International Journal of Innovative Research and Advanced Studies (IJIRAS)
Volume 12 Issue 9, September 2025

ISSN: 2394-4404

Review Of The Quality Of Herbal Medicines Marketed In Nigeria: Regulatory Challenges And Microbiological Safety Issues

Esenwah, Christiana Nkechi

Ubiaru, Ephraim Maduka

Onianwah, Fidelis Ifeanyichukwu

Amhanriamhen, Ilegbenose Reuben

Achuba, Ifeanyichukwu

Abstract: ***Herbal medicines are commonly used in Nigeria as part of traditional medicine in various communities in Nigeria; this practice is growing in popularity due to high cost of orthodox medicines. In many rural communities in Nigeria the use of herbal medicines forms important components of primary healthcare, and in some cases they are the only accessible healthcare measures available to the people. In Nigeria, herbal medicines are approved for sale by the National Agency for Food and Drug Administration and Control (NAFDAC); despite the acceptance of these herbal medicines in Nigeria and the regulatory functions of NAFDAC, there are still concerns about their quality and safety. This review discusses microbiological safety concerns arising from the use of herbal medicines, some important regulatory challenges associated with effective monitoring of their safety and recommendations that would contribute to the safe and effective use of herbal medicines in Nigeria. Literature search was conducted using various databases, including NAFDAC website for public health information (www.nafdac.gov.ng.), PubMed, Google Scholar and AJOL and some relevant studies on the topic were reviewed. The findings indicate that some herbal medicines sold in Nigeria are of poor quality, with issues related to microbial contamination, challenges in regulatory enforcement, and lack of effective collaboration between various stakeholders.***

Keywords: Herbal, Medicine, Regulation, Microbial Quality, Review.

I. INTRODUCTION

Herbal medicines have been used since ancient times in many cultures, including Chinese, Egyptian, Greek, Indian, and Native American. Today, about 80% of people in developing countries rely on traditional medicine for primary health care. The use of herbal medicines continues to expand rapidly across the world with many people now resorting to these products for treatment of various health challenges in different national healthcare settings These herbal medicines are now available not only in drug stores, but also in food stores and supermarkets (Bandaranayake, 2006; Schulz *et al*., 2001; Akande-Sholabi *et al.,* 2020). Consumers have reported positive attitudes towards herbal medicines, in large part because they believe them to be of 'natural' rather than 'synthetic' origin, they believe that such products are more likely to be safe than orthodox medicines, they are considered part of a healthy lifestyle, and they can help to avoid unnecessary contact with conventional orthodox medicine (Allison *et al*., 2001). Herbal medicines are commonly used in Nigeria as part of traditional medicine in various communities in Nigeria; this practice is growing in popularity due to the high cost of orthodox medicine especially the antibiotics and the re-occurring problem of antibiotic resistance which is very common in developing countries (Hack, 2005; Okeke *et al*., 1999; Parle & Bansal, 2006). Furthermore, the marketing strategies and efforts by various manufacturers of herbal medicines and their sales representatives have seriously projected these products into greater limelight. Various advertisements in the mass media including television and

ISSN: 2394-4404

radio programmes have significantly increased consumers' awareness and given the herbal products undue publicity. (Parle & Bansal, 2006).

The World Health Organization supports the safe and effective use of herbal medicines by developing guidelines and standards, and reviewing scientific literature towards regulating the safe use of herbal medicines. The WHO's goal is to improve healthcare and promote universal health coverage. They publish technical monographs that assess herbal medicines, they help countries develop policies to support traditional medicine and they also promote equitable access to ensure that traditional medicines are available to all people (WHO, 2004). In most developing countries, including Nigeria, the majority of the populace lives in the rural areas, where the use of herbal medicines is common. It is therefore imperative that relevant regulatory authorities put in place appropriate measures to protect public health by ensuring that all herbal medicines are safe and of suitable quality (Ekor, 2014).

The Nigerian Government has recognized the need and shown political will by approving and adopting guidelines for the practice of traditional medicine in the country. In this regard, the National Agency for Food and Drug Administration and Control is the regulatory authority in Nigeria. The Agency was established in 1993 with the mandate to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals. These functions are carried out through the enactment of relevant laws and regulations. NAFDAC has also taken steps to protect the health of consumers by drafting the 'Guidelines' for the Registration and Control of Herbal Medicinal Products and Related Substances in Nigeria (Osuide, 2002; Babarinde *et al*., 2023; Eruaga, 2024). NAFDAC has drafted the Herbal Medicine and Related Products (Labelling) Regulations, 2021 which repealed the NAFDAC Herbal Medicine and Related Products (Labelling) Regulations, 2005, the Herbal Medicines and Related Products (Advertisement) Regulations, 2021, and the Herbal Medicine and Related Products (Registration) Regulations, 2021. The enforcement of these guidelines and regulations is challenging, due to factors including inadequate funding, non-compliance among stakeholders and shortage of personnel among others (NAFDAC, 2018; NAFDAC, 2021). Other regulatory bodies involved in regulation of herbal medicine in Nigeria include the Traditional Medicine Development Division (TMDD) of the Ministry of Health, and state-level agencies. Additionally, there are traditional medicine councils at both federal and state levels, that collaborate with traditional healers to promote regulation and standardization within the traditional medicine sector (Kasilo & Wambebe, 2021; Odubo *et al*., 2023).

