol. 4(1), 43-58

However, irrespective of the above dangers and side effects identify concerning poorly processed and manufacture herbal medicine, there are other dangers and side effects that may inevitable. They include;

- a. Shortness of breath
- b. Hypertension
- c. Blur vision
- d. Constipation
- e. Stooling and vomiting
- f. Dermatitis
- g. Morbid spontaneous spinal epidural hematoma

IV. Global Regulation of Herbal Medicinal Products

It suffices to state that a cursory review of various international treaties, conventions and protocols shows that there is no legal framework concerning the manufacturing and processing of an herbal products¹⁶. However, in order to ensure a proper guidelines and regulations for the processing and manufacturing of herbal medicinal products within the global terrain, the World Health Organisation initiated ethical guidelines concerning the processing and manufacturing of an herbal products¹⁷. Some of the World Health Organisation guidelines concerning the

¹⁶ Angell M., and Kassirer J. P., (1998), Alternative medicine — the risks of untested and irregular remedies, *New England Journal of Medicine*, Vol. 339(12), 839–841

¹⁷ World Health Organisation guidelines on good agricultural and collection practices (GACP) for medicinal plants, Geneva; 2003.

processing and manufacturing of herbal medicinal products include the following;

- a. World Health Organisation Guidelines concerning good Agricultural and collection practices for medicinal plants
- b. World Health Organisation Guidelines on Quality Manufacturing Practice of Herbal Products
- c. World Health Organisation Guidelines on Quality Production of Herbal Dosage Forms

The essence of the above guidelines set out by the World Health Organisation is to ensure the processing and manufacturing of a safe, quality, and marketable herbal product. Furthermore, it also aims at ensuring technical regulation and support concerning quality herbal product processing and manufacturing.

Concerning the above, as stipulated by World Health Organisation Guidelines on Good Agricultural and collection practices concerning medicinal plants, it is required all medical plant must adhere to the standard of good post-harvest guidelines which includes;

That there must be proper Sorting of plants for herbal production

- a. Proper washing and cleaning
- b. The herbal plant should be properly sectioned and cut neatly
- c. Drying of herbal plants when required to minimize microbial infestation
- d. Fumigation
- e. Fermentation
- f. Irradiation

Furthermore, the World Health Organisation guidelines concerning the quality manufacturing practice of herbal medicinal

products are to ensure that there is no trace of the existence of undesirable and unwanted toxic constituents in the herbal plant material¹⁸. In this regard, the World Health Organisation stipulated in their guideline on the quality manufacturing practice of herbal products¹⁹, that for herbal product to be adjudged to be properly manufactured and processed from an herbal plant it must adhere to the following preparation and treatment²⁰ as follows;

- a. Proper extraction of the herbal constituent from the plant, such extraction include; maceration, digestion, percolation, decoction
- b. The plant material must undergo distillation and Purification
- c. Fractionation must be properly executed
- d. Concentration
- e. Proper fermentation
- f. Furthermore, subjecting the extracted material to a biological or physicochemical treatment

Also, the World Health Organisation further offer guidelines on quality and good herbal dosage form. In this regard, the World Health Organisation identifies a universal and common dosage form of herbal products to include;

¹⁸ WHO Supplementary Guidelines on GMP, "Technical Report Series, No. 937", 2006; WHO Guidelines on Herbal Product "Technical Report Series, No. 1010", 2018

¹⁹ Awang D. V. C., (1997), Quality control and good manufacturing practices: Safety and efficacy of commercial herbals, *Food Drug Law Journal*, (1997), Vol. 52, 341–344; World Health Organisation guidelines on good manufacturing practices (GMP) for herbal medicines. Geneva, 2007

²⁰ WHO Guidelines on GMP, 2007; WHO Guidelines on Herbal Product "Technical Report Series, No. 1010", 2018; WHO Supplementary Guidelines on GMP "Technical Report Series, No. 1010", 2018; WHO GMPP "Technical Report Series, No. 986", 2018

- a. Herbal liquid dosage forms such as; fluid extract, syrups, and aromatic waters
- b. Herbal solid dosage forms such as; herbal tea bags, granules, plant powders, pills, and capsules

Although it suffices to opine irrespective of the World Health Organisation guidelines concerning herbal medicine, there are also national laws concerning herbal products. Although, the challenges concerning the national laws is in regard to the fact that it is not a direct legal framework that provides for and regulates herbal products in Nigeria. In this regard, it will be relevant to examine some of these laws with regard to the extent they regulate herbal medicinal products in Nigeria.

V. Nigeria Laws concerning the Processing and Manufacturing of Herbal Medicine

In Nigeria, there are several laws concerning the regulation of drugs. Although, virtually all legislation review shows that the phrase ‘herbal medicine’ is not expressly mentioned in these legislations. However, by interpretation of section 31 of the National Agency for Food and Drug Administration and Control Act (NAFDAC Act)²¹, it defined drugs to mean thus;

“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”

²¹ National Agency for Food and Drug Administration and Control Act

Concerning the above, it suffices to opine that an interpretation of section 31 of the NAFDAC Act seems to include herbal medicine as drugs regulated by the Act and other relevant laws in Nigeria. This is concerning the fact that the provision of section 31 of the NAFDAC Act made mention of “vegetable” and “any preparation or admixture” which in essence include herbal constituents in making herbal medicine.

