Traditional Medicine Policy and Regulation in Nigeria: An Index of Herbal Medicine Safety

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Abstract: *Background*: The requirements and methods for research and evaluation of the safety and efficacy of herbal medicines are more complex than those for conventional pharmaceuticals. In addition to the aforementioned and contrary to the general belief that herbal medicines are safe and despite the profound therapeutic advantages possessed by medicinal plants, some of their constituents have been shown to be potentially toxic, carcinogenic, mutagenic, and teratogenic. Thus, traditional medicine policy and regulation have been made an integral part of the WHO proposed critical determinants of herbal medicine safety.

Objective: Therefore, this study is designed to assess the policy and regulation guiding herbal medicine in Nigeria as this information may form a safety index of herbal medicine use in Nigeria.

Methodology: Structured questionnaire adopted from WHO was used to obtain the opinions of relevant stakeholders in the field of herbal medicine on the policy and regulation of herbal medicine in Nigeria.

Results: The results show that 68.8% of respondents agreed that there is a national policy on TM with 31.2% disagreeing on this issue. 75% of respondents agreed that implementation of the manufacturing requirements of herbal medicines is ensured by control mechanisms while 25% disagreed. Only 25% said herbal medicines are sold by licensed practitioners, with 75% believing that herbal medicines are sold by non-licensed practitioners. 87.5% said support from the WHO is needed and should be in the form of workshops on national capacity building on safety monitoring of herbal medicines.

Conclusion: There is need for the Federal Ministry of Health to harmonize the varying opinions on traditional medicine and policy as documented in this study through collaboration and workshops on traditional medicine. These proposed approaches may guarantee the safety and regulation of herbal medicine use in Nigeria.

Keywords: Herbal medicine, regulation, safety, traditional medicine.

INTRODUCTION

An important component of the World Health Organization's (WHO) Traditional Medicine Strategy is to promote the integration of traditional medicine (TM) and complementary and alternative medicine (CAM) into health care systems of countries [1]. 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 World Health Organization [1] on National policy on Traditional Medicine (TM) and regulation of herbal medicines has shown that countries face major challenges in the development and implementation of the regulation of traditional, complementary/alternative and herbal medicines. These Challenges are related to regulatory status, safety assessment and efficacy, quality control, safety monitoring and lack of knowledge about TM/CAM within national drug regulatory authorities. Furthermore, the requirements and methods for research and evaluation of the safety and efficacy of herbal medicines are more complex than those for conventional medicines. The WHO has further proposed the organization and training of practitioners of traditional medicine for primary health care services to enable the utilization of traditional systems of medicine in individual countries, with appropriate regulations based on their national health systems [2].

Despite these challenges, countries of the European Union (EU), United Kingdom, China, India, Japan, Malaysia, Korea and Australia have made giant strides in putting in place national policies and regulations on traditional, complementary/alternative and herbal medicines. The policies and regulations may not be the same in all countries but all basically address the need to have a working framework for ensuring the safe use of herbal medicines.

Several issues have led to a greater awareness of the need to monitor herbal medicine safety and a better understanding of their possible harms and potential benefits [3]. These issues include an increasing use of herbal medicines in developed countries, lack of or weak regulation of these preparations in most countries and the occurrence of high profile safety concerns associated with the use of herbal medicines [3].

There have been different forms of regulations of herbal medicine all over the world; herbal remedies for human use have been regarded as medicines under United Kingdom

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legislation, in principle subject to the same extensive licensing procedures as pharmaceuticals. In recognition of a long history of safe use they have historically been exempted from licensing. A review of herbal regulation at European Union (EU) level was prompted by safety concerns and the market harmonization impact of varying national herbal regulatory regimes [4]. The EU law is aimed at protecting users from possible deleterious side-effects of over-the-counter herbal medicines. To date, the industry has been covered by the 1968 Medicines Act, drawn up when only a handful of herbal remedies were available and the number of herbal practitioners was very small. However, only products that have been assessed by the Medicine and Healthcare products Regulatory Agency (MHRA) are allowed to go on sale [5].