The safety and quality of herbal medicines are paramount considerations in regulatory oversight. Monitoring adverse events and ensuring product safety are essential aspects of the role of regulatory agencies in the use of herbal products worldwide. Additionally, the need for stringent quality surveillance and enforcement of guidelines to maintain standard quality of herbal medicines is emphasized in Nigeria (Builders *et al.*, 2015; Alshakka, *et al*., 2021; Wang *et al.*, 2023; Akindote *et al*., 2024; Okoro *et al*., 2024). However, despite the measures put in place for safe use of traditional medicines by consumers in Nigeria, there is concern about the purity and safety of these products. Research findings have reported the contamination of herbal medicines with microorganisms (Halt, 1998; Bugno *et al.*, 2006; Okunlola *et al*., 2007; Abba *et al*., 2009; Temu-Justin *et al.*, 2011; Olaniran *et al.,* 2022). The contamination of herbal medicines with microorganisms above the WHO permissible limit (total bacterial aerobic count is $\leq 10^7$ cfu/g for the plant material used as tea or infusion, and $\leq 10^5$ cfu/g for internal use; for yeast and mould are $\leq 10^4$ cfu/g for plant used as tea or infusion and $\leq 10^3$ cfu/g for internal use) can be of negative effect on the elderly and immune compromised patients; thus the need for more stringent rules and policies guiding the production of these herbal medicines to prevent complications (Amaike & Keller, 2011; De Sousa Lima *et al.*, 2020; Onyewenjo *et al*., 2022; Omoruyi *et al*., 2023).

This review examined microbiological safety concerns arising from the use of herbal medicines, some important regulatory challenges associated with effective monitoring of their safety and also recommendations that would contribute to the safe and effective use of herbal medicines in Nigeria. The study was designed to address and discuss the questions given below, with a view to improve strategies that could be implemented to enhance the quality and safety of herbal medicine production and use in Nigeria.

RESEARCH QUESTIONS

- ✓ What are the common microorganisms found in herbal medicines sold in Nigeria?
- ✓ How effective are current regulatory frameworks in ensuring the quality of herbal medicines?
- ✓ What are the perceptions and knowledge of herbal medicine producers and users regarding quality and safety?

By addressing these questions the review study aims to contribute to the development of effective policies and interventions that could promote the safe and effective use of herbal medicines in Nigeria.

II. METHODOLOGY

Literature search was conducted using various databases, including NAFDAC website for public health information (www.nafdac.gov.ng.), PubMed, Google Scholar and AJOL and some relevant studies on the topic were reviewed. Emphasis of the review study were on microbiological safety concerns of herbal medicines, highlight of some important regulatory challenges associated with effective monitoring of their safety by regulatory authorities, and possible recommendations for improvement on existing setbacks.

III. RESULTS

Research Question 1: What are the common microorganisms found in herbal medicines sold in Nigeria?

Sample Code	Bacterial Count (WHO Std ≤ 10^7 cfu/g for plant used as tea or infusion, and ≤ 10^5 cfu/g for internal use)	Fungal Count (WHO Std ≤ 10^4 For plant used as tea or infusion, and ≤ 10^3 cfu/g for internal use)	Identified Fungal Isolates
A	0	0	
B	0	$1.0X10^3$	*Rhizopus spp*, *Pichia cecembensis*, *Penicillium citrinum*
C	0	$1.2X10^3$	*Pichia cecembensis* and *Aspergillus niger*
D	$1.0X10^4$	$1.4X10^3$	*Mucor spp* and *Aspergillus niger*
E	0	$1.3X10^3$	*Fussarium spp and Aspergillus niger*
F	0	$1.0X10^3$	*Pennicillum citrium, Apergillus niger* and *Rhizopus spp*
G	0	$1.0X10^3$	*Pennicillum citrium* and *Mucor spp*
H	$2.3X10^5$	$3.0X10^4$	*Pichia cecembensis spp,*
I	$1.4X10^5$	$1.26X10^5$	*Pennicillum citrium, Apergillus niger* and *Rhizopus spp.*
J	$1.8X10^5$	$1.5x10^4$	*Penicillium citrinum*
K	$2.3X10^5$	$1.6X10^5$	*Aspergillus niger*
L	$1.5X10^5$	$3.1X10^4$	*Pichia cecembensis, Pennicillum citrium* and *Sacharomyces spp*
M	0		0
N	$2.7X10^5$	$2.4X10^4$	*Aspergillus niger, Fussarium spp,* and *Pennicillum citrium*
O	$3.2X10^5$	$1.9X10^4$	*Aspergillus niger* and *Pichia cecembensis*
P	$2.5X10^5$	$2.8X10^4$	*Pichia cecembensis* and *Fussarium spp*
Q	$1.7X10^5$	$1.1X10^4$	*Aspergillus niger* and *Pichia cecembensis*
R	$1.4X10^5$	$1.5x10^4$	*Aspergillus niger, Rhizopus spp* and *Pichia cecembensis*
S	$2.4X10^5$	$4.8x10^4$	*Rhizopus spp*
T	$2.8X10^5$	$2.9x10^4$	*Pichia cecembensis*

