The Role and Challenges of the National Agency for Food and Drug Administration and Regulation of Alternative Medicine in Nigeria

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Abstract

Alternative medicine (AM) is any range of medical therapies that are not considered orthodox by the medical profession. It includes herbalism, folk medicine, herbal medicine, naturopathy, and crystal healing. It has an ancient history and has gained importance all over the world. In recent times, it has fast become an integral part of the health systems of societies all around the globe. In Nigeria, alternative medicine is also of great benefit and importance, especially to most Nigerians. Sharp practices and abuse in alternative medicine practices have compelled the setting up of agencies and regulations by the Nigerian government to regulate such practices. One primary agency with such responsibilities is the National Agency for Food and Drug Administration and Control (NAFDAC), which is a Commission set up to, among other things, regulate the practice of alternative medicine in Nigeria. The article discusses alternative medicine and practice in Nigeria and the role of NAFDAC in regulating the practice of alternative medicine and legislation on alternative medicine in Nigeria. The article concludes that the institution of NAFDAC as a regulatory agency for alternative medical practice is commendable despite some challenges, which will be highlighted. However, more results can be achieved if the Commission is empowered through better policy formulation, funding, and other interventions to carry out its functions.

Keywords

Alternative Medicine, Practice, Commission, Regulate, Nigeria, NAFDAC.

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I. INTRODUCTION

In today's age, there is a constant recognition of the positive and negative effects of what goes into the human body. Notably, there is the recognition of the many advantages of using alternative medicine over typical mainstream prescriptions and medicines.[1] There is also an ever-increasing open approach by health care professionals worldwide to native medicines and the benefits they can have for the body. Internationally, a vital component of the World Health Organization's (WHO) Traditional Medicine Strategy is to promote the integration of traditional medicine (T.M.) and complementary and alternative medicine (CAM) into the health care systems of countries.[2] Thus, developing a national policy (that is, a proposed or adopted course or principle of action) and regulations are essential indicators of the level of traditional medicine integration within a national health care system. The report of the World Health Organization on National Policy on Traditional Medicine and regulation of herbal medicines has shown that countries face significant challenges in the development and implementation of the regulations of traditional, complementary/alternative, and herbal remedies.[3]

The practice of alternative medicine in Nigeria is as old as the Nigerian people and culture in different parts of the country.[4] Like in other African and Asian countries, the pre-colonial practice of alternative medicine has extended to the current 21st-century era and is still very much popular among many Nigerians.[5] Although alternative medicine has gained much popularity, the dangers and prevalence of its abuse by alternative medical practitioners pose a significant risk to public health and have become a cause of concern to the Nigerian government. The advancement, popularity and adverse effects of medical malpractice and negligence, which are subjects that bear strong influences on public welfare, awakened the need for nations to ensure the official monitoring, quality administration and standard procedures in the practice of medicine and the prescription of drugs for ailing patients. This process has been achieved in Nigeria by setting up the National Agency for Food and Drug Administration and Control (NAFDAC).[6] The federal agency is responsible for controlling and maintaining the sale, distribution, transportation, advertisement, exportation, importation, manufacture and use of packaged water, chemicals, medical devices, cosmetics, drugs, and food.[7] The agency also regulates the quality of medicines and herbal products of herbal practitioners to patients generally. The general regulatory framework and regulations set up by NAFDAC on alternative medical practice and a brief highlight of its challenges and performance shall be the main focus of this article.

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[1] Jamie Reno, 'Alternative Medicine Finally Becoming More Mainstream' (*Healthline*, 5 April 2016). Available: https://www.healthline.com/health-news/alternative-medicine-becoming-mainstream. All links in this article have been verified on 24 June 2021.

[2] World Health Organization, *WHO Global Report on Traditional and Complementary Medicine, 2019* (World Health Organization 2019) 28.

[3] World Health Organization (ed), *National Policy on Traditional Medicine and Regulation of Herbal Medicines: Report of a WHO Global Survey* (World Health Organization 2005) 1–10. See also West African Health Organization, *Harmonised Framework for Regulation of African Traditional Medicine Practices, Practitioners and Products in the Ecowas Region* (West African Health Organization 2013) 5. Available: https://www.wahooas.org/web-ooas/sites/default/files/publications/2186/harmonised-framework-tmpok_0.pdf.

[4] Ali Arazeem Abdullahi, 'Trends and Challenges of Traditional Medicine in Africa' (2011) 8 African Journal of Traditional, Complementary, and Alternative Medicines 115.

[5] Gerard Bodeker and Gemma Burford, *Traditional, Complementary and Alternative Medicine: Policy and Public Health Perspectives* (World Scientific 2007) 4–8.

[6] NAFDAC, 'NAFDAC Mandate' (*National Agency for Food and Drug Administration and Control*, 2020). Available: https://www.nafdac.gov.ng/about-nafdac/nafdac-organisation/nafdac-functions/.

[7] *ibid.*

II. INTERNATIONAL FRAMEWORK ON ALTERNATIVE MEDICINE

Currently, there is no substantive international legislation on the protection of alternative medicine. Therefore, owing to the territoriality and uniqueness of alternative medicine practices worldwide, regulations are imposed within territorial domains.[8] However, efforts have been made, and are still being made, to enact an international substantive legal framework on alternative medicine protection.[9] From a local perspective, alternative medicine practices within communities are primarily regulated by different customary laws and practices governing the communities.[10] These customary laws and practices are usually passed down among family members or among specific individuals with traditional healing abilities.[11] Alternative medical practices may also be considered communal property of an indigenous group.

The Beijing Declaration of 2008, where government officials representing WHO member states adopted a declaration that provides an endorsement of traditional medicine, was the first WHO Member State congress to discuss traditional medicine and advocacy documents.[12] The Declaration recognized the role of traditional medicine in improving public health and supported its integration into national health systems where appropriate. In addition, the Declaration encourages governments to create or enhance national policies on traditional medicine.