According to the World Health Organization [1], the national policy on TM/CAM was issued in China as far back as 1949 and regulations were issued in 1963, the same year national regulations on herbal medicine were issued as well as the publication of the Chinese pharmacopoeia. It is important to note that herbal medicines are subjected to the same stringent regulations as conventional pharmaceuticals. The same author further stated that herbal medicines are regulated as prescription and over the counter medicines, self-medication, dietary supplements, health foods and functional foods (foods containing additives which provide extra nutritional value) and as a separate regulatory category. In China, herbal medicines are sold in pharmacies as prescription and over the counter medicines, in special outlets and by licensed practitioners.

In Japan, according to the WHO [1], no information is available on the existence of a national policy on TM/CAM; however, national laws and regulations on TM/CAM were issued in 1950 in the Pharmaceutical Affairs Law and revised in 1960; these regulations are the same as those for conventional pharmaceuticals. In China however, herbal medicines are also regulated as prescription and over the counter medicines, dietary supplements. The post marketing surveillance system has included adverse effect monitoring since 1993.

Malaysia has a national policy and a national programme on TM/CAM which were both launched in the year 2001 [1]. The registration and licensing of TM/CAM are legislated through the Control of Drugs and Cosmetics Regulations 1984. Traditional medicines are allowed to be sold as over the counter medicines. Information from the report of the WHO highlights safety requirements for herbal medicines to include evidence of traditional use without demonstrating harmful effects, compliance with the limits set for heavy metals (mercury, arsenic, lead), testing for microbial and fungal contamination, other physicochemical tests as well as screening for adulterants.

The report of the World Health Organization in 2005 states that the national policy on TM/CAM in India was introduced in 1940, with national laws and regulations also issued in the same year and updated in 1964, 1970 and 1982 [1]. However, unlike the situation in China, laws and regulations on herbal medicines are partly the same as those for conventional pharmaceuticals. In addition, herbal medicines are regulated as prescription and over the counter medicines and dietary supplements. Herbal medicines may be sold with medical, health and nutrient content claims. Like China, herbal medicines in India are sold in pharmacies as prescription and over the counter medicines, in special outlets and by licensed practitioners.

Australia has a risk-based approach with a two-tiered system for the regulation of all medicines, including complementary medicines; Lower risk medicines can be listed on the Australian Register of Therapeutic Goods (ARTG) and Higher risk medicines must be registered on the ARTG. The Australian Regulatory Guidelines for Complementary Medicines (ARGCM) provide details on the regulation of complementary medicines and assist sponsors to meet their legislative obligations [6]. On the other hand, in the U.S, the Dietary Supplement Health and Education Act (DSHEA) of 1994 classify herbs as dietary supplements [7]. This law defines supplements quite broadly as "anything that supplements the diet." Supplements therefore include vitamins, minerals, herbs, amino acids, enzymes, tissues, metabolites, extracts, or concentrates. However, this regulatory structure has led to problems with the consistency and safety of herbal products [7]. The regulation of herbal medicine in Ghana is guided by the Food and Drugs Law and thus, the manufacture, import, export, distribution, use and advertisement of food, drugs, cosmetics, chemical substances and medical devices are controlled. Thus, no person may manufacture, prepare, supply, sell, distribute, export or import any herbal medicine or homoeopathic drug, unless it has been registered with the Food and Drugs Board. The Board's aim is to ensure that herbal medicines are safe, of good quality and efficacious. Regulations often recommend the information to be provided for the registration of herbal medicines and homoeopathic drugs [8].

The National Agency for Food, Drugs, Administration and Control (NAFDAC) is listing most ethnomedicinal preparations on the market in Nigeria [9] but not issuing a full status of registration to these products because of questionable/unproven safety, efficacy and quality. Full registration status on herbal medicinal products is issued only on evidence of satisfactory report of clinical trials to ascertain safety and efficacy. Herbal supplements could be beneficial to consumers but they could also cause serious side effects and potentially dangerous conditions. There have been reports of adverse reactions and herb-drug interactions with the use of herbal medicine in Nigeria. As aforementioned, NAFDAC only lists products based on safety studies and towards improving herbal medicine use in Nigeria, NAFDAC has recently formed Scientific/Expert Committee on Verification of Herbal medicine claims especially on safety, efficacy and quality.