Source: Onyewenjo, et al., 2022

Table1: Total Bacterial and Fungal Count of Herbal Remedies

MICROBIAL CONTAMINATION OF HERBAL MEDICINES SOLD IN NIGERIA

Studies revealed high levels of bacterial and fungal contamination in various herbal preparations, including those sold in powdered form and liquid extracts. Common contaminants include *Escherichia coli*, *Salmonella typhi*, *Klebsiella spp., Shigella spp., Pseudomonas spp, Proteus spp, Staphylococcus aureus*, and various fungal species like *Aspergillus niger, Mucor spp, Candida spp* and *Trichosporon mucoides* (Halt, 1998; Bugno *et al.*, 2006; Okunlola *et al.*, 2007; Abba *et al.*, 2009; Temu-Justin *et al.*, 2011; Olaniran *et al.,* 2022). In a study of the microbial quality and antimicrobial potential of some herbal remedies marketed in Owerri-West Nigeria (Onyewenjo *et al.*, 2022), *S. aureus*, *P. aeruginosa*, *E. coli* and *Bacillus spp* were the bacterial species isolated from the remedies. *Bacillus spp* was the highest in the occurrence of (53%), while the least was *E. coli* (7%) (Fig. 1). Seven species of fungi namely *Penicillium citrinum* (21.1%), *Pichia cecembensis* (21.1%), *Aspergillus niger* (26.3%), *Saccharomyces spp* (5.3%), Mucor spp (5.3 %), Fusarium spp (7.3%) and Rhizopus spp (13.2 %), were identified (Table 1). In another study to evaluate the microbial quality and safety of regulated and unregulated liquid herbal preparations in Benin City, Nigeria it was discovered that a larger proportion (36%) of the unregulated herbal preparations was contaminated with bacteria as compared with regulated ones (4%) (Omoruyi *et al.,* 2023). *Klebsiella pneumoniae* was the predominant bacterium isolated from unregulated herbal products. A proportion of 2% and 26% of the regulated and unregulated herbal preparations, respectively, exceeded the World Health Organization's acceptable limit for microbial contamination (De Sousa Lima *et al*., 2020). Similarly, in another study that investigated the contamination of herbal medicines marketed in Kaduna metropolis it was discovered that some traditionally prepared herbal medicines in Kaduna State were contaminated with a wide variety of potentially pathogenic bacteria. The results showed that out of a total of 150 samples, seventy (46.67%) were contaminated with *Salmonella typhi*, twenty nine (19.33%) with *Shigella spp.* Eighty eight (58.67%) and ninety eight (65.33%) were contaminated with *Escherichia coli* and *Staphylococcus aureus*, respectively (Abba *et al*., 2009).

Studies have also highlighted the presence of antibiotic-resistant bacteria in herbal preparations, posing further challenges to public health (Onyewenjo *et al.*, 2022). In a study to determined the therapeutic potential of selected pathogenic organisms from clinical sources; antibiotic susceptibility tests, minimum inhibitory and bactericidal concentration of the remedies were determined on *Escherichia coli*, *Pseudomonas aeruginosa*, *Candida albicans, Salmonella typhi* and *Staphylococcus aureus* using agar well diffusion method. It was discovered that the inhibitory activity of herbal medicines on pathogenic organisms ranged from 8mm -18mm. Minimum inhibitory concentration (MIC) ranged from 62.5 – 125mg/ml while Minimum bactericidal concentration (MBC) ranged from 125mg/ml – 250mg/ml. The lowest activity was seen with *Candida albicans* and *S. aureus* while the highest activity was seen with *P. aeruginosa;* while *Salmonella typhi* was resistant (Onyewenjo *et al*., 2022).

