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Review Article

Compliance with NAFDAC Herbal Medicine Labeling Regulations: A Case Study of Herbal Remedies in Lagos State

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Abstract

This study assesses the compliance of herbal remedies sold in Lagos State, Nigeria, with the regulations published by the National Agency for Food and Drug Administration and Control (NAFDAC). Herbal remedies (n = 60) 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. The implications of these findings are discussed in detail.

It is recommended that NAFDAC prioritize post-marketing surveillance, conduct periodic regulatory review, and strengthen enforcement mechanisms to ensure strict compliance with the regulations.

Keywords: Herbal; Medicine; NAFDAC; Regulations; Labeling

Introduction

Herbal medicines are an important component of complementary medicine. The use of herbal medicine holds immense significance in African traditional medicine, serving as the primary medical system accessible to countless individuals residing in urban and rural areas of Africa [1].

The use of herbal medicines is particularly widespread within primary health care, serving as a cornerstone in the management of numerous chronic ailments. The global market for herbal medicines currently exceeds US$60 billion annually, and it continues to grow steadily [2].

The global market for herbal medicine, particularly Chinese and Indian herbal products, is experiencing a significant surge in growth, The sales of medicinal plants in India have experienced remarkable growth, with a nearly 25% increase between 1987 and 1996, marking the highest growth rate globally [3].

Major issues with herbal medicine include its toxicity, adulteration, contaminations, safety, and quality, as well as, in some countries, lack of specific laws or regulations [4].

In Nigeria, herbal medicines are approved for sale by the National Agency for Food and Drug Administration and Control (NAFDAC) and the Herbal Medicine and Related Products (Registration) Regulations, 2021 provides the regulatory framework. The labelling of these products is regulated by this law. Furthermore, therapeutic claims on the labels are prohibited until clinical trials are conducted and approved for full registration [5].

NAFDAC defined herbal medicines and related products under the interpretation clause of rule 22 of the NAFDAC Herbal Medicines and Related Products Labeling regulations as "finished medicinal product containing plant and their preparation presented with therapeutic or prophylactic claim and includes all preparations containing a plant material in part or wholly" [6].

In many developing countries, including Nigeria, a significant portion of the population resides in rural areas and the use of herbal medicines is prevalent among the local communities. Although, the use of herbal medicines in urban areas has been steadily rising due to the global inflationary trend which has had a significant impact on the sustainable supply of conventional medicines, making them less accessible to the general population due to reduced purchasing power. As a result, more individuals are turning to herbal remedies as an alternative form of health care [7].

NAFDAC has played a significant role in the regulation of herbal remedies in Nigeria through the drafting of guidelines and various regulations, including 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 several factors, including poor funding, inadequate personnel, and a lack of awareness among herbal remedy manufacturers and marketers. The labels of herbal remedies sold in Nigeria must comply with the NAFDAC Herbal Medicine and Related Products Labelling Regulations, 2021. The regulations prescribe those herbal medicines manufactured, imported, exported, distributed, and sold in Nigeria must be labelled in accordance with standards stipulated in the regulations [6].

Despite the prevalent use of herbal medicines in Nigeria, there has been limited effort by NAFDAC to monitor the compliance of their labelling with the NAFDAC Herbal Medicine and Related Products (Labelling) Regulations, 2021.

Herbal remedy products manufactured, used, exported, imported, sold, and distributed in Nigeria must include on the product label the product's brand name, whether it's a botanical or common name, a detailed quantitative list of ingredients, the net contents of the product, and the name and factory location or address of the manufacturer [6].

In addition, labels of herbal remedies must provide clear instruction for usage, specifying the appropriate amount for usage within specific age groups, and should include information such as batch or lot numbers, date of manufacture, NAFDAC Registration Number, expiration date, dosage instructions, route of administration, frequency of administration, indications for product use, and recommended storage conditions. The inclusion of these critical components on product labels ensures consumer safety, effective usage, and compliance with regulatory standards [8].