In light of all these points, it may be reasonable to infer that the policies and regulations guiding the use of herbal medicines are important yard sticks to speculate the safety of herbal medicine. Therefore, this present study is driven towards assessing the policy and regulation guiding herbal medicines in Nigeria as this information may form a safety index of herbal medicines in Nigeria.

METHODOLOGY

Structured questionnaire adopted from WHO was used to obtain the opinions of top relevant stakeholders/decision

makers in the field of herbal medicine on the policy and regulation of herbal medicine in Nigeria. The sample size determination in cross sectional study should be determined using specific formula such as

$N = Z^2Pq/d^2$

where:

N = minimum sample size,

Z = confidence level at 95%,

P = proportion of traditional medicines policy makers in Nigeria which may be 65%,

q = (1-P), and d = level of precision.

Z = 95% = 1.96, P = 65% = 0.65, q = (1-P) = 0.35, d = 5% = 0.05

However, this present study is a specialized key informant opinion study and thus a total of sixteen (16) specific persons targeted questionnaires were distributed to selected professionals /key stakeholders and directors in Federal Ministry of Health (Herbal Medicine Division), The National Agency for Food, Drugs, Administration and Control (Herbal Medicine and Pharmacovigilance Division), The National Association of Nigeria Traditional Medicine Practitioners (NANTMP) and the Nigerian Institute of Pharmaceutical Research and Development (NIPRD). The questionnaire contains different sub-sections as; National policy on Traditional Medicine, Law and Regulation on Herbal Medicine, Safety of Herbal Medicine, National Programme and National Research Institute on Traditional Medicine, Registration and Manufacture of Herbal medicine. The data obtained were analyzed using simple percentages to collate the opinions of the stakeholders on the different questions in the questionnaire.

RESULTS

Table **1** shows that 68.8% of respondents answered in the affirmative about the issue of a national policy on TM while 31.2% disagreed about the availability of such a policy. 31.2% of respondents agreed about the existence of national law or regulation on TM while 68.8% disagreed. Of the respondents that said there is no national law or regulation on TM, 45.5% said that it is in the process of being established while 54.5% were of the belief that there are no attempts to enact such a law.

On whether a national programme on TM is in place in Nigeria, 37.5% agreed on this issue, with 62.5% of respondents disagreeing.

75% of respondents opined in the affirmative about a TM national office while 25% disagreed in this regard. On whether there is an expert committee on TM, 37.5% agreed about its existence while 62.5% were of the opinion that an expert committee is not in place in Nigeria. 50% of respondents confirmed the existence of a national research institute on TM while 50% disagreed.

On regulation of herbal medicine, 62.5% of respondents said there is a national law on herbal medicines while 18.8% disagreed. 6.3% believe it is the same law as for conventional pharmaceuticals, 93.7% did not accept this position. 31.3% believed it is a separate law, with 68.7% differing in this regard. While 12.5% affirmed that it is partly the same law as for conventional pharmaceuticals, 87.5% held the opposite view rejecting the position of the others (Table **2a**).

12.5% of respondents agreed that herbal medicines are prescription medicines, and 87.5% held a contrary view. While 25% said herbal medicines are Over the Counter (OTC) medicines, 75% believed they were not OTCs. 6.3% agreed that herbal medicines should be used for self-medication only and a greater percentage of respondents (93.7%) disagreed. Of the respondents, 43.8% of them said herbal medicines should be in a separate regulatory category but 56.2% were of the opposite opinion. 62.5% said they should be considered as dietary supplements and 37.5% disagreed; 18.8% agreed herbal medicines should be given the status of a health food but 81.2% disagreed with this position. Only 12.5% of respondents believed they should be given the status of functional food (a food containing additives which provide extra nutritional value), with 87.5% disagreeing.