Having established the fact that though the various Nigeria laws concerning drugs did not make mention herbal products, by interpretation of section 31 of the NAFDAC Act herbal medicine is inclusive of the definition of drugs by the said provision. In this regard, it is apt to state that the laws that regulate the processing and manufacturing of pharmaceutical drugs also indirectly applies to herbal medicinal product.

In furtherance of the above, it suffices to state that by section 1 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provision) Act²², it is an offense for anyone to indulge in manufacturing, import, selling or aid anyone in the manufacturing and selling of fake and counterfeit drugs in Nigeria. Furthermore, section 12 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods Act²³ stipulate that a drug (which also includes herbal medicine) is said to be counterfeit and fake on the following grounds;

- a. That the drugs are designed to confuse and mislead the public

²² Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, CAP C34, Laws of the Federation of Nigeria, 2004

²³ *Ibid*

- b. Any drug that do not state the proper direction of its usage, method of use, dosage format, its production date, and expiring date
- c. Where the manufacturer of such drugs fails to obtain a license and register such drugs with the relevant authority

In furtherance of the above, any drugs that fall or possess any of the above features are said to be fake and counterfeit. In this regard, section 3 of the Fake Drugs Act²⁴ further stipulates that the state task force shall be saddled with the power to confiscate any fake drugs and places a penalty of N 500,000 or five (5) years imprisonment upon conviction by a competent court.

Also, the National Drug Formulary and Essential Drugs List Act²⁵ is also a relevant law that deals with the regulation of drugs in Nigeria. This is concerning the fact that the Act seems to stipulate and specified the list of drugs allowable for production and importation²⁶. Section 3 of the National Drug Formulary and Essential Drugs List Act²⁷ further stipulates that the importation and manufacturing of drugs not recognized by the Act can only be allowed with the permission of the Minister of Health. Although, the permission of the minister may only be granted on the following ground;

- a. That such product is mainly for the treatment of rare diseases

²⁴ *Ibid*

²⁵ National Drug Formulary and Essential Drugs List Act, CAP 252, Laws of the Federation of Nigeria, 2004; Vanherweghem L. J., (1998), Misuse of herbal remedies: the case of an outbreak of terminal renal failure in Belgium (Chinese herbs nephropathy), *Journal of Alternative Complement Medicine*, Vol. 4(1), 9–13

²⁶ *Ibid* section 1

²⁷ *Ibid*

- b. That the recognized drugs by the Act are not responsive and effective in the treatment of a particular diseases

However, by section 7 of the National Drug Formulary and Essential Drugs List Act²⁸ a drug that is proven to be more effective in the treatment of a disease, may be recommended to the National Drug Formulary and Essential Drug List Review Committee. The essence of the recommendation is aimed at incorporating such drugs as part of the drugs recognize by law.

Furthermore, the Nigeria Drug Products Advertisement Regulation stipulates that National Agency for Food and Drug Administration and Control must issue approval and pre-clearance before any manufacturer can advertise and sell their drugs to the general public²⁹. Furthermore, Articles 11 and 16 of the Act³⁰ also stipulate that when advertising any drugs, the following caution should be properly stated;

- a. The usage of the product
- b. Vital information concerning the safety and effectiveness
- c. Contra-indication, and side effects

The essence of the above is to avoid the incidence of misleading claims, information, and impression concerning a product. in the case of *George Abi V. Central Bank of Nigeria & Ors*³¹, the court was of the view that although, a medical officer is required to inform a patient concerning the risk and side effect of effects of drugs being administered. However, if a medical officer

²⁸ *Ibid*

²⁹ Section 2 of Nigeria Drug Products Advertisement Regulation under the schedule to the Subsidiary Legislation of the National Agency for Food and Drug Administration and Control Act, CAP N1 Laws of the Federation of Nigeria, 2004

³⁰ *Ibid*

³¹ (2012) 3 NWLR (Pt. 1286)

has exercised his professional knowledge and skill in administering the prescription of the drugs, the medical officer said not to be liable for any resultant damage and side effect suffered by a patient. In this regard, it suffices to state that, the purport and essence of this decision concerning this case, is aimed at making the owner of the medicinal product liable for failing to properly state the risk and possible side effects of their drugs.

Furthermore, Article 12 of the regulation further stipulates that manufacturers of drugs who state or describe their product as possessing a special status, safe, non-toxic, and therefore guarantee its efficacy, must substantiate their findings concerning the safety and non-toxicity of their product³².