The regulatory framework in Nigeria has promoted the production of refined packaged herbal medicines, leading to a significant increase in the availability of such products in the Nigerian markets. There is a prevalent use of herbal medicines in Lagos among adults who take these remedies, even in the absence of chronic illness symptoms [9].

However, existing research assessing the compliance of herbal remedies with NAFDAC herbal medicines regulations is limited. No study has been conducted to assess the compliance of herbal remedies sold in Lagos with the NAFDAC Regulations.

The aim of this study is to assess the compliance of herbal medicines sold in Lagos State with the NAFDAC Herbal Medicine and Related Products (Labelling) Regulations, 2021.

Methods and Materials

A cross-sectional study design was used to collect data on the labelling information of herbal remedies that were available for sale in the three senatorial districts of Lagos State during the months of July and August in the year 2023. A quantitative approach was adopted to establish the compliance of herbal remedies sold in Lagos State with the NAFDAC Herbal Medicines and Related Products Regulations, 2021. The sampled products were available in various forms such as liquid, capsules, powders, and ointments, all of which contained at least one herbal ingredient or herbal extract as their active component and were sold as herbal remedies. These are herbal products that had been pre-packaged, either produced locally or imported, and made available for purchase by the public.

A total of 60 products were randomly selected for the assessment of product labelling compliance with the NAFDAC Herbal Medicines and Related Products Regulations, 2021. Packed samples of various sizes were purchased from herbal retail outlets, stores, pharmacies, and markets located in the three senatorial zones of Lagos State.

The Herbal Medicines and Related Products Labeling Regulations, 2021 and a checklist for vetting the label of herbal remedies obtained from NAFDAC was employed for the assessment.

The products were assessed under the four major labelling categories of the Regulations: (1) Labelling information requirement (mandatory) (ii) Forms and presentations (iii) Precautionary and warning information requirements; (iv) Conditional or voluntary labelling information. There are 20 criteria that are essential for herbal medicine label compliance with NAFDAC Herbal Medicines and Related Products Regulations, 2021 and they fall in one or more of the four major labelling categories of the regulations listed above. The label for each herbal medicine product was assessed against every criterion.

Results

A total of 60 herbal remedy products sold in the three senatorial zones of Lagos State, Nigeria, were assessed. The compliance of the products with the NAFDAC Herbal Medicines and Related Products Regulation, 2021, is shown in table 1.

Only n (6.7%) of the products were fully compliant with the NAFDAC Herbal Medicines and Related Products (Labeling) Regulations 2021, while the vast majority (93.4%) did not meet all the

Herbal remedy labeling requirement	Compliant (frequency)	Compliant (percentage)	Non-Compliant (frequency)	Non-Compliant (percentage)
Product name	60	100.0	0	0
List of ingredients	47	78.3	13	21.7
Name and address of manufacturer	60	100.0	0	0.0
Direction for use	35	58.3	25	41.7
Lots or batch number	31	51.6	29	48.4
Production date	52	86.7	8	13.3
Expiration date	53	88.3	7	11.7
Storage condition(s)	28	46.7	32	53.3
NAFDAC Registration No.	38	63.3	22	36.7
Dosage	45	75.0	15	25.0
Route of administration	8	13.3	52	86.7
"These claims have not been evaluated by NAFDAC" disclaimer	14	23.3	56	76.7
Net contents	33	55.0	27	45

Table 1: Compliance of herbal remedies with the labelling information requirements of the NAFDAC Herbal Medicines and Related Products Regulations, 2021. (n = 60).

stipulated standards. All the products assessed have a product name on their label that defines the identity and nature of the products. Generally, over 70% of the assessed herbal remedies complied with some of the requirements, such as the list of ingredients, name and address of the manufacturer, production date, expiration date, and dosage.

Only n (63%) of the assessed products has NAFDAC registration numbers, which suggests that about 37% of the products sold in the market are unregistered or unapproved by NAFDAC. About 58% or less complied with the directions for use, warning or precautionary statement, and lot or batch number. Less than 50% of products provided storage conditions, and less than 25% of products comply with the NAFDAC mandatory disclaimer "These products have not been evaluated by NAFDAC". Compliance with the route of administration requirement is the least complied with (13.3%).