75% of respondents believed that herbal medicines are sold with claims and 12.5% did not support this position. 31.3% said herbal medicines are sold with medical claims, though 68.7% of respondents disagreed. 56.3% of respondents believe that they are sold with health claims but 43.7% did not agree to this position. 37.5% said herbal medicines are sold with nutrient content claims, a position that was opposed by 62.5% of respondents. 18.8% of respondents were of the opinion that no claims can be made according to the law and 81.2% had the contrary opinion (Table **2a**).

Table 1. Policy and Regulation of Traditional Medicine

S. No.		Yes (n %)	No (n %)	Process of Being Established (if Answer is No) n (%)		
				Yes	No	Not Sure
1	Is there a national policy on TM?	11 (68.8)	5 (31.2)	5 (100)		
2	Is there a national law or regulation on TM?	5 (31.2)	11 (68.8)	5 (45.5)		6 (54.5)
3	Is there a national programme on TM?	6 (37.5)	10 (62.5)	3 (30)	3 (30)	4 (40)
4	Is there a TM national office?	12 (75)	4 (25)	1 (25)	2 (50)	1 (25)
5	Is there an expert committee on TM?	6 (37.5)	10 (62.5)	3 (30)	2 (20)	5 (50)
6	Is there a national research institute on TM?	8(50)	8 (50)	2 (25)	5 (62.5)	1 (12.5)

n=16.

Table 2a. Regulation of Herbal Medicine

S. No.		Yes (n %)	No (n %)
1	**Is there a national law or regulation on herbal medicines?**	**10 (62.5)**	**3 (18.8)**
A	Same law as for conventional pharmaceuticals	1 (6.3)	12 (92.3)
B	Separate law for herbal medicines	5 (31.3)	8 (61.5)
C	Partly the same law as for conventional pharmaceuticals	2 (12.5)	11 (61.5)
2	**Which regulatory status is given to herbal medicines?**		
A	Prescription Medicines	2 (12.5)	14 (87.5)
B	Over-the-counter Medicines (O.T.C.)	4 (25)	12 (75)
C	Self-medication only	1 (6.3)	15 (93.7)
D	Herbal Medicines as a separate regulatory category	7 (43.8)	9 (56.2)
E	Dietary Supplements	10 (62.5)	6 (37.5)
F	Health Food	3 (18.8)	13 (81.2)
G	Functional Food	2 (12.5)	14 (87.5)
3	**Are herbal medicines sold with claims?**	**12 (75)**	**4 (25)**
A	Medical claims	5 (31.3)	11 (68.7)
B	Health claims	9 (56.3)	7 (43.7)
C	Nutrient content claims	6 (37.5)	10 (62.5)
D	Structure claims	3 (18.8)	13 (81.2)
E	No claims can be made according to the law	3 (18.8)	13 (81.2)

n=16.

Table 2b. Regulation of Herbal Medicine

S. No.		Yes (n %)	No (n %)
1	**Is there a national pharmacopoeia including herbal medicines?**	**8 (50)**	**8 (50)**
2	**Are there national monographs on herbal medicines?**	**3 (18.8)**	**13 (81.2)**
3	**What regulatory requirements apply to the manufacturing of herbal medicines?**		
A	Adherence to information in pharmacopoeia/monographs	2 (12.5)	14 (87.5)
B	Same rules of Good Manufacturing Practice(GMP) as for conventional pharmaceuticals	5 (31.3)	11 (68.7)
C	Special GMP rules	4 (25)	12 (75)
D	No requirements	2 (12.5)	14 (87.5)
E	Others: *Safety and efficacy of the herbal medicines*	2 (12.5)	14 (87.5)
4	**Is implementation of the manufacturing requirements of herbal medicines ensured by any control mechanisms?**	**12 (75)**	**4 (25)**
5	**What are the main difficulties faced by your country as regards regulatory issues on herbal medicines**		
A	Lack of research data	10 (62.5)	6 (37.5)
B	Lack of expertise within the health authorities and control agency	5 (31.3)	11 (68.7)
C	Lack of appropriate mechanisms for control of herbal medicine	11 (68.7)	5 (31.3)
D	Lack of education and training	8 (50)	8 (50)
E	Others: *Lack of Legislation* *Lack of political will*	2 (12.5) 1 (6.3)	14 (87.5) 15 (93.7)

n=16.