RESEARCH QUESTION 2: How effective are current regulatory frameworks in ensuring the quality of herbal medicines?

CHALLENGES IN REGULATORY ENFORCEMENT

Regulatory agencies in Nigeria encounter resource limitations that hinder its enforcement activities, impacting its ability to effectively regulate and control regulated products. These limitations include inadequate funding, insufficient manpower, and modern equipment, among other challenges. Limited funding restricts the agencies ability to procure essential equipment, train staff, and expand its reach to all parts of the country; while shortage of skilled and trained personnel weakens the agency's capacity to identify, investigate, and prosecute violations of regulations.

(Nnaemeka *et al*., 2024). Other Challenges include logistics, such as difficulties in transportation and communication in remote areas, which impede their ability to reach all areas where regulated herbal medicines are sold. In addition coordination issues with relevant government agencies and stakeholders also create obstacles to enforcement. Another challenge is the penalties that the regulatory agencies impose on defaulters; existing laws may not be stringent enough, allowing defaulters to operate with relative impunity (Adeyeye, 2024).

LACK OF STANDARDIZATION IN HERBAL MEDICINE REGULATION

Regulatory agencies face challenges in standardizing herbal medicine regulation in Nigeria, including inconsistencies in national and state-level regulations, lack of standardized training and certification requirements, limited data on safety and efficacy, lack of standardized production and quality control parameters (Veziari *et al*., 2021; Onyeaka *et al*., 2024). These gaps lead to difficulty in ensuring consistent quality and safety of products causing potential public health risks. A significant portion of herbal medicines on the market are unregistered, indicating poor compliance with regulatory requirements and a lack of effective oversight. Only about 1% of the finished herbal medicines are listed with NAFDAC (Adigwe *et al*., 2022). In a study on the challenges associated with addressing substandard medicines in Nigeria, a total of 390 valid responses were received the respondents indicated that online medicine commerce (72.68%), inadequate inspection (90.93%), inadequate legislation (88.83%), poor collaboration (89.94%), and poor cross-border enforcement (90.43%) were primary challenges to the mitigation of substandard medicine circulation in Nigeria (Adigwe *et. al*., 2022).

Research Question 3: What are the perceptions and knowledge of herbal medicine producers and users regarding quality and safety?

PUBLIC AWARENESS AND ENLIGHTENMENT BY NAFDAC

NAFDAC conducts public awareness campaigns through various media (print, radio, television and social media) to educate consumers about the importance of buying registered products and identifying potential substandard items. They organize workshops and seminars for consumers, healthcare professionals, and traditional medicine practitioners to provide accurate information on herbal medicine use. They also distribute informational materials such as pamphlets and brochures to educate the public about the proper use and potential risks of herbal medicines (Adegoke *et al.*, 2020). NAFDAC mandates the registration or listing of all herbal medicines, both indigenous and imported, and carries out other regulatory functions to ensure that stakeholders meet quality and safety standards. By implementing these strategies, NAFDAC aims to create a well-informed public that can make safe and effective choices regarding herbal medicines. In a study to investigate the various NAFDAC sensitization programmes on counterfeit and substandard medicines and level of consumers knowledge application in identifying counterfeit and substandard medicines, it was discovered that 57% of the respondents got their information about NAFDAC from NAFDAC sponsored programmes. The finding also revealed that 81% of the respondents were adequately knowledgeable about the existence of counterfeit and substandard medicines but very few of them are applying the knowledge (Adegoke *et al.,* 2020). In another study to assess the compliance of herbal medicines sold in Lagos State Nigeria, with the regulations published by the NAFDAC; sixty herbal medicines were randomly selected from the three senatorial districts of Lagos State and assessed for their compliance with NAFDAC's Herbal Medicine and Related Products (Labelling) Regulations 2021. Only 6.7% of the products were found to be fully compliant with the regulations. Of the assessed products, 63% had NAFDAC registration numbers, which indicates that one in every three of the products sold in the market is unregistered or unapproved by NAFDAC (Olatunde *et al*., 2024).

Similarly, in a study to determine the development of herbal medicine in relation to compliance to regulatory guidelines and product development in pursuance of the integration of herbal medicine into the healthcare system in Nigeria, a cross-sectional investigation was conducted among one hundred traditional medicine practitioners (TMPs) in Imo state. All the TMPs claimed knowledge of the existence of NAFDAC as the regulatory authority for herbal medicine. Only 5% had any contact with the agency in relation to product registration, while only 1% of the products owned by the TMPs had NAFDAC registration number. Also, 97% of the TMPs produced only extemporaneous products for their patients, and only 6% have any knowledge on the formulation of some conventional dosage forms. Of the 300 herbal medicines owned by the TMPs, only 8% were presented in conventional dosage forms with appropriate packaging. The few number of herbal medicines registered with NAFDAC reflects the low level of development of herbal medicine in Nigeria. The study therefore concluded that the products were unsafe for integration into the healthcare system at the present stage (Adigwe *et al*., 2022).