Also, periodically, WHO, a specialized agency of the United Nations, actively promotes traditional/alternative medicine globally. It developed the WHO Traditional Medicine Strategy 2014–2023 in response to the World Health Assembly resolution on traditional medicine.[13] The goals of the strategy are to support member states in:

1. Harnessing the potential contribution of T.M. to health, wellness, and people-centred health care.
2. Promoting the safe and effective use of T.M. by regulating, researching, and integrating T.M. products, practitioners, and practice into health systems, where appropriate.[14]

The United Nations is another institution that promotes alternative medicine. In September 2007, the U.N. General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples.[15] This Declaration was the product of more than twenty years of discussion within the U.N. system, and indigenous representatives played a key role in developing this Declaration.[16] Today, there are over 370 million indigenous people in 90 countries worldwide.[17] The Declaration is the most comprehensive international instrument on the rights of indigenous peoples, which establishes a universal framework of minimum

[8] Emmanuel Kabengele Mpinga and Others, 'Traditional/Alternative Medicines and the Right to Health: Key Elements for a Convention on Global Health' (2013) 15 Health and Human Rights 44, 47–48.
[9] Irehobhude Iyioha, 'Medical Integration: Law and Policy on Alternative and Integrated Medical Practice', *Comparative Health Law and Policy* (Routledge 2015). Available: https://lawexplores.com/medical-integration-law-and-policy-on-alternative-and-integrated-medical-practice/.
[10] Elisa Morgera, Elsa Tsioumani and Matthias Buck, 'Access to Traditional Knowledge Associated with Genetic Resources', *Unraveling the Nagoya Protocol* (Brill 2015) 170–171.
[11] *ibid*.
[12] Ryan Abbott, *Documenting Traditional Medical Knowledge* (World Health Organization 2014) 13.
[13] WHO, *WHO Traditional Medicine Strategy 2014-2023* (World Health Organization 2014) 21–22. Available: https://www.who.int/publications/i/item/9789241506096.
[14] *ibid*.
[15] Art.24 and Art.31.
[16] Mauro Barelli, 'The Role of Soft Law in the International Legal System: The Case of the United Nations Declaration on the Rights of Indigenous Peoples' (2009) 58 The International and Comparative Law Quarterly 957.
[17] *WHO Traditional Medicine Strategy 2014-2023* (n13) 21–22.

standards for the survival, dignity and well-being of the indigenous peoples of the world.[18] It also elaborates on existing human rights standards and fundamental freedoms as they apply to the specific situation of indigenous peoples.[19]

Alternative medical practice protection through international intellectual property rights protection has been a viable alternative over the years. With the continuous rising concerns of developing countries about misappropriation of natural resources, discussions, as well as negotiations, occurred and are still ongoing at the World Intellectual Property Organization (WIPO), within the framework of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC), and the World Trade Organization (WTO) on the proper approach to traditional medicine protection.[20]

Furthermore, the Convention on Biological Diversity (CBD) adopted in 1992 came into force to promote the conservation of biological diversity, sustainable use of natural resources, and fair and equitable benefit-sharing arising from the use of genetic resources. [21] It recognizes that states have the sovereign right to exploit their own resources and control access to genetic resources.[22]

Other types of protection of traditional or alternative medical practice through intellectual property are trade mark protection, geographical indications (GIs), plant variety and trade secret legislation.[23] Trade mark protection, established either through registration or use in commerce, helps to distinguish authentic goods for consumer benefit.[24] However, trade mark protection is not perfect in protecting traditional knowledge used for alternative medicine as it most times cannot prohibit third parties from using traditional knowledge.[25] GI protection is also another type of protection that can be used to distinguish products by their specific geographical location.[26] Lastly, another effort towards international protection of alternative medicine is through plant varieties and trade secret protections. Plant variety protection provides intellectual property rights protection in law to breeders of new varieties of plants that are sexually reproduced by seed or tuber-propagated.[27] Plant varieties may be protected by more than one form of intellectual property legislation, such as by patent or under a *sui generis*

[18] United Nations, 'United Nations Declaration on the Rights of Indigenous Peoples' (*United Nations Department of Economic and Social Affairs Indigenous Peoples*, 5 June 2015). Available: https://www.un.org/development/desa/indigenouspeoples/declaration-on-the-rights-of-indigenous-peoples.html/.
[19] *Ibid.*
[20] For the latest session, see WIPO, '41st Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions', *Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions* (2021). Available: https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_41/wipo_grtkf_ic_41_inf_7.pdf.
[21] The Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 1760 UNTS 69. Its protocol is the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (adopted 29 October 2010, entered into force 12 October 2014). Arising from the utilization to the Convention on Biological Diversity the Nagoya Protocol provides a legal framework for access and benefit-sharing (ABS) arising from the utilization of GRs and associated traditional knowledge. The Protocol establishes more detailed rules regarding the mechanisms for providing information to national patent offices and other stakeholders, and for sharing benefits on mutually agreed terms.
[22] Art.1 and Art.3.
[23] J Janewa OseiTutu, 'Emerging Scholars Series: A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law' (2011) 15 The Marquette Intellectual Property Law Review 149–213.
[24] World Intellectual Property Organization, *Introduction to Trademark Law & Practice: The Basic Concepts: A WIPO Training Manual* (WIPO 1989) 7–17. Trade marks, GIs, plant varieties and trade secrets are legislated in the Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) UNTS 828 and The Agreement on Trade-related Aspects of Intellectual Property Rights (adopted on May 26, 1989, entered into force 1995) 1869 UNTS 299.
[25] *WHO Traditional Medicine Strategy 2014-2023* (n13) 21–23.
[26] Irene Calboli, 'Expanding the Protection of Geographical Indications of Origin under TRIPS: Old Debate or New Opportunity' (2006) 10 Marquette Intellectual Property Law Review 181, 184.
[27] Thippeswamy Swamy, 'Plant Variety Protection: An Historical Perspective' (2017) 2 International Journal of Legal and Research Studies 120–124.

protection system.[28] The International Convention for the Protection of New Varieties of Plants (the UPOV Convention) is a major convention on plant varieties to provide and promote an effective plant variety protection system and encourage the development of new varieties of plants for national benefit.[29] On the other hand, trade secrets confer owners the right to prevent information lawfully within their control from being disclosed, acquired or used by others without their consent in a manner contrary to honest commercial practice.[30] While trade secret protection has been recommended to protect alternative medicine practices, its possibilities have yet to be examined in sufficient depth.[31]

III. ALTERNATIVE MEDICINE AND PRACTICE IN NIGERIA

There are many definitions of alternative or complementary medicine. It is defined as "diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine."[32] It is made up of a confusingly large and heterogeneous array of techniques, with both therapeutic and diagnostic approaches, and is perceived as "a broad term encompassing a variety of medical modalities. These are typically supported by tradition and seldom taught in a Western medical setting."[33] Herbal medicine, a subset of traditional medicine, is plant-derived materials or preparations with therapeutic or other human health benefits, containing raw or processed ingredients from one or more plants.[34] In some traditions and cultures, the material of inorganic or animal origin may also be present. Herbal medicines have been used for hundreds of years among different ethnic groups and societies in Nigeria and worldwide.[35] There is also always the common belief that herbal medicines are effective and safe, perhaps due to their natural origins.