Table 2 shows compliance of herbal remedies with the labelling requirement of the NAFDAC Herbal Medicines and Related Products (Labelling) Regulations, 2021 (forms and presentation).

Label forms and presentation	Compliant (frequency)	Compliant (percentage)	Non-compliant (frequency)	Non-Compliant (percentage)
Legible label	28	46.7	32	53.3
Clear and prominent label	30	50	30	50
English language	52	86.7	11	13.3

Table 2: Percentage of compliance of herbal remedies with the labelling requirement of the NAFDAC Herbal Medicines and Related Products Regulations, 2021 (forms and presentation).

Less than 50% of the products assessed complied with the label legibility requirements of the NAFDAC Herbal Medicines and Related Products Regulations, 2021, and only 50% of products have clear and prominent labelling information. More than 80% of products complied with the language requirements of the regulation. About 13% of products have the labelling information written in a non-English language without translation.

Table 3 shows the compliance of herbal remedies with the precautionary and warning information requirements of the NAFDAC Herbal Medicines and Related Products Regulations, 2021.

Less than 40% of the herbal remedies assessed complied with the precautionary and warning information requirements, such as "not to be taken by pregnant women", "not to be taken by children

Precautionary and warning statement	Compliant (frequency)	Compliant (percentage)	Non-compliant (frequency)	Non-compliant (percentage)
Not to be taken by pregnant women	20	33.3	40	66.7
Not to be taken by children below 5 years	2	3.3	58	96.7
Keep all medicines out of reach of children	15	25.0	45	75.0

Table 3: Compliance of herbal remedies with the precautionary and warning information requirements of the NAFDAC Herbal Medicines and Related Products Regulations, 2021, frequency (percentage).

under 5 years", and "keeping all medicines out of the reach of children". Although the NAFDAC Herbal Medicines and Related Products Regulations of 2021 do not mandate the inclusion of labeling information such as "shake before use," "Consult your doctor if symptoms persist," "Do not exceed recommended dosage," and "Do not use if seal is broken," these pieces of information are valuable for consumers of herbal remedies.

Despite not being obligatory, the products were assessed for the presence of these voluntary information, and the degree of compliance is presented in table 4.

Conditional or voluntary information	Compliant (frequency)	Compliant (percentage)	Non-compliant (frequency)	Non-compliant (percentage)
Shake before use	20	33.3	40	66.7
Do not exceed the dosage	0	0.0	60	100.0
Do not accept if seal is broken	0	0.0	60	100.0

Table 4: Compliance of herbal remedies with conditional or voluntary information requirements of the NAFDAC Herbal Medicines and Related Products Regulations, 2021, frequency (percentage).

Discussion

The label of herbal medicines comprises essential constituents that hold considerable significance. The inclusion of product names is imperative to establish a comprehensive identification system for herbal medicines. The inclusion of net contents, active ingredients, manufacturer's name and address, batch number, manufacturing license number (NAFDAC Reg. No.), date of manufacturing and expiry, warning or precaution statements, direction for use, dosage, route of administration, and storage information is imperative for both regulatory compliance and the assurance of prescribed herbal medicines safety and quality control. The overall compliance rate of the assessed herbal remedies with the NAFDAC Herbal Medicines and Related Products Regulations, 2021, was generally low. Only 4 (6.7%) of the 60 products (n= 60) analyzed were fully in compliance with the NAFDAC Herbal Medicines and Related Products Labelling Regulations, 2021. While 56 (93.4%) of the 60 products assessed were not in compliance with the NAFDAC Herbal Medicines and Related Products Labelling Regulations, 2021. The study's findings showed that all the 60 herbal remedies assessed exhibited full conformity, with a compliance rate of 100%, to the provisions regarding the product's name as well as the manufacturer's name and address. The observed phenomenon can potentially be attributed to the manufacturers' inclination towards product promotion and their desire for customers to establish a direct link between the product and its origin. The product name serves the purpose of facilitating straightforward recognition and choice of the item within the market and preventing confusion among related products.