VI. Legal Issues or Challenges Concerning Herbal Products in Nigeria

Concerning the evaluation of this study, it suffices to opine that, it has been opined that no doubt herbal medicinal product possesses a lot of health benefit. This is concerning the fact that its content is natural in nature and distill from chemical composition or preservative method. Furthermore, an herbal medicinal product has also been adjudged to be very effective and reliable as a food supplement and treatment of infectious and non-infectious diseases. However, despite this undoubted and relevant health benefit of an herbal medicinal product, there seem to be challenges and issues as concerns the influx of poorly processed and manufacture herbal products. However, the challenges of the influx of fake and poorly processed herbal products in Nigeria is

³² *Ibid* Article 18 and 19

stem from the following legal unwariness concerning herbal products, which are;

- a. There is an absence of a primary international and national legal framework regulating herbal products
- b. The bureaucratic administrative process involves approving a credible person skilled in herbal medicine production
- c. The multiplicity of secondary national regulatory laws that indirectly regulate herbal product
- d. The challenge and difficulties of establishing the tort of the negligence of a manufacturer (doctrine of *Res Ipsa Loquitur*)

VII. Presentation and Analysis of Data

The study adopts an online questionnaire sent to the respondent's domicile in Nigeria. Furthermore, the data obtained or generated through the questionnaire is therefore analysed below as follows:

1. Sample Size and Techniques

The researchers used an online questionnaire survey to disseminate the questionnaire survey to ascertain if the respondents are residing or living in Nigeria. However, in selecting the respondents, the researchers adopted in their study simple random sampling techniques. This technique according to Aidonojie et al.³³, in several of their study has been regarded as a

³³ Aidonojie P. A, Odojor A. O., and Agbale O. P., (2021), The Legal Impact of Plea Bargain in Settlement of High Profile Financial Criminal Cases in Nigeria, *Sriwijaya Law Review*, Vol. 5(2), PP. 161-174; Aidonojie P. A., (2022), The Societal and Legal Missing Link in Protecting a Girl Child against abuse before and Amidst the Covid-19 Pandemic in Nigeria” *Jurnal Hukum UNISSULA*, Vol. 38(1), PP. 61-80; Aidonojie P. A., Anne O. O., and Oladele O. O., (2020), An Empirical Study of the Relevance and Legal

very suitable, reliable, and potent technique means in selecting or choosing respondents from a heterogeneous population like Nigeria. Furthermore, it suffices to state that in plethoral studies

Challenges of an E-contract of Agreement in Nigeria” *Cogito Multidisciplinary Research Journal*, Vol. 12(3), P. 181; Aidonojie P. A., Ikubanni O. O., Okoughae N. and Ayoedeji A. O., (2021), The challenges and relevance of technology in administration of justice and human security in Nigeria: Amidst the Covid-19 pandemic, *Cogito Multidisciplinary Journal*, Vol. 13(3), PP. 149 – 170; Aidonojie P. A., Majekodunmi, T. A., Ikubanni, O. O. and Ibrahim N., (2022), The causes of the Rising incidence of domestic violence in Nigeria: Proposing Judicial Separation as a Panacea, *Jurnal Hukum UNISSULA*, Vol. 38(2), PP. 61-80

by Aidonojie *et al.*³⁴, Oladele *et al.*³⁵, and Majekudumi *et al.*³⁶ It has been also argued that a simple random sampling technique is hassle-free in selecting respondents and it is bereft of any form bias.

-
- ³⁴ Aidonojie, P. A. and Odojor, A. O., (2021), Impact and Relevance of Modern Technological Legal Education Facilities amidst the Covid-19 Pandemic: A Case Study of Law Students of Edo University Iyamho, *KIU Journal of Humanities*, Vol. 5(4), 7-19; Aidonojie, P. A., Nwazi, J. and Ugiomo E., (2022), The Legality, Prospect, and Challenges of adopting Automated Personal Income Tax by States in Nigeria: A Facile Study of Edo State, *Cogito Multidisciplinary Journal*, Vol. 14(2), 149 – 170; Aidonojie, P. A., Odojor, A. O., Ikubanni, O. O., Oyeade, A. A., Oyedeji, A. I. and Okuoghae, N., (2022), The Challenges and Impact of Technological Advancement to the Legal Profession in Nigeria given the Covid-19 Pandemic, *KIU Journal of Humanities*, Vol. 6(4), 5-19; Aidonojie, P. A., Okuoghae N., Agbale, O. P., Idahosa, M. E., (2022), Supervisor and Supervisee Relationship: The Legal and Ethical Issues Concerning Academic Theft in Nigeria Tertiary Institution, *Euromentor Journal*, Vol. 13(1), 113-138; Aidonojie P. A., Ikubanni O. O. and Okuoghae N., (2022), The Prospect, challenges and Legal Issues of Digital Banking in Nigeria, *Cogito Multidisciplinary Journal*, Vol. 14(3), P186 – 209; Aidonojie, P. A., Imoisi S. E. and Oaihimire, I. E., (2022), A Facile Study concerning the Prospect and Challenges of Conducting a Hybrid Method of Legal Research in Nigeria, *Euromentor Journal*, Vol. 13(3), PP. 113-138; Majekodunmi, T. A., Oluwaseun, J. A., Aidonojie P. A., Ikubanni, O. O. and Oyeade A. A., (2022), Legal Issues in Combating the Scourge of Terrorism; Its Impact on International Trade and Investment: Nigeria as a Case Study, *KIU Journal of Humanities*, Vol. 7(3), 129-139
- ³⁵ Oladele, O. O., Aidonojie, P. A., Uzualu, J. E., Ikubanni, O. O. and Oyedeji, A. I., (2022), An Empirical Study of Criminalizing Minor Infractions of Tax Laws in Nigeria: The Need for Negotiated Punishments, *KIU Journal of Humanities*, Vol. 7(2), PP. 23-35
- ³⁶ Majekodunmi, T. A., Oluwaseun, J. A., Idahosa, M. E., Ikubanni, O. O. and Aidonojie, P. A., (2022), The causes of the Rising incidence of Terrorism occasioning Deprivation of the Right to Life in Nigeria, *KIU Journal of Humanities*, Vol. 7(2), PP. 5-19

However, 313 respondents residing in Nigeria were selected randomly to respond or give an informed response concerning the legal and ethical issues of phytomedicine in Nigeria.