The practice of herbal medicine in the world has increased tremendously over the past years, with not less than 80 per cent of people worldwide who rely on it for treatment.[36] Although therapies involving traditional medicines have shown promising potential with the efficacy of a good number of herbal products established, many of them remain untested, and their use is either poorly monitored or not even monitored at all.[37] In Nigeria, traditional medicine is widely practised, especially among rural communities all over the country. One can see hawkers of herbal products daily on the streets and marketplaces and the constant blaring on car speakers by herbal 'doctors' who advertise their products and treatments for different ailments. One common traditional medical practice in Nigeria is bone setting, as limb amputation has become

[28] *Ibid* 122–123. The Agreement on Trade-related Aspects of Intellectual Property Rights (adopted on May 26, 1989, entered into force 1995) 1869 U.N.T.S. 299, Art.27.3(b), requires that member states "shall provide for the protection of plant varieties either by patents or by an effective 'sui-generis system or by any combination thereof."
[29] See the International Convention for the Protection of New Varieties of Plants (adopted on 2 December 1961, revised in 1972, 1978 and entered into force 1991).
[30] Deepa Varadarajan, 'A Trade Secret Approach to Protecting Traditional Knowledge' (2011) 36 Yale Journal of International Law 371, 372–416.
[31] Varadarajan (n30) 375.
[32] E Ernst, 'The Role of Complementary and Alternative Medicine' (2000) 321 BMJ: British Medical Journal 1133.
[33] Lisa A Kisling and Regan A Stiegmann, 'Alternative Medicine', *StatPearls* (StatPearls Publishing 2020). Available: http://www.ncbi.nlm.nih.gov/books/NBK538520/.
[34] Martins Ekor, 'The Growing Use of Herbal Medicines: Issues Relating to Adverse Reactions and Challenges in Monitoring Safety' (2014) 4 Frontiers in Pharmacology. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3887317/.
[35] Anselm Adodo and Maurice M Iwu, *Healing Plants of Nigeria: Ethnomedicine and Therapeutic Applications* (CRC Press 2020) 40-52.
[36] Martins Ekor, 'The Growing Use of Herbal Medicines: Issues Relating to Adverse Reactions and Challenges in Safety' (2014) 4 Frontiers in Pharmacology. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3887317/.
[37] *Ibid.*

a significant cause of disability in Nigeria.[38] Also, high costs and lack of health facilities for limb salvage procedures have increased the resort to traditional methods of bone setting in Nigeria.[39] As time passed, the safety and efficacy of herbal medicine and quality control became concerns for both health authorities and the public. Therefore, there was a need for legislation and the setting up of regulatory bodies who would strategize ways of ensuring that safety standards were abided by, and a priority is placed on public health and public interest.

IV. LEGISLATION ON ALTERNATIVE MEDICINE IN NIGERIA

Despite the general belief that herbal medicines and practice are safe, and regardless of the methods applied and the therapeutic advantages possessed by some of the medicinal plants, some of their constituents are potentially toxic, mutagenic, carcinogenic, and teratogenic.[40] In response, the Nigerian Government has developed regulation, policies, and regulatory procedures to determine the safety, efficacy, and quality of alternative medicine. It is essential to state that legislation and policies for medicine in Nigeria lie within the constitutional concurrent legislative powers of both the federal and state governments. Thus, before 1966, there was no established relationship between the government and practitioners of traditional medicine, although the government showed sufficient interest in the traditional medical system.[41]

The first official move of the Nigerian Government to promote alternative medicine was in 1966 when the Federal Ministry of Health permitted the University of Ibadan to research the medicinal properties of local herbs.[42] This trend continued with subsequent policies, collaboration with other universities, and establishing research institutes like the Center for Research in Traditional, Complementary and Alternative Medicine (CRTCAM),[43] National Biotechnology Development Agency.[44] National Centre for Genetic Resources and Biotechnology,[45] the Nigerian Institute of Medical Research (NIMR)[46] and other research institutes to advance alternative medical practice. The article will briefly outline in succeeding discussions important legislation like federal and state government policy and legislation, the Medical and Practitioners Act, National Health Act, and the Code of Medical Ethics in Nigeria.

It is pertinent to say that the regulation of alternative medical practice in Nigeria is regulated by the federal and state governments.[47] There are two types of registration at the federal level: registration for practice by the practitioner and registration of the product through

[38] Adedamola Dada and Others, 'Review of the Practice of Traditional Bone Setting in Nigeria' (2011) 11 African Health Sciences 262.
[39] John E Onuminya, 'Misadventure in Traditional Medicine Practice: An Unusual Indication for Limb Amputation' (2005) 97 Journal of the National Medical Association 824.
[40] Olufunsho Awodele and others, 'Traditional Medicine Policy and Regulation in Nigeria: An Index of Herbal Medicine Safety' (2014) 9 Current Drug Safety 16.
[41] Yusuf Abdul Azeez and Abdullahi Saliu Ishola, 'Alternative Medicine in Nigeria: The Legal Framework' (2015) ELK Asia Pacific Journal of Social Sciences 62.
[42] *Ibid.*
[43] Center For Research In Traditional, Complementary And Alternative Medicine, 'Center For Research In Traditional, Complementary And Alternative Medicine' (*The Nigerian Institute Of Medical Research*, 10 June 2021). Available: https://nimr.gov.ng/centre-for-traditional-complementary-and-alternative-medicine/.
[44] National Biotechnology Development Agency, 'National Biotechnology Development Agency' (*National Biotechnology Development Agency*, 10 June 2021). Available: https://nabda.gov.ng/.
[45] 'National Centre for Genetic Resources and Biotechnology' (*IPBES secretariat*, 10 September 2018). Available: http://ipbes.net/national-centre-genetic-resources-biotechnology-nacgrab.
[46] Nigerian Institute Of Medical Research, 'NIMR Pedestal' (*The Nigerian Institute Of Medical Research*, 10 June 2021). Available: https://nimr.gov.ng/.
[47] Azeez and Ishola (n41) 64–65.

advertisement and labelling.[48] However, generally, the Constitution of the Federal Republic of Nigeria[49] provides *inter alia* the basic legal framework for the policy direction, regulation and governance of health in Nigeria.[50] Strikingly, it provides *inter alia* that "…the state shall direct its policy towards the provision of adequate medical and health facilities towards all people"[51] and that the "…health of all persons in employment is safeguarded and not endangered or abused."[52] It also sets out basic patient rights derived from the fundamental human rights provisions that potentially protect patients from medical malpractice.[53]

Thus, in the case of the practitioner's registration, the enabling law in Nigeria is the Medical and Practitioners Act,[54] which is the general law for regulating the practice of medicine and dentistry in the country. The Act[55] is an extensive legislation that generally ensures the proper medical practice guidelines to avoid malpractice in medical practice proactively.[56] Hence, section 1 of the Act,[57] while providing for the establishment and functions of the Medical and Dental Council of Nigeria, makes provision for determining the standards of knowledge and skills to be attained by persons to become members of the medical and dental profession and reviewing those standards from time to time as circumstances may permit.[58]