Table **2b** shows more results for regulation of herbal medicines where 50% of respondents affirmed that a national pharmacopoeia including herbal medicines was available, with the same number (50%) disagreeing on the issue. In answer to whether there are national monographs on herbal medicines, only 18.8% affirmed to the positive while 81.2% replied in the negative. 12.5% supported the position that adherence to information in pharmacopoeia/monographs is part of requirements that apply to the manufacturing of herbal medicines with 87.5% not agreeing; 31.3% said the

same rules of Good Manufacturing Practice (GMP) apply for herbal medicines as for conventional pharmaceuticals while 68.7% disagreed. Of the total respondents, 25% agreed that herbal medicines should have special GMP rules and 75% differed on this issue. 12.5% said there are no special requirements with 87.5% holding the view that it should not be so. Only 12.5% of respondents said that safety and efficacy of the herbal medicines should constitute requirements that apply to the manufacturing of herbal medicines and 87.5% opposed this view. However, 75% of respondents agreed that implementation of the manufacturing requirements of herbal medicines is ensured by control mechanisms with 25% disagreeing.

62.5% of respondents agree that the main difficulties faced by Nigeria with regards to regulatory issues on herbal medicine has to do with lack of research data and 37.5% differed; 31.3 % believe it is lack of expertise within the health authorities and control agency and 68.7% did not believe so; 68.7% said it is lack of appropriate mechanisms for control of herbal medicine, 31.3% differed on that issue. For 50 % of the respondents, it has to do with lack of education and training and 50% did not support this. 12.5% said the main difficulty is lack of legislation, with 87.5% differing. 6.3% believe it is lack of political will by the Government with 93.7% believing that is not the case.

Table **3** showed 43.8% of respondents agreed that herbal medicines should have the same regulatory requirements for the safety assessment as for conventional pharmaceuticals but 56.2% did not agree with this position. 62.5% of respondents said the herbal medicines should be considered safe if they are used without demonstrated harmful effects, a position opposed by 37.5% of the respondents. While 50% of respondents said reference should be made to documented scientific research on similar products in considering the regulatory requirements for the safety assessment of herbal medicines, another 50% did not consider it important.

75% of the respondents believed that implementation of the safety requirements for herbal medicines is ensured by control mechanisms and 25% differed from this view. When asked to consider the issue of a registration system for herbal medicines, 87.5% responded to the positive while only 12.5% disagreed and when asked whether herbal medicines are included in the national essential medicine list, 6.3% believed that was the case and 93.7% did not agree with the question. 25% of respondents believed that there is a post-marketing surveillance system for herbal medicines but 75% disagreed that a post-marketing surveillance system is in place (Table **3**).

All respondents (100%) were of the opinion that herbal medicines are not and should not be sold in pharmacies as prescription drugs. While 37.5% of respondents said herbal medicines are sold in pharmacies as over-the-counter drugs, 62.5% differed from this position. 31.3% said herbal medicines are sold in special outlets, 68.7% disagreed. Only 25% said herbal medicines are sold by licensed practitioners, with 75% believing that herbal medicines are sold by non-licensed practitioners as well. 68.7% indicated that there are no restrictions for selling herbal products in Nigeria but 31.3% of the respondents differed on this issue (Table **3**).