IV. DISCUSSION

Literature search conducted in this study shows that herbal medicines are mostly contaminated with microorganisms that can affect the property of the medicine and constitute significant public health concern due to their potential for serious health implications for consumers including antimicrobial resistance in some of the bacterial isolates investigated which can contribute to evasion of bacteria to treatment with antibiotics making them difficult or impossible to treat in life threatening infections (Onyewenjo *et al.*, 2022). Microbial contamination of these herbal products can reduce or inactivate the therapeutic activity of the products and can adversely affect the patients taking the medications. Therefore, the microbiological status of herbal medicinal products should be ascertained before distribution to consumers for use. Some of the isolates found in the herbal remedies are normal flora of the soil, water and vegetation. Some are part of the microbiota

ISSN: 2394-4404

of the human intestine and other animals used as indicator organisms and as an index of possible contamination by human faecal matter (Abba *et a*l., 2009; Onyewenjo *et al*., 2022; Omoruyi *et al*., 2023). Contaminated herbal medicines have potential health risks like gastrointestinal issues and even more serious health complications, particularly for individuals with weakened immune systems, like children, the elderly and immuno-compromised patients. *Staphylococcus aureus* may cause infections such as skin infection, food poisoning, septicaemia, toxic shock syndrome and arthritis. *Bacillus cereus* produces heat-stable spores and causes food intoxication when ingested. Poor hygiene during harvesting, processing, storage and transportation of herbal raw materials are major contributors to contamination. The importance of quality control methods in monitoring various aspects of herbal product manufacturing and distribution can not be overemphasized (Raynor *et al*., 2011; Wang *et al.*, 2023). To safeguard public health, there is need for standardized manufacturing processes, in-process quality control measures and adherence to regulatory standards. Effective quality control measures involve evaluating processes and identifying areas for improvement. By streamlining operations, eliminating bottlenecks, and addressing inefficiencies, organizations can enhance productivity and achieve higher output levels with fewer resources (*Gong* et al*., 2023*).

NAFDAC is the agency mandated to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of herbal medicines in Nigeria. These functions are carried out through the enactment of relevant laws and regulations; however, challenges persist in the effective regulation of these products, including inadequate enforcement of regulations due to limited resources for monitoring and inspections, and challenges in coordinating efforts between regulatory agencies. Moreover, there is a lack of harmonization between national and state-level regulations, leading to inconsistencies in implementation and oversight. (Noah *et al.*, 2021). To bridge the gap between the manufacture and clinical development of herbal medicines in Nigeria, NAFDAC has called for a strong collaboration between the research & development institutions and pharmaceutical companies. This according to the agency would help to bridge the gap between the discovery and clinical development of herbal medicines in the country (Orhii, 2014). A close and complementary relationship between the academic community and the herbal industry is critical to ensuring a robust national pharmaceutical research capacity for the development of medicinal products. The relationship between the academia and the pharmaceutical companies is complementary and naturally leads to the formation of joint research enterprises. While the academia brings strong insight into the fundamental mechanisms of disease along with expertise in patient care and clinical practice, the industry possesses the knowledge and tools to translate basic research discoveries into practical applications in patients (Orhii, 2014). NAFDAC enforcement directorate, is principally responsible for ensuring compliance with the agency's mandate on regulatory activities. The Investigation and Enforcement directorate coordinates enforcement activities of all other directorates, zonal and states offices of NAFDAC Nationwide as the law enforcement arm of the agency in line with the Administration of Criminal Justice Act, 2015 as stipulated in section 1 of the Enactment. Despite NAFDAC regulations, the agency struggles to ensure compliance due to insufficient enforcement mechanisms. The primary challenge in controlling herbal medicines in Nigeria by NAFDAC is inadequate enforcement, stemming from factors like insufficient resources and a lack of synergy between relevant agencies. Perhaps, this factor of inadequate resources has hampered how effective and efficient the country makes its effort in regulation of herbal medicine enforcement and safety. It is worth highlighting that despite the public awareness campaigns been carried out by NAFDAC to enlighten stakeholders and the general public on the safe use of medicines, there is still a high level of non-compliance to regulatory guidelines. This leads to the proliferation of poor quality products, unregistered, substandard, and counterfeit herbal products on the market, posing significant risks to public health (Adigwe *et al*., 2022).