Other legislation that pertains to alternative medical practice is the Medical Rehabilitation Therapist (Registration *etc*),[59] the Community Health Practitioners Board of Nigeria (Registration) Act,[60] the Pharmacists Council of Nigeria Act,[61] and the Nursing and Midwifery (Registration *etc*) Act.[62]

Another legislation is the National Health Act,[63] which is the most daring legislative response that represents a good attempt to provide redress to the vacuum created by the absence of adequate constitutional provisions for the health sector and medical malpractice in a pivotal legal framework. Thus, it provides a legal framework aimed at supporting, strengthening, and stabilizing the health sector in Nigeria, including potent provisions for the protection of the patient from medical malpractice.[64] The National Health Act[65] has as primary objectives the following:

1. Encompass public and private providers of health services.[66]

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[48] *Ibid* 65. Registration of the practitioner through the Medical and Dental Practitioner Act CAP M8 2004, Medical Rehabilitation Therapist Act M9 2004 the Community Health Practitioner Registration Board of Nigeria CAP C19 2004.
[49] Section 1(1) & (3) 1999 Constitution of the Federal Republic of Nigeria (as amended). See also, Ese Malemi, *The Nigerian Constitutional Law* 3rd Ed. (Lagos, Princeton Publishing Company, 2012) 61-62.
[50] S 17(3) (b) & (d) Chapter II of the 1999 Constitution of the Federal Republic of Nigeria, (as amended) this is in addition other Rights as explained in Irehobhude Iyioha, 'Medical Negligence and the Nigerian Health Insurance Scheme: Civil Liability, No-Fault or Hybrid Model?' (2010) African Journal of International Comparative Law (AJICL) 43; the African Charter on Peoples' Rights entered into force 21 October 1968 and the Universal Declaration of Human Rights.
[51] Section 17(3)(d) 1999 Constitution of Federal Republic of Nigeria, (as amended).
[52] Section 17(3)(C) 1999 Constitution of Federal Republic of Nigeria, (as amended).
[53] Sections 33, 34, 35, 37, 38, 41 & 42 1999 Constitution of Federal Republic of Nigeria (as amended).
[54] CAP M8 *Laws* of the Federation of *Nigeria* (2004). The Act provides the necessary requirements for registration of a traditional medicine practitioner and exempts the practice of traditional medicine from registration prior to engagement in it.
[55] CAP M8 Medical and Dental Practitioners Act, LFN, 2004.
[56] *Ibid*.
[57] *Ibid*.
[58] S 2(a) Medical and Dental Practitioners Act, LFN, 2004.
[59] (LFN, 2004).
[60] (LFN, 2004). Under this Act, it is prohibited for any person to engage in the medical practice of physiotherapy, chiropractic, occupational therapy, osteopathy, or speech therapy unless he is registered and licensed to practice.
[61] (LFN, 2004).
[62] SS 6-16.
[63] The National Health Act, 2014 (hereinafter referred to as the *Act*).
[64] Anthony Okechukwu Nnadi, *Distribution of Resources in the Nigerian Health Care System: Ethical Considerations and Proposals Applying Catholic Social Teaching* (Xlibris Corporation 2020) 221.
[65] The National Health Act, 2014 (Hereinafter referred to as the *Act*).
[66] *Ibid.*

2. Promote the spirit of cooperation and shared responsibility among all providers of health services in the Federation.[67]
3. Provide persons living in Nigeria the best possible health services within the limits of available resources.[68]
4. Set out the rights and obligations of health care providers, health workers, health establishment and users.[69]
5. Protect, promote, and fulfil the rights of the people living in Nigeria to have access to health services.[70]

Another legislation is the Code of Medical Ethics in Nigeria,[71] which was made by the Medical Dental Council of Nigeria (MDCN) under its powers.[72] The Criminal Code[73] applies in southern states, while the Penal Code[74] applies to the northern states of Nigeria (including the Federal Capital Territory) as the core *corpus juris* in criminal proceedings. The Penal and Criminal Codes[75] constitute the legal framework wherein patients are protected from medical malpractice by spelling out clearly, offences that can be committed in the course of medical practice.

The National Agency for Food and Drug Administration and Control (NAFDAC) carries out registration of the product, its advertisement and labelling, which is the second registration method at the federal level. The agency will be discussed below.[76]

Finally, none of the legislation mentioned above clearly defines alternative medicine. What is also worse is that Nigeria does not currently have a *sui generis* legislation on alternative medicine, although the urgency to have one has been brought up many times by stakeholders. The only relevant agency for traditional medicine protection is the Nigeria Natural Medicine Development Agency (NNMDA), established through the Federal Ministry of Science and Technology in 1997.[77] It was established to, among other things, enable the Federal Ministry of Science and Technology to actualize its critical and strategic mandate to research, develop, document, preserve, conserve and promote Nigeria's natural medicine.[78] However, recent developments indicate that politicians and policymakers are opening up to the importance and necessity of enacting legislation to regulate strictly alternative medicine. A significant step towards harnessing alternative medicine is the recent presential assent to the Plant Variety Protection Act 2021 to create a window for protecting plant varieties and plant breeder rights in Nigeria.[79] Another step is also the recent debate by legislators and policymakers to legalize cannabis for medicinal purposes.[80]

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[67] *Ibid.*
[68] *Ibid.*
[69] *Ibid.*
[70] *Ibid.*
[71] 2008.
[72] In S 1 Medical and Dental Practitioners Act, Cap M.8, Laws of the Federation of Nigeria, 2004.
[73] Criminal Code Act, Cap C38, LFN, 2004.
[74] Penal Code (Northern States) Federation Provision Act, Cap 3, LFN, 2004.
[75] The Penal Code, Act Cap 3, LFN, 2004 and Criminal Code, Cap C38, LFN, 2004.
[76] See 60, *infra.*
[77] Federal Ministry of Science and Technology, 'Nigeria Natural Medicine Development Agency' (2021). Available: http://nnmda.gov.ng/.
[78] *Ibid.*
[79] Adebiyi Adedapo, 'Nigeria: Buhari Signs Plant Variety Protection Act' (*allAfrica.com*, 20 May 2021). Available: https://allafrica.com/stories/202105260175.html.
[80] Lolu Ojo, 'The Cannabis Legalisation Debate' *The Guardian Nigeria News* (Lagos Nigeria, 23 June 2021). Available: https://guardian.ng/opinion/the-cannabis-legalisation-debate/.

V. NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND ITS REGULATION OF ALTERNATIVE MEDICINE

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999.[81] The legislation is currently the NAFDAC and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004.[82] It empowers NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents (collectively known as regulated products).[83] NAFDAC lists most ethnomedicinal preparations on the market in Nigeria. However, it does not issue the full status of registration to these products because of questionable/unproven safety, efficacy, and quality. The legislation enforced by NAFDAC is the National Agency for Food and Drug Administration and Control Act, which is the enabling act, the Food, Drug and Related Products (Registration) Act,[84] the Food and Drugs Act,[85] the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provision) Act[86] and other relevant regulations.

The agency has an Investigation and Enforcement Directorate/Federal Task Force on Counterfeit Drugs and Unwholesome Processed Foods.[87] The task force is mainly responsible for enforcing compliance with the agency's mandate on regulatory activities.[88] It also coordinates enforcement activities of all other Directorates, Zonal and States offices of NAFDAC Nationwide.[89] The agency also registers herbal medicinal products. Registration is carried out when there is satisfactory evidence of reports of clinical trial report ascertaining the safety and efficacy of the herbal products sought to be registered. Herbal supplements could benefit consumers, but they could also cause serious side effects and potentially dangerous conditions. In 2013, NAFDAC and Nigeria Institute of Pharmaceutical Research and Development (NIPRID) set up limited clinical trial on some Nigerian herbal medicines used for life-threatening ailments. The initiatives are meant to ensure that only good quality, safe and effective herbal medicines were distributed and used became a part of the federal ministry of health.[90]

The main objective of NAFDAC is to provide the best products in the Nigerian market. Therefore, it functions to undertake an appropriate investigation of the production, manufacturing, raw materials.[91] Its objective is to safeguard public health by ensuring that only the right quality drugs, food and other regulated products are manufactured, imported, distributed, advertised, sold, and used in Nigeria.[92] Generally, the functions of NAFDAC[93] are to:

1. Regulate and control the importation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water, and cosmetics.

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[81] NAFDAC, 'National Agency for Food & Drug Administration & Control' (*National Agency for Food & Drug Administration & Control*, 2020). Available: https://www.nafdac.gov.ng/.
[82] *Ibid.*
[83] *Ibid.*
[84] CAP F.33 LFN 2002.
[85] CAP F32 LFN 2004.
[86] CAP C34 LFN 2004.
[87] Mojisola Christianah Adeyeye, 'The Challenges of Illegal Use of Medicines/ Drugs' (NAFDAC, 2019) 3.
[88] *Ibid*.
[89] *Ibid.*
[90] Chioma Obinna, 'NAFDAC to Begin Herbal Medicine Trial' *Vanguard News* (Lagos, 1 September 2013). Available: https://www.vanguardngr.com/2013/09/nafdac-to-begin-herbal-medicine-trial/.
[91] 'National Agency for Food & Drug Administration & Control' (n81).
[92] *Ibid*.
[93] See NAFDAC Act (n51) s.7. See also Azeez and Ishola (n41).

2. Conduct appropriate texts and ensure compliance with standard specifications designated and approved by the council for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals and their raw materials as well as their production processes in factories and other establishments.
3. Undertake appropriate investigations into production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water, and chemicals and establish relevant quality assurance systems, including certification of production sites and the regulation products.
4. Compile standard specifications and guidance for the production, importation, exportation, sale and distribution of food, drug, cosmetics, medical devices, bottled water, and chemicals.
5. Undertake the registration of food, drug, cosmetics, medical devices, bottled water, and chemicals.
6. Pronounce defined assessments on the quality and safety of food, drugs, cosmetics, medical devices, bottled water, and chemicals after appropriate analysis.
7. Issue guidelines on approval and monitoring of advertisements for food, drugs, cosmetics, medical devices, bottled water, and chemicals.
8. Determine the suitability, or otherwise, of medicines, food, drugs, cosmetics, medical devices, bottled water, and chemicals for human and animals use.

NAFDAC plays a vital role in regulating the activities of traditional/alternative medicine practitioners, mainly in the aspect of herbal medicines. It makes it mandatory through its regulations to register, advertise, and label medical products to comply with specific requirements.[94] In the case of registration, the NAFDAC Herbal Medicines and Related Products Registration Regulations of 2019 has 10 sections.[95] Section 2 states:

> "Prohibition. (1) No herbal medicine and related product shall be manufactured, imported, exported, distributed, advertised, sold or used in Nigeria unless it has been registered in accordance with the provisions of these regulations. (2) No person to whom a certificate of registration has been issued under these Regulations shall lend, hire, sell, transfer or otherwise dispose of the certificate of registration to any other person without the approval of the agency."

Section 3 states an exception to section 2. It states that "the Agency may grant a permit for the importation or manufacture of samples of herbal medicine and related products for the purpose of a clinical trial or any such process as may be approved by the Agency." It also states that "the importation or manufacture shall be in accordance with the conditions specified in the permit." Section 4 states the procedure that needs to be followed in registering herbal products with NAFDAC, and section 5 states that the power of NAFDAC to seal offices that commit offences. The sealing shall subsist "until such time as the regulated product is removed or such time as the regulated product is removed or such reasonable time as the Minister may determine." Finally, section 6 stipulates penalties for offenders. Under the section, there is a sentence of

[94] See the NAFDAC Registration, Advertisement and Labelling Regulations of 2019. See also 'National Agency for Food and Drug Administration and Control (NAFDAC)' (*Practical Law*). Available: http://uk.practicallaw.thomsonreuters.com/2-6050525?transitionType=Default&contextData=(sc.Default)&firstPage=true. See also Olaniwun Ajayi, 'Marketing, Manufacturing, Packaging and Labeling, Advertising: Nigeria' (*PharmaBoardroom*, 6 November 2019). Available: https://pharmaboardroom.com/legal-articles/marketing-manufacturing-packaging-labeling-advertising-nigeria/.

[95] It is divided into Scope, Prohibition, Exceptions, Application for the registration, Power to seal, Penalty, Forfeiture, Interpretations, Repeal and Citation.

one year imprisonment for individual and body corporates, a fine not exceeding N50,000 for individuals and N100,000[96] for body corporates. There also punishment on firms or other association of individuals.