Table **4** showed that 75% of respondents want information sharing on regulatory issues as a kind of support on herbal products related topics in Nigeria from WHO; 56.3% agreed that workshops on national capacity to establish regulations on herbal medicine will be important; 62.5% said the WHO should provide general guidelines for research and evaluation of traditional medicine while 87.5% said the support should be in the form of workshops on national capacity building on safety monitoring of herbal medicines. 75% said this support can include provision of databases and 43.8% of respondents want the WHO to arrange global meetings while 6.3% want the WHO to train individuals to be experts in development, evaluation and

Table 3. Safety of Herbal Medicines

S. No.		Yes	No
1	**What are the regulatory requirements for the safety assessment of herbal medicines?**		
A.	Same requirements as for conventional pharmaceuticals	7 (43.8)	9 (56.2)
B	Traditional use without demonstrated harmful effects	10 (62.5)	6 (37.5)
C	Reference to documented scientific research on similar products	8 (50)	8 (50)
2	**Is implementation of the safety requirements for herbal medicines ensured by any control mechanism?**	**12 (75)**	**4 (25)**
3	**Is there a registration system for herbal medicines?**	**14 (87.5)**	**2 (12.5)**
4	**Are herbal medicines included in the national essential medicine list?**	**1 (6.3)**	**15 (93.7)**
5	**Is there a post-marketing surveillance system for herbal medicines?**	**4 (25)**	**12 (75)**
6.	**How are herbal medicines sold?**		
A	In pharmacies as prescription drugs	0 (0)	16 (100)
B	In pharmacies as over-the-counter drugs	6 (37.5)	10 (62.5)
C	In special outlets	5 (31.3)	11 (68.7)
D	By licensed practitioners	4 (25)	12 (75)
E	No restrictions for selling herbal products	11 (68.7)	5 (31.3)

n=16.

Table 4. World Health Organization Support on Herbal Products

S. No.	What Kind of Support on Herbal Products Related Topics is your Country Interested to Receive from WHO?	n	%
1.	Information sharing on regulatory issues	12	75
2.	Workshops on national capacity to establish regulations on herbal medicine	9	56.3
3.	General guidelines for research and evaluation of traditional medicine	10	62.5
4.	Workshops on national capacity building on safety monitoring of herbal medicines	14	87.5
5.	Provision of databases	12	75
6.	Arrangement of global meetings	7	43.8
7.	Others: *Training individuals to be experts in development, evaluation and establishment of safe herbal medicine outlets*	1	6.3

n=16.

establishment of safe herbal medicine outlets in Nigeria (Table **4**)

DISCUSSION

Herbal medicine which is a subset of traditional medicine is plant derived materials or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. In some traditions and cultures, material of inorganic or animal origin may also be present [1]. Herbal medicines have been in use for a long time in Nigeria and all over the world with general belief that it's safe perhaps due to their natural origin. However, despite the general belief that herbal medicines are safe and regardless of the profound therapeutic advantages possessed by some of the medicinal plants, some of their constituents have been shown to be potentially toxic, mutagenic, carcinogenic and teratogenic [10, 11]. The safety and efficacy of herbal medicine, as well as quality control, have become important concerns for both health authorities and the public [12]. It can therefore be deduced that the nature of policy and strategies of regulatory procedures of herbal medicines will determine the safety, efficacy and quality of herbal medicines. The policies and regulations on herbal medicine ought to basically determine the status of herbal medicines, requirement for registration of herbal medicines, number of registered herbal medicine products and quality control requirements of herbal medicine [12].

The importance of policy and regulation of traditional medicine cannot be overemphasized as this forms the frame work on which traditional medicine can be properly regulated to ensure that they meet set down requirements for quality. Results from this study show that on the issue of policy and regulation of traditional medicine, majority of respondents (about 68.8%) surveyed affirmed that a national policy on TM is in place in Nigeria. However, the vital nature of policy and regulation of traditional medicine in any society can be seen from stringent regulations put in place in such environment as practiced by the European Union (EU), the United States of America, China, Japan, Malaysia, Ghana and Australia [1, 7, 8] among many.