V. CONCLUSION

The review carried out in this study showed that herbal medicines are mostly contaminated with microorganisms that can affect the property of the medicine and constitute significant public health concern due to their potential for serious health implications for consumers including antimicrobial resistance in some of the bacterial cultures investigated by other researchers. Effective regulation of herbal medicines by NAFDAC and other regulatory agencies is challenged by limited resources for monitoring and inspections. Moreover, there is a lack of harmonization between national and state-level regulations, leading to inconsistencies in relevant implementation and oversight functions. The future of herbal medicine regulation in Nigeria, therefore, calls for collaborative action and adequate funding for all stakeholders towards effective regulation and safeguarding the health of the nation. This includes policymakers, regulatory agencies, healthcare practitioners, traditional healers, consumers, and civil society organizations collaborating to address the prevailing setbacks by implementing reforms, and promoting the responsible and safe use of herbal medicines in Nigeria. Effective collaboration and adequate funding would create a regulatory environment that safeguards public health, advances scientific knowledge, and uphold the rich heritage of herbal medicine in Nigeria.

VI. RECOMMENDATIONS

The setbacks mentioned in this study highlight the urgent need for NAFDAC to strengthen its enforcement capacity to ensure compliance with regulations, improve inter-agency collaboration, and increase public awareness to effectively regulate the herbal medicine market. It is recommended that the National Agency for Food and Drug Administration and Control should improve on intelligence gathering and monitoring strategies of herbal products in the country for a robust and effective mechanism to ensure consumer safety and

public health. The Investigation and Enforcement Directorate as well as the Pharmacovigilance and Post Market Surveillance Directorates of the agency should be strengthened for effective operation, as this would help to eradicate or significantly reduce the sales of poor quality herbal products in Nigeria. Furthermore, the penalties for violating regulations of herbal medicines should be more severe to act as sufficient deterrent to intending offenders. It is also recommended that the agency should encourage the standardization of herbal medicine production and quality control through the development and implementation of relevant guidelines and standards. In addition, there should be effective collaboration between various stakeholders including NAFDAC and other regulatory bodies, law enforcement agencies, and even within NAFDAC, researchers, traditional medicine practitioners, and the industry. Effective collaboration would enhance standardization, validation, and scientific proof of claims regarding herbal medicines, and ultimately impact on their safety and efficacy.

REFERENCES

[1] Abba, D., Inabo, H. I., Yakubu, S. E. and Olonitola, O. S. (2009). Contamination of herbal medicinal products marketed in Kaduna metropolis with selected pathogenic bacteria. *African Journal of Traditional, Complementary and Alternative Medicines*, 6 (1), 70-77 https://www.ajol.info/index.php/ajtcam/article/view/57076.

[2] Adegoke, S. P., Osokoya, M. M. and Adegoke, A. O. (2020). NAFDAC Sensitization programme and level of consumers knowledge application in identifying counterfeit and substandard medicines. *International Journal of Scientific Research in Education,* 13(2), 228-243.

[3] Adeyeye, M. J. (2024). The challenges of illegal use of medicines/ drugs (The Tramadol menace). https://www.nafdac.gov.ng/wpcontent/uploads/Publications/Others/Press_Release_PDF/THE-CHALLENGES-OF-ILLEGAL-USE-OF-MEDICAMENT-OR-DRUGS-INTERPOL-WEEK.pdf.

[4] Adigwe, P. O., Builders, F. P., Ibekwe, N. N. and Onavbavba, G. (2022). Herbal medicine development and compliance to regulatory guidelines in Imo State Nigeria. *Journal of Medicinal Plants Research,* 16(4), 118-125.

[5] *Adigwe*, P. O., *Onavbavba*, G., and *Oyin-mieyebi, W.* D. (2022). Challenges associated with addressing counterfeit medicines in Nigeria: An exploration of pharmacists' knowledge, practices, and perceptions**.** *Integrated Pharmacy Research and Practice* (11) 177-186. *https://doi.org/10.2147/IPRP.S387354.*

[6] Akande-Sholabi, W., Iluyomade, A., Ilesanmi, O.S. R. and Adisa, R. (2020). Perception and use of herbal medicines among clients visiting selected community pharmacies in Ibadan, Nigeria. African Journal of Biomedical Research*, 23(2)*, 147-153.

[7] Akindote, O. J., Adegbite, A. O., Omotosho, A., Anyanwu, A. and Maduka, C. P. (2024). Evaluating the effectiveness of IT project management in healthcare digitalization: *A review. International Medical Science Research Journal*, 4(1), 37-50.