NAFDAC Regulations on advertisement have 16 sections.[97] Regulations legislate on NAFDAC requirements and procedures for advertising herbal medicinal products. The regulations stipulate that "no herbal medicine and related product shall be manufactured, imported, advertised, sold or distributed in Nigeria unless it has been registered."[98] Also, a manufactured herbal medicine may be imported before being registered if the agency grants a permit for the importation of samples of such herbal products "for the purpose of registration or clinical trial."[99] Other conditions for advertisement include the requirements that the advertisement must be given pre-clearance and approval.[100]

NAFDAC also provides regulations for the labelling of herbal products. Accordingly, any herbal medicine that is not labelled as legally stipulated is prohibited from being manufactured, imported, exported, advertised, or sold.[101] The regulation has 22 sections.[102] Under the regulations, it is unlawful for any person to "sell, advertise, display or orally present any herbal medicine or related product to the general public whose label contains such words as 'for vitality.'"[103] Similarly, no herbal medicine is allowed to be labelled as "a treatment, preventive as identified in Schedule I to the Food and Drugs Act 1990 (as amended)."[104] This law also stipulates that the inner and outer labels of every herbal medicine are required to disclose and display the Agency registration number assigned to the product. For a herbal medicine product to be considered as correctly labelled, the information in its inner and outer labels[105] must disclose that:

> 1. The herbal brand name, botanical or common name, if any, shall be qualified as herbal, homeopathic, animal or mineral medical product and/or admixture thereof.[106] In this case, herbs can acquire brand names if they are registered as trade marks in Nigeria under the Nigerian Trademarks Act.[107] Mainly, Part 5 of the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the

[96] 50,000 Naira is equivalent to 88.22 Pound Sterling and 100,000 is the equivalent of 176.45 Pound Sterling.
[97] See the NAFDAC Herbal Medicines and Related Products Advertisement Regulations, 2019. The regulation provides for all advertisements or promotion of Herbal Medicine and Related Product manufactured, imported, exported, distributed, advertised, sold, or used in Nigeria.
[98] NAFDAC Herbal Medicines and Related Products Registration Regulations, 2019, s.2(1)(2) (Regulations made "in exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by SS 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and S 12 of the Food, Drugs (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf"). See the Commencement part of the Regulations.
[99] See NAFDAC Herbal Medicines and Related Products Registration Regulations (*ibid*), S.3. See also Azeez and Ishola (n41) 67–69. Failure to comply with the requirement for the registration of herbal medicines is a criminal offence punishable with both or either terms of imprisonment and or fine, as the case may be.
[100] S.2.
[101] NAFDAC Herbal Medicines and Related Products Labelling Regulations, 2019, ss 2 and 3 (Regulations made "in exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by SS 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and S 12 of the Food, Drugs (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf"). See the Commencement part of the Regulations.
[102] It provides for issues on prohibition, labelling information, name and address of manufacturer, packer or distributor, no reference to international bodies etc., declaration of ingredients., brand name/trade mark, identification number assigned by the agency, identification mark, adequate labelling, labelling of bulk package, labelling information for practitioners, information on package insert, prohibition of labelling of herbal medicine and related products for certain treatments, herbal medicine and related products not for use in pregnancy & children below 5 years 16. Warning for children, misleading information and misinformation, penalty, forfeiture, interpretation, repeal, and citation.
[103] SS 14, 15.
[104] *Ibid.*
[105] S.11.
[106] This is important in order to curb counterfeiting the Nigerian Trademarks Act
[107] Nigerian Trademarks Act cap T13 2004.

Registration of Marks categorizes registration of brand names for pharmaceutical and medical products.[108]

2. The name shall not be suggestive of any therapeutic claim.

3. Each product shall have a distinct design. Besides these, the "name or index number of colour used in the preparation shall be on the label"[109] while "a qualitative list of ingredients of the herbal medicines by their common names"[110] is to be declared quantitatively on the label. Any herbal medicine that has a trademark displayed on its label must "not give a wrong impression."[111] Also, where there is a conflict between any Agency regulation requirements and trade mark regulation, the Agency's requirements shall prevail.[112] This is because, at the stage of registration with NAFDAC, the NAFDAC regulations are strictly adhered to and not the provisions of the Nigerian Trademarks Act. Even though it is essential to abide by trade mark registration requirements, NAFDAC ensures that it does not assume the role of the Trademarks and Patent Department of the Federal Ministry of Trade and Investment in Nigeria. Therefore, it is confined to its mandate and regulations, even though it still reserves the power to refuse registration on the ground of non-compliance with the Nigerian Trademarks Act.

There is also the requirement that the label's information shall be clearly and prominently displayed and readily discernible to the consumer.[113] The sections, among others, state that the name of the product shall reveal the connection between "the person and the manufacturer, such as 'manufactured for' 'distributed by…', or any other wording that expresses the facts where the herbal medicine is not manufactured by a person whose name appears on the label."[114] The products shall also bear identification marks, and "where tablets, capsules, caplets and similar dosage forms bear identification marks, the identification marks shall be traceable to the Certificate of Registration Holder or the manufacturer of the herbal product."[115] For herbal medicine and other products not for use in pregnancy and for children below five years, the regulation states that "both the inner and outer labels of all herbal medicine and related products shall carry a warning statement directing pregnant women and children below five years of age not to use them, except there is adequate evidence of safety in pregnancy and children under five years of age."[116]

VI. INTERPLAY OF NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND INTELLECTUAL PROPERTY PROTECTION IN NIGERIA

Intellectual property protection in Nigeria is still at a primary stage, as the country is still developing. NAFDAC plays a role in safeguarding intellectual property legislation in Nigeria. Intellectual property rights are the rights given to persons over the creations of their minds,

[108] The Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks (as amended on September 28, 1979).
[109] NAFDAC, Herbal Medicine and Related Products Labelling Regulations, 2019, s.6(2).
[110] S.6(1).
[111] S.7(1)(2).
[112] *Ibid*. See also SS 11-14.
[113] SS 10-11.
[114] S.4(1).
[115] S.9.
[116] S.15.

which usually give the creator an exclusive right to use his/her creation for a certain period.[117] It is defined as the protection of creations of the mind and the ideas that make inventions.[118] Under intellectual property, "owners are granted certain exclusive rights to a variety of intangible assets, such a literary, and artistic works; discoveries and inventions; words, phrases, symbols, and designs."[119] Therefore, trade marks, patents and consumer protection are relevant to the regulatory and control function of the agency.[120] For trade marks, NAFDAC pre-registration guidelines require proof of a registered trade mark in Nigeria. This requirement is meant to encourage product identity and compel compliance with brand differentiation of food and drugs intended to be available in the market for potential consumers. It is also meant to prevent confusion, counterfeiting and fake products proliferating the Nigerian market. The registration of trade marks is governed by the Nigerian Trade marks Act.[121] Statutorily, 7 years is the initial validity period for a trademark in Nigeria.[122] The period can be further renewed for 14-years, after which it can be renewed from time to time indefinitely.[123] A renewal application should be made not less than three months from the due date.[124]

For planning purposes, it is essential for brand owners who desire to make inroads into the Nigerian market to ensure that their trade marks are registered with NAFDAC before the anticipated product launch date. This requirement is in line with NAFDAC's mandate under section 5 of the NAFDAC Act. Failure to secure a trade mark registration will significantly delay the NAFDAC registration process and potentially result in substantial financial losses for brand holders who are prevented from selling their products in Nigeria until they have secured the requisite NAFDAC registration.