This aligns with a study conducted by Thomas P. Cheung and others in 2006 on Chinese herbal products, which shows that confusion in Chinese names for related raw herbs and imprecise labelling of manufactured herbal products may contribute to the inadvertent use of toxic herbal species in Chinese medicine practice [10].

Labelling is part of packaging and packaging plays a significant role in marketing, particularly at the point of sale, is significant and can be regarded as a crucial factor that impacts consumer purchasing decisions [11].

Labelling does not only include a brand name but also other important labelling information [12]. Several indigenous medicinal

plants such as *Flueggea virosa* (white currant or grape), *Cassia siamea*, *Terminalia bellirica* (known as Bahera or Beleric or bastard myrobalan) and *Terminalia chebula* (king of medicine) are used for the treatment of certain diseases including gastrointestinal disease and malaria and or as remedy in infants and children [13].

In addition to their therapeutic properties, empirical investigations have demonstrated that certain medicinal plants, namely Ephedra species, Aconitum species, Datura species, and Lobelia species, exhibit pronounced toxicological effects, particularly when administered over an extended duration, with a heightened susceptibility observed in pediatric populations [14-16].

Toxicological studies conducted on animal models have yielded significant findings regarding the medicinal properties of certain herbs, namely daouri and juniper tar. These herbs are commonly employed in the treatment of chronic eczema and various skin ailments. However, the results of these studies indicate the potential presence of nephrotoxic and hepatotoxic effects associated with the use of these plants. Consequently, it is imperative to reassess the use of these herbal remedies, particularly in pediatric populations [17].

This study demonstrates a low adherence to "Not to be taken by children below 5 years" warning statement 2 (3.3%). Many of the herbal remedies assessed for compliance with the "Not to be taken by children below 5 years" warning or precaution statement include *Cassia alata* as active ingredients, even though ethnographic appraisals documented in literature describe that children under the age of two should avoid *Cassia alata*, also known as *S. alata* formulations [18]. Some of the herbal products also contain extracts of the neem tree (*Azadirachta indica A. Juss*), which have been demonstrated to cause toxic encephalopathy in infants and children [19]. The use of herbal products in pediatric populations is a subject of concern, as there exists a paucity of available information regarding their potential advantages and associated risks in this demographic [20,21].

In Nigeria, most herbal medicines have not been subjected to clinical trials. Consequently, there is a continued lack of evidence-based information regarding the safety and efficacy of herbal products in children [22].

Herbal medicines use in acutely ill children has been reported in Nigeria and a report by the World Health Organization (WHO) has shown that herbal medicines are the primary treatment for 60% of children with high fever resulting from malaria in Nigeria, Ghana, Mali, and Zambia [23]. However, the use of herbal medicines in children's health management should be used with caution.

This study demonstrates a low adherence to "Not to be taken by pregnant women" 20 (33.3%) warning or precaution statement. The warning or precaution statement "Not to be taken by pregnant women" is important for herbal medicines labelling. Herbs may contain compounds or substances that can cause premature birth, miscarriage, injury to the fetus or uterine contractions [24].

The current body of literature lacks substantial research on the safety of herbal medicines during pregnancy. Consequently, it is imperative to exercise caution when using herbal medicines during this period, as their indiscriminate administration may lead to adverse consequences for both the expectant mother (maternal) and the developing fetus. The potential consequences of the inappropriate use of herbal remedies or the concurrent administration of these remedies with prescribed pharmaceuticals remain largely unexplored, thereby posing a significant risk of adverse outcomes during pregnancy or leading to severe fetal complications [25].

Some of the products assessed contain *Zingiber officinale* (Ginger) and *Allium sativum* (garlic) Even though, these herbals among others such as damakasse, tenaadam, and eucalyptus are the most frequently consumed herbal medicines during pregnancy, the potential effects of these herbals on the fetus during pregnancy are still unknown. It is important to note that there are still numerous medicinal plant species that have not undergone extensive research, which means that we cannot disregard the possibility of teratogenic effects [26].