2. Data Analysis

The data derived or obtained in this study with the use of a questionnaire survey is hereby analysed below:

Research Question One

What State do you reside in Nigeria?

313 responses

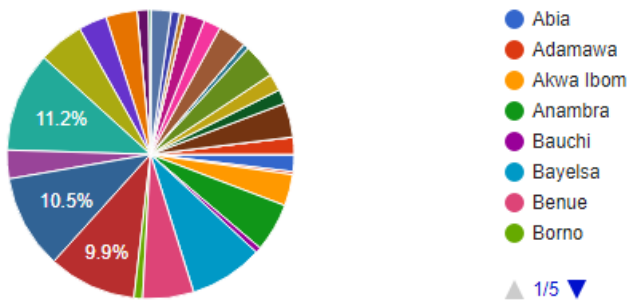


FIGURE 1. Clarifying if the respondents reside in Nigeria

TABLE 1. Valid Clarifying if the respondents reside in Nigeria

S/N	States in Nigeria	Responses of Respondents	Percent
1	Abia	6	1.9%
2	Adamawa	1	0.3%
3	Akwa Ibom	11	3.5%
4	Anambra	17	5.4%
5	Bauchi	2	0.6%
6	Bayelsa	26	8.3%
7	Benue	18	5.8%
8	Borno	3	1%
9	Cross River	31	9.9%

S/N	States in Nigeria	Responses of Respondents	Percent
10	Delta	33	10.5%
11	Ebonyi	10	3.2%
12	Edo	35	11.2%
13	Ekiti	16	5.1%
14	Enugu	10	3.2%
15	(FCT) Abuja	11	3.5%
16	Gombe	Nil	Nil
17	Imo	4	1.3%
18	Jigawa	1	0.3%
19	Kaduna	7	2.2%
20	Kano	3	1%
21	Katsina	2	0.1%
22	Kebbi	Nil	Nil
23	Kogi	7	2.2%
24	Kwara	6	1.9%
25	Lagos	10	3.2%
26	Nassarawa	Nil	Nil%
27	Niger	2	0.6%
28	Ogun	12	3.8%
29	Ondo	6	1.9%
30	Osun	5	1.6%
31	Oyo	12	3.8%
32	Plateau	Nil	Nil
33	Rivers	6	1.9%
34	Sokoto	Nil	Nil
35	Taraba	Nil	Nil
36	Yobe	Nil	Nil
37	Zamfara	Nil	Nil
	TOTAL	313	100%

Figure 1 and Table 1 above represent valid data presentations that reflect the valid responses of the respondents stating or identifying the places they reside in Nigeria.

Research Question Two

Do you agree that there have been rising cases of an infectious and non-infectious diseases in Nigeria?

311 responses

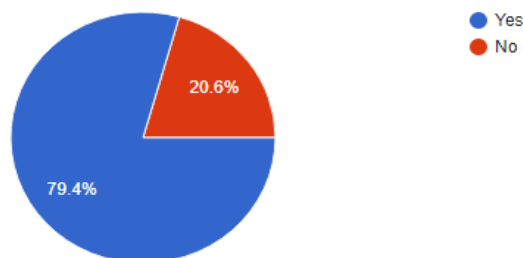


FIGURE 2. Respondents' identifying if there is a rising case of diseases in Nigeria

TABLE 2. Respondents' Valid responses identifying if there is rising cases of diseases in Nigeria

	Response	Percent
Valid Yes	247	79.4
Valid No	64	20.6
Total	311	100%

Figure 2 and Table 2 above are a representation of the respondents' identification of whether there is a rising incidence of infectious diseases in Nigeria.

Research Question Three

Which of the following infectious and non-infection disease have over time ravaged Nigeria? You can tick more than one option

311 responses

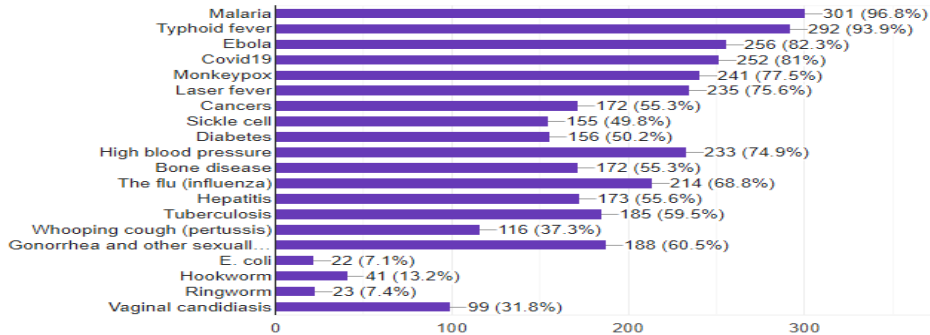


FIGURE 3. Cluster responses by respondents identifying various infectious and non-infectious diseases ravaging Nigeria