[8] Allison, D. B., Fontaine, K. R., Heshka, S., Mentore, J. L. and Heymsfield, S. B. (2001). Alternative treatments for weight loss: A critical review. *Critical Reviews in Food Science and Nutrition*, 41, 1–28.

[9] Alshakka, M., Badulla, W. F. S., Alshagga, S., Awadh, N. A., Jha, N. and Ibrahim, M. I. M. (2021). Monitoring the safety of herbal medicines in Yemen: A call for action. *Journal of Pharmaceutical Research International*, 33(49A), 59–63.

[10] Amaike, S. and Keller, N. P. (2011). *Aspergillus flavus*. *Annual Review of Phytopathology*, 49,107-133.

[11] Babarinde, A. O., Ayo-Farai, O., Maduka, C. P., Okongwu, C. C., Ogundairo, O. and Sodamade, O. (2023). Review of AI applications in healthcare: Comparative insights from the USA and Africa. *International Medicine Science Research Journal*, 3(3), 92–107.

[12] Bandaranayake, W. M. (2006). "Quality control, screening, toxicity, and regulation of herbal drugs,'' In *Modern Phytomedicine. Turning Medicinal Plants into Drugs* eds.

[13] Bugno, A., Almodovar, A. A. B., Pereira, T. C., Pinto, T. J. A. and Sabino, M. (2006). Occurrence of toxigenic fungi in herbal drugs. *Brazilian Journal of Microbiology*, 37, 47-51.

[14] Builders, P. F., Alalor, C. A., Avbunudiogba, J. A. and Justice, I. E. (2015). Survey on the pharmaceutical quality of herbal medicines sold in Nigeria. *Journal of Applied Pharmaceutical Science*, 5(6), 97–103. https://doi.org/10.7324/japs.2015.50616.

[15] De Sousa Lima, C. M., Fujishima, M. A. T., De Paula Lima, B., Mastroianni, P. C., De Sousa, F. F. O. and Da Silva, J. O. (2020). Microbial contamination in herbal medicines: a serious health hazard to elderly consumers. *BMC Complementary Medicine and Therapies,* 20(1), 17. doi: *10.1186/s12906-019-2723-1*.

[16] Ekor, M. (2014). The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. *Frontiers in Pharmacology*. doi: 10.3389/fphar.2013.00177. PMID: 24454289; PMCID: PMC3887317.

[17] Eruaga, M. A. (2024). The role of regulatory authorities in the regulation and control of herbal medicines: A case study of NAFDAC. *International Medical Science Research Journal,* 4(3), 259–265.

[18] Gong, L., Xie, J. B., Luo, Y., Qiu, Z. D., Liu, J. R. and Mei, N. J. (2023). Research progress of quality control for the seed of *Ziziphus jujuba* var. spinosa (Bunge) Hu ex H.F. Chow (Suan-Zao-Ren) and its proprietary Chinese medicines. *Journal of Ethnopharmacology* 307, 116204.10.1016/j.jep.2023.116204 [doi] [*PubMed*] [*Google Scholar*].

[19] Hack, S. K. (2005). Dot not put too much value on conventional medicine. *Ethnopharmacology,* 3(2), 37-39.

[20] Halt, M. (1998). Moulds and mycotoxins in herb tea and medicinal plants. *European Journal of Epidemiology,* 14, 269-274.

[21] Kasilo, O.M. and Wambebe, C., 2021. Traditional and complementary medicine in global health care. In *Handbook of Global Health* (pp. 1-47). Cham: Springer International Publishing.

[22] NAFDAC (2018). Guidelines for Registration of Herbal Remedies/Dietary Supplements Made in Nigeria. https://www.nafdac.gov.ng/wpcontent/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/LOCAL/Gudelines-for-the-Registration-of-Herbal-Remedies-andDietary-Supplements-made-in-Nigeria.pdf

[23] NAFDAC (2021). "Herbal Medicines and Related Products Labelling Regulations 2021.

[24] Nnaemeka, O. F., Brown, G. N. and Solomon, B. T. (2024). Emerging complexities in drug law enforcement and security in Nigeria: An explorative study. *Mass Media Review* 6(1) https://www.researchgate.net/publication/385707216.

[25] Noah, A.O., Adhikari, P., Ogundele, B.O. and Yazdifar, H., 2021. Corporate environmental accountability in Nigeria: an example of regulatory failure and regulatory capture. *Journal of Accounting in Emerging Economies*, 11(1), 70-93.

[26] Odubo, T.C., Iyiola, A.O., Adetola, B.O., Kolawole, A.S., Izah, S.C., Raimi, M.O. and Ogwu, M.C. (2023). Socioeconomic values of herbal medicine. In *Herbal Medicine Phytochemistry: Applications and Trends* (pp. 1-31). Cham: Springer International Publishing.