In discharging its functions on regulating food and drug in Nigeria, NAFDAC also complements patent protection. In the aspect of patent protection, among other products and processes, health and biotechnology-related inventions are patentable under the Nigerian Patents and Designs Act.[125] Also, with the rise of local pharmaceutical and food industries in Nigeria over the years and their quotation in the Nigerian Stock Exchange,[126] there are increased patronage and frequent interactions between the NAFDAC office and the Nigerian Patents and Trademark Office.

NAFDAC also complements Nigerian competition law and policy. It aids the Federal Competition and Consumer Protection Act[127] to ensure that the manufacture, importation, advertisement, distribution, sale and use of foods and drugs in Nigeria are carried out within the confines of a safe, fair, legal, and competitive environment. This conforms with the major functions of the Federal Consumer Protection Commission, which is to "initiate broad-based policies and review economic activities in Nigeria to identify anti-competitive, anti-consumer protection and restrictive practices which may adversely affect the economic interest of

[117] WTO, 'What are Intellectual Property Rights?' (WTO, 2021). Available: https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm.
[118] Nwabachili C Chudi, *Intellectual Property and Law in Nigeria* (Malthouse Press 2016) 1.
[119] Adekola Tolulope Anthony and Eze Sunday Chinedu, 'Intellectual Property Rights in Nigeria: A Critical Examination of the Activities of the Nigerian Copyright Commission' (2015) 35 Journal of Law, Policy and Globalization 56.
[120] WIPO Advisory Committee on Enforcement, 'Third Session Geneva, Consideration of Intellectual Property Rights In Regulation And Control: Activities of the National Agency for Food and Drug Administration and Control (NAFDAC) '2. Available: https://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_3/wipo_ace_3_9.pdf.
[121] Nigerian Trademarks Act (n90). See SS 3 and 4 that provide for registration of trade mark and application for registration.
[122] S.10.
[123] S.11.
[124] *Ibid.*
[125] Cap P2, LFN 2004. SS 1 and 2.
[126] Foluke Dada, 'Legal Effects of the Nigerian Patent Law on Sale of Drugs and Consumer Protection in Nigeria' (2014) 14 Global Journal of Human Social Science: E Economics 9, 9–11.
[127] Federal Competition and Consumer Protection Act (No. 18, 2019).

consumers…".[128] Therefore, besides controlling the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals and detergents, another objective of NAFDAC is to ensure that Nigeria's national unfair competition policies which consist of acts contrary to honest practices and good faith market practices are upheld. Consumer protection is also an integral aspect of NAFDAC's functions. This became necessary from past experiences when the country experienced a worrisome proliferation of fake drugs and foods. Before NAFDAC was established in 1993, the problem of counterfeit drugs had overwhelmed the Nigerian healthcare system, with so many deaths recorded as a result.[129] Some recorded incidents are the death of some children in the University of Nigeria Teaching Hospital, Enugu, due to taking poorly compounded Chloroquine syrup.[130] Similarly, between 1995 and 1996, fake meningitis vaccines obtained from Onitsha drug market killed thousands of children in Nigeria and the neighbouring Niger Republic.[131]

VII. CHALLENGES AND THE WAY FORWARD

In playing its role in regulating alternative medical practice in Nigeria, NAFDAC is faced with specific challenges. Some of them include corruption which is a hinderance to successfully achieving its goals. There are many situations where alternative medical practitioners bribe and connive government officials to evade arrest or compliance with regulatory standards. Another problem is the penalties that NAFDAC imposes on defaulters. However, such penalties are usually non-severe and do not serve as deterrents to intending offenders. The lack of resources, lack of systems and manpower for proper monitoring are some setbacks to regulating alternative medicine practice. There is also the challenge of lack of awareness by many illiterate Nigerians[132] and the lack of synergy for sharing information among government agencies.[133] A more complex problem is the never-ending evolution of internet commerce, which has reshaped counterfeit technology and trade networks, making it increasingly difficult to control medical practice in Nigeria.

In light of the setbacks mentioned, the following solutions will be suggested to confront them. The suggested solutions are not exhaustive but are meant to complement the many solutions that policymakers and academics have suggested to the challenges faced by NAFDAC in regulating alternative medical practice in Nigeria. The proposed solutions are also viable as they bother on current issues that serve as clusters to solutions for the success of NAFAC operations in Nigeria. Therefore, they will contribute to overcoming the many issues faced by NAFDAC.

1. The Nigerian Government should pay more attention to the scourge of corruption affecting health provision in the country. There should be a holistic approach towards fighting corruption and a zero-tolerance on corruption in critical sectors of the country.

[128] SS 17 and 18.
[129] Olusegun Akiny, 'Counterfeit Drugs in Nigeria: A Threat to Public Health' (2013) 7 African Journal of Pharmacy and Pharmacology, 2573.
[130] Ufuoma Akpotaire, 'Documented Cases of Counterfeit Drugs Resulting in Deaths in Nigeria' (*Nigerian Law Intellectual Property Watch Inc.*, 3 September 2013). Available:https://nlipw.com/documented-cases-of-counterfeit-drugs-resulting-in-deaths-in-nigeria/.
[131] *Ibid.*
[132] The literacy rate of Nigeria currently is 62.02 percent. This means 37.98 percent of Nigerians are illiterate. See Macrotrends, Nigeria Literacy Rate 1991-2021 (*Macrotrends* 19 July 2021). Available: https://www.macrotrends.net/countries/NGA/nigeria/literacy-rate.
[133] Olugbenga Ebenezer Olatunji, 'Leadership Effectiveness and Regulatory Performance in the Public Sector: The Experience of the National Agency for Food and Drug Administration and Control (NAFDAC)' (2014) 3 International Journal of Innovative Research and Development 224.

The dilapidated nature of Nigeria's health sector was evident during the Covid-19 pandemic. It was apparent that over the years, funding for the health sector had been very poor.[134]

2. It is recommended that Nigeria's educational institutions teach and award degrees in alternative medicine the same way medical science is taught, and practice licenses or certificates are awarded for treating patients. Nigerians should be able to make choices between either medical science or alternative medicine. Progress has, however, been made over the years. Examples are the establishment of alternative medicine departments in the 36 state ministries of health and the FCT, Abuja, by the National Council on Health, the establishment of Complementary alternative medicine clinics and efforts by the Federal Ministry of Health to establish a Federal College of Complementary and Alternative Medicine.[135]

3. Efforts must be made towards ensuring that laws are in place in Nigeria that will guide the practice of traditional medicine and the use of herbal medicines. Countries like China,[136] Japan,[137] Korea,[138] Ghana,[139] and countries in Europe[140] have stringent laws that ensure that herbal medicines consumed are safe, good, and efficacious.[141] However, it is interesting to note that there was a Bill at the National Assembly to establish the Traditional Medicine Council of Nigeria.[142] The Bill passed its second reading and was scheduled for third reading at the House of Representatives.[143] The Bill was passed by the Nigerian National Assembly in 2017 and was assented by the President in 2020. On 21 October 2020, the Federal Executive Council approved the Bill to establish the Council for Traditional, Alternative and Complementary Medicine Practice in the country.[144] This unprecedented step was to strengthen the practice of alternative medicine in Nigeria.