TABLE 3. Valid Cluster of respondents identifying various infectious and non-infectious diseases ravaging Nigeria

Infectious and Non-infectious diseases	Cluster of Response	Percentage
Malaria	301	96.8%
Typhoid fever	292	93.9%
Ebola	256	82.3%
Covid19	252	81%
Monkeypox	241	77.5%
Laser fever	235	75.6%
Cancers	172	55.3%
Sickle cell	155	49.8%
Diabetes	156	50.2%
High blood pressure	233	74.9%
Bone disease	172	55.3%
The flu (influenza)	214	68.8%
Hepatitis	173	55.6%
Tuberculosis	185	59.5%
Whooping cough (pertussis)	116	37.3%
Gonorrhea and other sexually transmitted diseases (STD)	188	60.5%

Infectious and Non-infectious diseases	Cluster of Response	Percentage
E. coli	22	7.1%
Hookworm	41	13.2%
Ringworm	23	7.4%
Vaginal candidiasis	99	7.4%

Figure 3 and Table 3 are respondents’ valid clusters of responses identifying the various kind of infectious and non-infectious diseases ravaging Nigeria and various prospects of the digital banking system in Nigeria.

Research Question Four

Do you agree that given the rise of infectious and non-infectious disease in Nigeria there have been increased production of phytomedicine (herbal) product?

313 responses

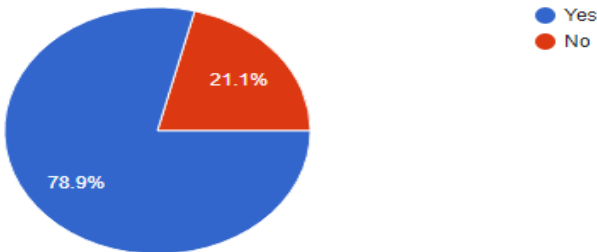


FIGURE 4. Respondents clarifying the rise in phytomedicine products as a result of diseases ravaging Nigeria

TABLE 4. Valid Respondents' clarification of the rise in phytomedicine products as a result of diseases ravaging Nigeria

	Response	Percent
Valid Yes	247	78.9%
Valid No	66	21.1
Total	313	100%

Figure 4 and Table 4 are valid respondents' cluster responses stating or identifying the increase in the production of phytomedicine products as a result of the rise of infectious and non-infectious diseases in Nigeria.

Research Question Five

Has there been due compliance with the International legal and ethical guidelines concerning the production of Phytomedicine (herbal) products in Nigeria?

312 responses

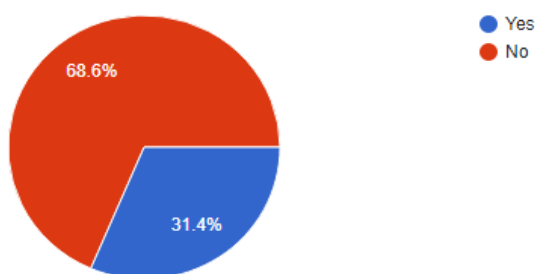


FIGURE 5. Respondents stating if there is compliance concerning the guidelines of phytomedicine production in Nigeria

TABLE 5. Valid Respondents' responses if there is compliance with the guidelines of phytomedicine production in Nigeria

	Response	Percent
Valid Yes	98	31.4%
Valid No	214	68.6%
Total	312	100%

Figure 5 and Table 5 are respondents' valid clusters of responses clarifying if there has been compliance with the international legal and ethical guidelines concerning the production of phytomedicine products in Nigeria.

Research Question Six

Which of the following international legal and ethical guidelines has not been duly observed in the production of a phytomedicine (herbal) product in Nigeria? You can tick more than one option

236 responses

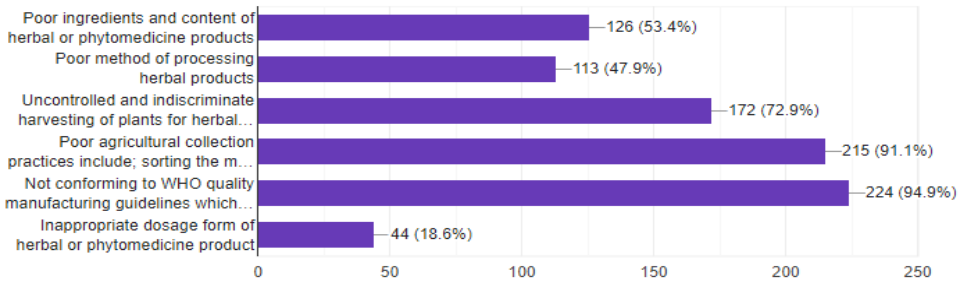


FIGURE 6. Respondents stating the guidelines not observed in the production of phytomedicine products in Nigeria

Table 6. Valid cluster of respondents stating the guidelines not observed in the production of phytomedicine products in Nigeria

Some guidelines for phytomedicine production	Cluster of Responses	Percentage
Poor ingredients and content of herbal or phytomedicine products	126	53.4%
Poor method of processing herbal products	113	47.9%
Uncontrolled and indiscriminate harvesting of plants for herbal production	172	72.9%
Poor agricultural collection practices include; sorting the medicinal plant, cleaning, and washing, leaching, cutting and sectioning, drying the medicinal plants to reduce damage by microbial infestation	215	91.1%
Not conforming to WHO quality manufacturing guidelines which include; proper extraction, purification, fractionation, distillation, fermentation, fractionation, concentration, and subjecting the said	224	94.9%

Some guidelines for phytomedicine production	Cluster of Responses	Percentage
material to biological or physicochemical treatment.		
Inappropriate dosage form of herbal or phytomedicine product	44	18.6%

Figure 6 and Table 6 are valid respondents' cluster responses stating or identifying the various guidelines that have not been duly observed in the production of phytomedicine medicine products in Nigeria.