[27] Olatunde, O. I., Kumolalo, O. R and Edozien, L. C. (2024). Compliance with NAFDAC herbal medicine labeling regulations: A case study of herbal remedies. *Acta Scientific Nutritional Health* 8(6), 29-37.

[28] Omoruyi, Z. 1., Okundaye, M. I. and Egunjobi, T. O. (2023). Evaluation of the microbial quality and safety of regulated and unregulated liquid herbal preparations in Benin City, Nigeria. *International Journal of Advanced Research in Biological Sciences,* 10(2), 59-71. doi: 10.22192/ijarbs Coden: IJARQG (USA).

[29] Onyeaka, H., Ghosh, S., Obileke, K., Miri, T., Odeyemi, O.A., Nwaiwu, O. and Tamasiga, P., (2024). Preventing chemical contaminants in food: Challenges and prospects for safe and sustainable food production. *Food Control* 155, https://research.birmingham.ac.uk/en/publications/preventing-chemical-contaminants-in-food-challenges-and-prospects.

[30] Onyewenjo, C., Agbagwa, O. E., Frank-Peterside, N. and Onyewenjo, S. C. (2022). Microbial quality and antimicrobial potential of some herbal remedies marketed in Owerri-West Nigeria. *African Journal of Health Sciences 35(4)*, 537-549.

[31] Okeke, I. N., Lamikanra, A. and Edelman, H. (1999). Socioeconomic and behavioural factors leading to acquired bacterial resistance to antibiotics in developing countries. *Emerging Intestine Diseases*, 2(5), 18-27.

[32] Okoro, Y. O., Ayo-Farai, O., MaduKa, C. P., Okongwu, C. C. and Sodamade, O. T. (2024). The role of technology in enhancing mental health advocacy: a systematic review. *International Journal of Applied Research in Social Sciences*, 6(1), 37-50.

[33] Okunlola, A., Babatunde, A. A. and Oluwatoyin, A. O. (2007). Evaluation of pharmaceuticals and microbial quality of some herbal medicinal product in South Western Nigeria. *Tropical Journal of Pharmaceutical Research*, 61(1), 661-670.

[34] Olaniran, O. B., Ajayi, S. E., Oluwatobi, O.B. and Adeleke, O. E. (2022). Assessment of microbial quality and detection of extended spectrum β-lactamase genes in Gram-negative bacterial isolates of herbal mixtures commonly hawked in Sagamu metropolis, Ogun State, Nigeria. *African Journal of Clinical and Experimental Microbiology*, 23(3),257-268. DOI:10.4314/ajcem.v23i3.5.

[35] Orhii, P. (2014). NAFDAC seeks collaboration on herbal medicine standardization. *Pharmanews. https://pharmanewsonline.com/nafdac-seeks-collaboration-on-herbal-medicine*-standardization/mane

[36] Osuide, G. E. (2002). Regulation of herbal medicines in Nigeria: the role of the National Agency for Food and Drug Administration and Control (NAFDAC). *Advances in Phytomedicine*, 1(C), 249-258.

[37] Parle, M. and Bansal, N. (2006). Herbal medicines: are they safe? *Natural Product Radiance,* 5, 6–14 [Google Scholar]

[38] Raynor, D. K., Dickinson, R., Knapp, P., Long, A. F. and Nicolson, D. J. (2011). Buyer beware? Does the information provided with herbal products available over the counter enable safe use? *BMC Medicine,* 9, 94. *http://doi*.org/10.1186/1741-7015-9-94 [DOI] [PMC free article] [PubMed] [Google Scholar].

[39] Schulz, V., Hänsel, R. and Tyler, V. E. (2001). *Rational Phytotherapy. A Physician's Guide to Herbal Medicine*, 4th Ed. Berlin, Springer-Verlag.

[40] Temu-Justin, M., Lyamuya, E. F. and Makwaya, C. K. (2011). Source of microbial contamination of natural therapeutically used locally prepared herbal medicines sold on the open market in Dares Salaam, Tanzania. *African Journal of Health Sciences,* 18, 1-2.

[41] Veziari, Y., Kumar, S. and Leach, M. (2021). Addressing barriers to the conduct and application of research in complementary and alternative medicine: a scoping review. *BMC Complementary Medicine and Therapies*, 21(1), 1-12.

[42] Wang, H., Chen, Y., Wang, L., Liu, Q., Yang, S. and Wang, C. (2023). Advancing herbal medicine: enhancing product quality and safety through robust quality control practices. *Front Pharmacology,* 14, 1265178. doi: 10.3389/fphar.2023.1265178.

[43] WHO (2004). Quality control methods for medicinal plant materials. *World Health Organization*, *Geneva*, 112- 113.