The presence of certain substances in medicinal plants and herbal remedies can pose a potential risk to the mother and the developing fetus. The potential consequences of the unregulated use of herbal medicines include embryotoxicity, teratogenicity, and abortifacient effects. Certain components of plants could traverse the placenta and access the developing fetus.

Phytochemicals and their metabolites have been observed to elicit uterine contractions and disrupt hormonal balance, potentially leading to abortion. Changes in the hormonal profile have the potential to impact fertility, trigger harmful effects on fetal development, and potentially result in pregnancy loss or the development of birth defects [27].

Pregnant women often do not discuss the use of herbal medicines with healthcare professionals. Available research data showed that almost 95% of pregnant women in Ethiopia did not consult the usage of herbal medicines with healthcare professionals, notably the doctor or nurse.

In Norway, some pregnant women (less than 12%) followed the advice of a healthcare professional to use herbal medicines [28]. This reflects a lack of awareness among expectant mothers regarding the presence of active compounds in herbal medicines that can potentially lead to miscarriage, premature labour, uterine contractions, or harm to the developing fetus. Also, healthcare professionals may lack comprehensive understanding regarding the safety of herbal remedies in pregnancy. According to the United States Food and Drug Administration (FDA), ginger is safe for consumption; it is "generally regarded as safe". However, it is important to note that in Finland, the Finnish Food Safety Authority advises against the consumption of ginger products, such as ginger tea or food supplements, during pregnancy. This recommendation is based on the absence of established safe consumption limits for ginger during pregnancy [28].

Due to limited knowledge regarding the effect of herbal medicine consumption during pregnancy, it is advisable to include a precautionary statement on the labels of herbal remedies sold in Lagos, explicitly stating that they should not be taken by pregnant women. The lack of such warnings on herbal medicines labelling poses risk to both maternal and fetal health.

This study demonstrates a significant adherence to ingredient lists 47 (78.3%). In essence, the inclusion of an ingredient list on herbal medicine products serves to provide consumers with knowledge regarding the specific ingredients contained within the products. This information aids in guiding their selection of herbal medicines that are appropriate for addressing their ailment or health condition. The Guidelines for the Assessment of Herbal Medicines have also been issued by the World Health Organization [29]. The purpose of these guidelines is to provide a set of standards for evaluating the quality, safety, and effectiveness of herbal medicines. They aim to assist national regulatory authorities, scientific organizations, and manufacturers in the assessment of documentation, submissions, and dossiers related to these products [30].

The guidelines emphasized the importance of evaluating effectiveness, which involves examining the pharmacological and clinical impacts of the active components. Additionally, the guidelines require labelling that provides a specific list of the active ingredient(s), dosage information, and any contraindications [31].

According to the NAFDAC Herbal Medicines and Related Products 2021, date markings (production and expiration dates) are mandatory. They give an indication of the minimum durability of the herbal remedy.

They are important as safeguards against herbal remedies that might be unfit for consumption. Herbal medicines are mandated to have an expiration date. It is also a WHO requirement as stated in the WHO Guidelines on Good Manufacturing Practices (GMP) for herbal Medicines [32].

The inclusion of date markings allows consumers to make informed choices and maximize the effective use of herbal remedies, thereby minimizing the likelihood of experiencing adverse medicine reactions. In this current study, expiration dates were present in most of the products examined. This was followed by production dates. In all the herbal products assessed in this study, over 75% of the products provided date markings. Despite the seemingly positive prevalence rate, it is crucial to recognize that the current level of compliance is significantly insufficient given the critical importance of this information for the health and well-being of consumers. Although the expiration of drugs including herbal medicines does not necessarily indicate that the herbal medicines will cause significant harm, it does signify that it may experience a decrease in stability and potency. The decline in potency can pose a significant health risk, particularly when using the remedy to combat an infection [33].

Out of the total of 60 products that were assessed, it was found that only 38 of them, which accounts for approximately 63.3%, have a NAFDAC Registration number on their labels. This indicates that approximately 36.7% of the herbal remedies available for purchase are unapproved by NAFDAC. This implies that these products have not undergone any regulatory procedures, such as laboratory testing, to assess their safety, quality, and effectiveness.