Research Question Seven

Which of the following could aid in salvaging the non-compliance of the international legal and ethical guidelines concerning the production of Phytomedicine (herbal) products in Nigeria? You can tick more than one option

238 responses

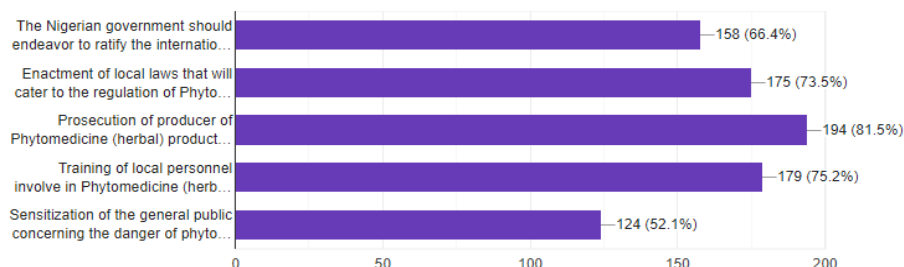


Figure 7. Respondent responses concerning remedies in salvaging poorly processed phytomedicine products in Nigeria

Table 7. Valid cluster of respondents stating the remedies for salvaging poorly processed phytomedicine products in Nigeria

Remedies concerning poorly process phytomedicine products in Nigeria	Cluster of Responses	Percentage
The Nigerian government should endeavor to ratify the international treaty and ethical guidelines concerning the herbal product	158	66.4%
Enactment of local laws that will cater to the regulation of Phytomedicine (herbal) products in Nigeria	175	73.5%

Remedies concerning poorly process phytomedicine products in Nigeria	Cluster of Responses	Percentage
Prosecution of producer of Phytomedicine (herbal) product not in compliance with the legal and ethical guidelines during production	194	81.5%
Training of local personnel involve in Phytomedicine (herbal) product production in Nigeria	179	75.2%
Sensitization of the general public concerning the danger of phytomedicine product that does not comply with the legal and ethical guidelines during production	124	52.1%

Figure 7 and Table 7 are respondents' clusters of valid responses stating some of the possible remedies that could remedy the incessant poorly produce phytomedicine product that does not conform to the international legal and ethical guidelines in Nigeria.

VIII. Discussion of Findings

Concerning the data collated from the respondents to the questionnaire, figure 1 and table 1, is to the effect that the 313 respondents are persons or individuals who live and reside in Nigeria. In this regard, it is apt to opine that the reasons for figure 1 and table 1 are aimed at ascertaining and ensuring that the respondents are persons who possess verifiable knowledge to respond or give an informed answer to the questions concerning issues as they relate to phytomedicine (herbal) products in Nigeria.

However, in figure 2 and table 2, 79.4% of the respondents identify that in Nigeria there has been a rise incidence of infectious and non-infectious diseases. Furthermore, in figure 3 and table 3

the respondents were able to identify some of the most prevalent infectious and non-infectious diseases in Nigeria as follows;

- 1) 96.8% of the respondents identify malaria
- 2) 93.9% stated identifying typhoid fever
- 3) 82.3% stated ebola
- 4) 81% Covid19
- 5) 77.5% stated monkeypox is one of the infectious diseases
- 6) 75.6% stated laser fever
- 7) 50.2% identify diabetes as one of the diseases
- 8) 74.9% stated high blood pressure is one of the non-infectious diseases
- 9) 68.8% identify flu (influenza)
- 10) Furthermore, 59.5% of the respondents also identify tuberculosis as one of the diseases.

Given the above, it suffices to state that it is no news that the above identify infectious and non-infectious diseases have significantly crippled and significantly derange the health of most of Nigeria. In this regard, in figure 4 and table 4 78.9% of the respondents were able to identify that in search for a solution to complement the regular medical treatment, has led to an increase in the production of phytomedicine products by those skilled and unskilled in the act of phytomedicine and herbal production. However, in figure 5 and table 5, 68.6% of the respondents there has not been compliant with the international legal and ethical guidelines concerning the production of phytomedicine products in Nigeria. In figure 6 and table 6 the respondents were able to identify some of the international legal and ethical issues that have been not been observed by some individuals in the production of phytomedicine products as follows;

- 1) 53.4% of the respondents stated that there are poor ingredients and content of herbal or phytomedicine products
- 2) 91.1% identify that there are poor agricultural collection practices include; sorting the medicinal plant, cleaning, washing, leaching, cutting and sectioning, and drying the medicinal plants to reduce damage by a microbial infestation.
- 3) 94.9% also stated that WHO quality manufacturing guidelines which include; proper extraction, purification, fractionation, distillation, fermentation, fractionation, concentration, and subjecting the said material to biological or physicochemical treatment are not often observed in the production of phytomedicine products.
- 4) 47.9% identify the poor method of processing herbal products as one of the issues concerning phytomedicine products.
- 5) 72.9% stated that there is uncontrolled and indiscriminate harvesting of plants for herbal production.