4. Considering regulatory issues on herbal medicines further, Nigeria is faced with some challenges; chief amongst them is need for highly trained alternative practitioners to

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[134] Ngozika Anthonia Obi-Ani and others, 'Covid-19 Pandemic and The Nigerian Primary Healthcare System: The Leadership Question' (2021) 8 Cogent Arts & Humanities.
[135] Lawal Sherifat, 'Nigeria: Govt Takes Steps to Promote Alternative Medicine' (*allAfrica.com*, 6 December 2019). Available: https://allafrica.com/stories/201912060178.html.
[136] Art 21 of the Constitution of the People's Republic of China 1982, the 1988 Provisional Management Stipulations (225) which regulates private health care offered by traditional Chinese medical physicians within the State-sponsored socialist health-care system, and Regulations Concerning Medical Qigong (227) enacted in 1989 to protect patients from abuse and deception,
[137] The Japanese Pharmacopoeia, in accordance with Art 41 of the Pharmaceutical Affairs Law 145 of 1960, the Japanese Herbal Medicine Codex (242), the Japanese Standards for Herbal Medicines which contains 248 articles: 165 from the Japanese Pharmacopoeia and 83 from the Japanese Herbal Medicine Codex.
[138] The National Policy of Traditional Medicine/Complementary Alternative Medicine 1993, the Pharmaceutical Affairs Law 1994, and the Korea Pharmacopoeia issued in 1959.
[139] The National Policy on Traditional Medicine/Complementary Alternative Medicine 2002, Traditional Medicine Practice Act, 575, 2000.
[140] Directive of the European Parliament and of the Council Regarding Traditional Herbal Medicinal Products (2004/24/EC of 31 March 2004). A large number of countries in the European Region have through their national health agencies developed national policies and regulations on Traditional Medicine/Complementary Alternative Medicine through different means, there is a high level of commitment to ensuring the safety, quality and efficacy of herbal medicines through strong regulatory and policy systems in the European Union. See World Health Organization (n4) 116.
[141] World Health Organization (n3).
[142] Vanguard News, 'Bill to Regulate, Promote Traditional Medicine in Nigeria Passes 2nd Reading' *Vanguard News* (Lagos, Nigeria, 8 March 2017). Available: https://www.vanguardngr.com/2017/03/bill-regulate-promote-traditional-medicine-nigeria-passes-2nd-reading/; Anthony Ailemen, 'FG Approves Bill for Establishment of Council for Traditional, Alternative and Complementary Medicine Practice in Nigeria' *Businessday NG* (Lagos Nigeria, 21 October 2020). Available: https://businessday.ng/health/article/fg-approves-bill-for-establishment-of-council-for-traditional-alternative-and-complementary-medicine-practice-in-nigeria/.
[143] Vanguard News, 'Bill to Regulate, Promote Traditional Medicine in Nigeria Passes 2nd Reading' (n142).
[144] Ailemen (n142).

deliver services in the country, by producing herbal medicines, ensuring thorough toxicity assessment and pharmacovigilance. The regulatory bodies for herbal medical practice and medicines are the Medical and Dental Council of Nigeria and NAFDAC. There is a need for the creation of alternative medicine institutions and the harmonisation of government agencies to avoid duplication of efforts, especially as regards the documentation, preparation, standardization, and measurability of alternative medicine. For example, the Standards Organisation of Nigeria, the Nigerian Customs, the Economic and Financial Crimes Commission and other government agencies need to focus more on curbing excesses in alternative medicine practices and counterfeit products within the market.

5. With the proliferation of herbal medicines in the Nigerian market, it is essential to properly categorize herbal medicines into affordable therapeutic classes to ensure people access the right herbal medicine. Access to medicine, especially in developing countries, is a global phenomenon. There is, therefore, the need to explore ways to overcome the challenge through a strategic focus on herbal medicine.

6. Furthermore, the Federal Ministry of Health should meet the present challenge by collaborating with stakeholders and organizing workshops to train and raise awareness of herbal medicines' safety and efficacy. Nigeria may not be able to meet and surmount this challenge all on its own entirely and would need the assistance of global partners, especially the WHO. The established programs of the WHO, which include information sharing on regulatory issues as obtains in other countries and local and international workshops on building national capacity to develop regulations and safety monitoring on herbal medicine, should be strengthened in Nigeria. Having a clear understanding that the safety of herbal medicine use is dependent on policy and regulation, the government, international organizations, and stakeholders should step up efforts to harmonize all structures that will ensure effective implementation of policy and regulations to guarantee the safe use of herbal medicines in Nigeria.

7. There is a need to provide more effective and strategic methods of ridding the country of the frequency of infiltration by impersonators and unqualified persons medical profession, mainly traditional medical practitioners who roam around the country selling medicines and claiming to have cures and treatments for different ailments. Furthermore, Nigerian authorities can adopt and incorporate intelligent ways of apprehending and penalizing offenders through the collaborative efforts of the legislative, executive, and judicial arms of government. In essence, there should be adequate funding, sound strategy and implementation, and judicial activism in this respect.

VIII. CONCLUSION

The article has discussed the practice of alternative medicine and offered an overview of legislation that regulates alternative medicine in Nigeria with particular reference to NAFDAC. The article has also highlighted some challenges of NAFDAC to discharging its regulatory role and suggested some ways forward. Importantly, NAFDAC has made tremendous achievements in regulating alternative medicine as an agency. Those achievements notwithstanding, there

continues to be room for improvement. The agency is limited in discharging its role in the regulation of alternative medical practice in Nigeria. Besides NAFDAC, there is no other government agency that regulates alternative l medicine practices in Nigeria. Other regulatory roles are played by the Federal and State Ministries of Health and medical professional bodies. Alternative medical practice is a broad and complex profession that can significantly benefit Nigerian public health despite its shortcomings in Nigeria. Therefore, there is the take into consideration some of the solutions suggested in this article and, in addition, either amend the NADAC Act to expand the regulatory roles of NAFDAC on alternative medical practice or establish a separate agency that will be empowered to regulate NAFDAC.