The 38 herbal products were subjected to additional scrutiny using the NAFDAC Registered Products Automated Database (NARPAD). The data showed that only 29, accounting for approximately 76% of the 38 herbal products, had been duly registered. These findings indicate that a significant proportion, exceeding 20% of the products in question have had their NAFDAC registration numbers falsified.

Cases of forgery of NAFDAC Registration Numbers have been widely reported in Nigerian news media [34]. However, there is a lack of comprehensive documentation regarding the prosecution of those responsible for these fraudulent acts in the Nigerian court. The NAFDAC Reg. No. is the certification mark by NAFDAC and unlike in the UK where its inclusion on product label is optional, it is mandatory to include NAFDAC Reg. No. on herbal remedies labels before they are sold in Lagos State, and all states of Nigeria [35].

NAFDAC Reg. No. on product labels informed consumers that the products' safety has been evaluated by NAFDAC.

The 60 herbal products were accessed for some voluntary or conditional information on product labels, such as "shake before use", "If symptoms persist, consult your doctor", "Do not exceed the dosage" and "Do not accept if seal is broken". There was no compliance with "Do not exceed the dosage" and "Do not accept if seal is broken," and there was low compliance with "Shake before use" (33.3%) and "If symptoms persist, consult your doctor (8.5%).

This result may be attributed to the non-mandatory nature of including this information on the product label of herbal medicines.

Conclusion and Recommendation

The overall compliance rate of the assessed herbal remedies with the NAFDAC Herbal Medicines and Related Products Regulations, 2021, was generally low. Only 4 (6.7%) of the 60 products (n= 60) analyzed were fully in compliance with the NAFDAC Herbal Medicines and Related Products Labelling Regulations, 2021. 56 (93.4%) of the products assessed were not in compliance with the NAFDAC Herbal Medicines and Related Products Labelling Regulations, 2021.

Compliance with critically required labelling information such as warning and precaution statements and label legibility was not adhered to, even though requirements such as the list of ingredients, name and address of the manufacturer, production date, expiration date, and dosage were most adhered to.

We recommend that the National Agency for Food and Drug Administration and Control (NAFDAC) undertake proactive efforts to create awareness regarding the potential health risks resulting from the use of herbal remedies that fail to comply with the provisions of the NAFDAC Herbal Medicines and Related Products Regulation, 2021.

It is recommended that the National Agency for Food and Drug Administration and Control step up its monitoring of herbal products on the Lagos market to ensure consumer safety and health. The Investigation and Enforcement Directorate (I and E) as well as the Pharmacovigilance and Surveillance Directorate should be strengthened for effective operation, as this would help to eradicate or significantly reduce the sales of counterfeit herbal remedies in Lagos State. It is further recommended that the Agency carry out a well-coordinated awareness campaign to align the herbal remedies manufacturers with the NAFDAC Herbal Medicines and Related Products Regulation, 2021. NAFDAC should build capacity for their regulatory officers on effective herbal medicines to enable them to have the relevant knowledge on how to enforce this regulation.

There is a need for NAFDAC to harmonize the Herbal Medicines and Related Products Regulations. That is, the Herbal Medicines and Related Products Labelling Regulations, 2021, the NAFDAC Herbal Medicines and Related Products Registration Regulations, 2021, and the NAFDAC Herbal Medicines and Related Products Advertisement Regulations, 2021, should be harmonized. The Health Canada's Natural Products Regulations approach may be adopted, as this will minimize confusion among herbal remedy manufacturers as to which regulations apply to herbal remedies in Nigeria.

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Conflict of Interest Statement

We did not have any conflict of interest with respect to this study and we did not have any financial relationships to the work that could have appeared to affect this study.

Consent for Publication

All the authors of this study read and approved the final manuscript.

Author Contributions

Olatunde Olalekan Isaac: Conceptualization or design of the work, methodology, data curation, interpretation of data for the work and drafting of the manuscript.

- **Oluwatosin R. Kumolalo**: Formal analysis and writing (review and editing).
- **LeRoy C. Edozien**: Final approval of the version to be published including review and editing.

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