Given the above, it suffices to state that in circumstances where the above legal and ethical guidelines concerning the production of phytomedicine or herbal are not duly complied with, will lead to the toxic production of herbal drugs that could be lethal. However, to curtail the continuous production of phytomedicine product that does not accede to international legal and ethical guidelines, in figure 7 and table 7 the respondents further identify a possible solution that could aid in savaging the non-compliance of legal and ethical guidelines concerning the production of Phytomedicine products in Nigeria as follow;

- 1) 66.4% of the respondents stated that the Nigerian government should endeavor to ratify the international treaty and ethical guidelines concerning the herbal product

- 2) 73.5% stated that there is a need for enactment of local laws that will cater to the regulation of phytomedicine (herbal) products in Nigeria
- 3) 81.5% identify that there should be prosecution of producers of phytomedicine (herbal) products not in compliance with the legal and ethical guidelines during production
- 4) 75.2% stated that training of local personnel involve in phytomedicine (herbal) product production in Nigeria could aid in improving the content of an herbal product
- 5) Furthermore, 52.1% also state that there is a need to sensitize the general public concerning the danger of phytomedicine product that does not comply with the legal and ethical guidelines during production.

IX. 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 communicable and non-communicable diseases affecting the international community. It was also stated that the quest for finding an effective treatment concerning communicable and non-communicable diseases, 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 into 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 Nigerian 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;

- 1) 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.
- 2) 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
- 3) 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

X. References

Abioha E. E., Ajala A. S., and Matobo T. A., (2010), Analysis of the Performance of Expanded Programme on Immunisation (EPI) for Four Killer Disease under the Military and Civilian

- Regimes in Nigeria, 1995-1999; 2000-2005, *Ethno Med Journal*, Vol. 4(1), 43-58
- Abkeller K., (1991), Legal requirements for the use of phytopharmaceutical drugs in the Federal Republic of Germany, *Journal of Ethnopharmacol*, Vol. 32 (3), 225–229
- Abwang D. V. C., (1997), Quality control and good manufacturing practices: Safety and efficacy of commercial herbals, *Food Drug Law Journal*, (1997), Vol. 52, 341–344; World Health Organisation guidelines on good manufacturing practices (GMP) for herbal medicines. Geneva, 2007
- Acalixto J. B., (2000), Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phytotherapeutic agents), *Brazilian Journal of medical & biological Research*, Vol. 33(2), 179–189
- Admckenzie A., Sokpo E., and Ager A., (2014), Bridging the Policy Implementation Gap in Federal Health Systems: Lessons from the Nigerian Experience, *Journal of Public Health in African*, Vol. 5(3), 381-397
- Aernst E., (1998), Harmless herbs? A review of the recent literature, *America Journal of Medicine*, Vol. 104, 170–178.
- Aidonojie P. A., Odojor A. O., and Agbale O. P., (2021), The Legal Impact of Plea Bargain in Settlement of High Profile Financial Criminal Cases in Nigeria, *Sriwijaya Law Review*, Vol. 5(2), PP. 161-174
- Aidonojie P. A., (2022), The Societal and Legal Missing Link in Protecting a Girl Child against abuse before and Amidst the Covid-19 Pandemic in Nigeria” *Jurnal Hukum UNISSULA*, Vol. 38(1), PP. 61-80
- Aidonojie P. A., Anani O. A., Agbale P. O., Olomukoro J. O. and Adetunji C. O., (2020). “Environmental Law in Nigeria: A Review on its Antecedence, Application, Judicial Unfairness and Prospects”, *Archive of Science & Technology*, Vol. 1(2), 212 – 221

- Aidonojie P. A., Anne O. O., and Oladele O. O., (2020), An Empirical Study of the Relevance and Legal Challenges of an E-contract of Agreement in Nigeria” *Cogito Multidisciplinary Research Journal*, Vol. 12(3), P. 181
- Aidonojie P. A., Ikubanni O. O. and Okoughae N., (2022), The Prospect, challenges and Legal Issues of Digital Banking in Nigeria, *Cogito Multidisciplinary Journal*, Vol. 14(3), PP. 186 – 209,
- Aidonojie P. A., Ikubanni O. O., Okoughae N. and Ayodeji A. O., (2021), The challenges and relevance of technology in administration of justice and human security in Nigeria: Amidst the Covid-19 pandemic, *Cogito Multidisciplinary Journal*, Vol. 13(3), PP. 149 – 170
- Aidonojie P. A., Majekodunmi, T. A., Ikubanni, O. O. and Ibrahim N., (2022), The causes of the Rising incidence of domestic violence in Nigeria: Proposing Judicial Separation as a Panacea, *Jurnal Hukum UNISSULA*, Vol. 38(2), PP. 61-80
- Aidonojie, P. A. and Odojor, A. O., (2021), Impact and Relevance of Modern Technological Legal Education Facilities amidst the Covid-19 Pandemic: A Case Study of Law Students of Edo University Iyamho, *KIU Journal of Humanities*, Vol. 5(4), PP 7-19
- Aidonojie, P. A., Imoisi S. E. and Oaihimore, I. E., (2022), A Facile Study concerning the Prospect and Challenges of Conducting a Hybrid Method of Legal Research in Nigeria, *Euromentor Journal*, Vol. 13(3), PP. 113-138
- Aidonojie, P. A., Nwazi, J. and Ugiomo E., (2022), The Legality, Prospect, and Challenges of adopting Automated Personal Income Tax by States in Nigeria: A Facile Study of Edo State, *Cogito Multidisciplinary Journal*, Vol. 14(2), PP. 149 – 170
- Aidonojie, P. A., Oaihimore, I. E. and Agbale, O. P., (2022), The Legal and Ethical Issues concerning Diagnosing and