The positive benefits of traditional or herbal medicine cannot be brought to bear on the health situations of the people in Nigeria without adequate national laws, even with the most experienced experts and well-intended policy statements. This is particularly important given the fact that herbal medicines, which have the potential to affect human bodily functions, can impact positively or negatively on the health of people. In Nigeria, NAFDAC currently only lists ethno medicinal preparations on the market [9] without issuing a full status of registration to most of these products. This is a far cry when the case of China, Japan, Korea, Ghana and other countries in Europe are considered, which have stringent laws that ensure that herbal medicines consumed in those countries are safe, of good quality and efficacious. Efforts must therefore be geared towards ensuring that laws are in place in Nigeria that will guide the practice of TM and use of herbal medicines, a position supported by most (62.5%) of respondents who believe a national law on herbal medicines is already in place in Nigeria, with only 31.3% agreeing that the law should be separate for herbal medicines. It is interesting to note that there is a Bill currently at the National Assembly for the establishment of the Traditional Medicine Council of Nigeria (TMCN).

Considering regulatory issues on herbal medicines further, Nigeria is faced with some challenges; chief amongst them is the issue of lack of appropriate mechanisms for control of herbal medicine where 68.7% of the respondents feel strongly on this issue. 62.5% feel lack of research data is a major hindrance while 31.3% see lack of expertise within the health authorities and control agency as an issue.

The issue of safety assessment of herbal medicines is a crucial one that has been recognized by the World Health Organization's report in 2005, which stated that some of the challenges faced by many nations include assessment of safety and efficacy. Our findings show that 43.8% of respondents believe that herbal medicines in Nigeria have the same regulatory requirements with regard to safety as conventional pharmaceuticals. 75% are of the opinion that implementation of the safety requirements for herbal medicines is ensured by control mechanisms, and as much as 87.5% stated that there a registration system for herbal medicines. All these are big steps towards ensuring that herbal medicines use in Nigeria are of good quality, safe and efficacious and are in line with what is obtainable in Europe, Australia and in Ghana. In recognition of the importance of expert committees to offer expert advice on herbal medicine, NAFDAC recently formed a Scientific Committee on Verification of Herbal medicine claims especially on safety,

efficacy and quality, though only 37.5% of respondents were aware of the existence of such a committee.

With the proliferation of herbal medicines in the Nigerian market, it is important to properly categorize herbal medicines into therapeutic classes to ensure people get access to the right herbal medicine for the right condition. There is some ambiguity as to the proper classification of herbal medicines among respondents, though in the U.S, the Dietary Supplement Health and Education Act (DSHEA) of 1994 classifies herbs as dietary supplements [7]. As seen from the findings of this study, 25% of respondents affirmed that herbal medicines can be considered as Over-the-Counter medicines, 12.5% believe they are prescription medicines, 62.5% feel they are dietary supplements and 43.8% of respondents were of the opinion that herbal medicines should be placed in a separate regulatory category.

In view of all the above, there is need to ensure that herbal medicines used in Nigeria are of good quality, safe and efficacious. Thus it is imperative for regulatory authorities to adopt and incorporate the concept of pharmacovigilance in the national laws and regulations of herbal medicines. This is particularly pertinent considering the fact that no medicine, herbal or orthodox, is completely devoid of adverse effects.

CONCLUSION

Nigeria is on the fast track to ensuring the safety and efficacy of herbal medicine use and a clear indication in this regard is NAFDAC's recent constitution of a Scientific Committee on Verification of Herbal medicine claims especially on safety, efficacy and quality. The Federal Ministry of Health is also expected to meet the present challenge by stepping up collaboration with stakeholders and organizing workshops to train and raise awareness on the issue of safety and efficacy of herbal medicines. Nigeria may not be able to completely meet and surmount this challenge all on its own and would need the assistance of global partners, especially the World Health Organization. The established programs of the WHO which include information sharing on regulatory issues as obtains in other countries, as well as local and international workshops on building national capacity to establish regulations and safety monitoring on herbal medicine should be strengthened in Nigeria. Having the 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 safe use of herbal medicines in Nigeria.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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PATIENT CONSENT

Declared none.

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