- Treatment of Patients by Pharmacists in Nigeria, *Euromentor Journal*, Vol. 13(2), PP. 113-138
- Aidonojie, P. A., Odojor, A. O., Ikubanni, O. O., Oyebade, A. A., Oyedeji, A. I. and Okuoghae, N., (2022), The Challenges and Impact of Technological Advancement to the Legal Profession in Nigeria given the Covid-19 Pandemic, *KIU Journal of Humanities*, Vol. 6(4), PP. 5-19
- Aidonojie, P. A., Okuoghae N., Agbale, O. P., Idahosa, M. E., (2022), Supervisor and Supervisee Relationship: The Legal and Ethical Issues Concerning Academic Theft in Nigeria Tertiary Institution, *Euromentor Journal*, Vol. 13(1), PP. 113-138
- Aidonojie, P.A., & Francis, E.C. (2022). Legal Issues Concerning Food Poisoning in Nigeria: The need for Judicial and Statutory Response. *Jurnal Media Hukum*, 29(1), 65-78
- Angell M., and Kassirer J. P., (1998), Alternative medicine — the risks of untested and irregular remedies, *New England Journal of Medicine*, Vol. 339(12), 839–841
- Jiang W. Y., (2005), Therapeutic wisdom in traditional Chinese medicine: a perspective from modern science, *Trends Pharmacol. Science*, Vol. 26(11), 558–563.
- Mahady G. B., (2001), Global harmonization of herbal health claims, *Journal of Nutrition*, Vol. 131(3), 1120S–1123S.
- Majekodunmi, T. A., Oluwaseun, J. A., Aidonojie P. A., Ikubanni, O. O. and Oyebade A. A., (2022), Legal Issues in Combating the Scourge of Terrorism; Its Impact on International Trade and Investment: Nigeria as a Case Study, *KIU Journal of Humanities*, Vol. 7(3), PP. 129-139
- Majekodunmi, T. A., Oluwaseun, J. A., Idahosa, M. E., Ikubanni, O. O. and Aidonojie, P. A., (2022), The causes of the Rising incidence of Terrorism occasioning Deprivation of the Right to Life in Nigeria, *KIU Journal of Humanities*, Vol. 7(2), PP. 5-19
- Okoli RI, Aigbe O, Ohaju-Obodo JO, Mensah JK. Medicinal herbs used for managing some common ailments among

- Esan people of Edo State, Nigeria. *Pak. J. Nutr* 2007;6(5):490-496.
- Oladele, O. O., Aidonojie, P. A., Uzualu, J. E., Ikubanni, O. O. and Oyedeji, A. I., (2022), An Empirical Study of Criminalizing Minor Infractions of Tax Laws in Nigeria: The Need for Negotiated Punishments, *KIU Journal of Humanities*, Vol. 7(2), PP. 23-35
- Oshikoya KA, Senbanjo IO, Njokanma OF, Soipe A. Use of complementary and alternative medicines for children with chronic health conditions in Lagos, Nigeria. *BMC Complement Altern Med* 2008;8:66. doi:10.1186/1472-6882-8-66.
- Ukhurebor K. E. and Aidonojie P. A., (2021), The influence of climate change on food innovation technology: review on topical developments and legal framework, *Agric & Food Security*, Vol. 10(50), 1-11 <https://doi.org/10.1186/s40066-021-00327-4z>
- Vanherweghem L. J., (1998), Misuse of herbal remedies: the case of an outbreak of terminal renal failure in Belgium (Chinese herbs nephropathy), *Journal of Alternative Complement Medicine*, Vol. 4(1), 9–13
- WHO Guidelines on GMP, 2007; WHO Guidelines on Herbal Product “Technical Report Series, No. 1010”, 2018
- WHO Supplementary Guidelines on GMP “Technical Report Series, No. 1010”, 2018; WHO GMPP “Technical Report Series, No. 986”, 2018
- WHO Supplementary Guidelines on GMP, “Technical Report Series, No. 937”, 2006; WHO Guidelines on Herbal Product “Technical Report Series, No. 1010”, 2018
- World Health Organisation guidelines on good agricultural and collection practices (GACP) for medicinal plants, Geneva; 2003.

This page is intentionally left blank

Acknowledgment

None

Funding Information

None

Conflicting Interest Statement

There is no conflict of interest in the publication of this article.

Publishing Ethical and Originality Statement

All authors declared that this work is original and has never been published in any form and in any media, nor is it under consideration for publication in any journal, and all sources cited in this work refer to the basic standards of scientific citation.