

Original Research Article

HERBAL MEDICINE PRODUCTS SOLD IN NIGERIA: A PILOT SURVEY

Abstract

Background: The use of herbal medicine is believed to be on the increase. There is a gradual shift from the use of crude drugs to well packaged, developed and registered herbal medicinal product. Evidence of this trend in Nigeria is seen in the increasing number of herbal medicine products on store shelves.

Objectives: The aim of the survey was to examine and document herbal medicine products sold in retail stores, pharmacies, generally closed and open markets in the Federal Capital Territory, Abuja

Methodology: A cross-sectional study using open ended semi-structured questionnaire and data collection tool was employed; descriptive and inferential statistics was done.

Results and Discussion: Open markets primarily stocked crude drugs (95.7%). In the open markets, only 26.1% of stalls had herbal medicine products. Over 70% of herbal medicines consumed in the FCT are administered orally. Sixty-eight percent of herbal medicine products are made in Nigeria with indications centred around bitters and detoxification (26.4%), fertility and aphrodisiac (16.7%), diabetes and cardiovascular disease (10%). Only 39.3% of products had a form of NAFDAC registration/listing. In the open markets a huge gap exists in the knowledge of branding, packaging and registration of herbal medicines.

Conclusion: There is a need to educate TMPs on the essence of drug development and packaging to improve acceptability, national relevance and international recognition. Herbal medicine producers must be further enlightened on the registration requirements and encouraged to register their products.

Keywords: Herbal medicines, Registration, Regulation, Herbal products, TMPs

Introduction

Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products. They are not classified as drugs in some climes because the rules that apply to registering them are not as stringent as with conventional drugs [1]. Some still believe that herbal medicines are primarily for promoting wellbeing and not for curative purposes. Data showing, they have been in folkloric use and considered safe over time, often eaten as food along with preliminary pharmacological data to justify traditional use are in some countries sufficient for registration as a supplement by regulatory bodies. In many countries, the regulatory status most often given to herbal medicines is as over-the-counter medicines, prescription medicines or as dietary supplements and health food [2]. There are also concerns about herbal medicine use which chiefly include adulteration of herbal medicine products (HMPs) with undeclared constituents such as corticosteroids, non-steroidal anti-inflammatory agents and other active pharmaceutical ingredients, possibility of inherent renal and hepatotoxicity along with other side effects which may be adverse in nature [3].

Herbal medicinal products contain active substances exclusively herbal drugs or herbal drug preparations. They may be made from one or more herbs and may contain excipients from natural origin in addition to the active herbal drug. Generally, however, finished products or mixed products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal [4, 5].

The use of herbal medicines in various forms such as crude drug, preparations, unfinished/finished products has been said to increase considerably throughout the world with a considerable number of people using herbal medicine products (HMPs) to manage many health problems [6]. Reasons for the increase has been attributed to cost, availability, the belief that herbal medicines serve both prophylactic and curative functions for many diseases such as hypertension, diabetes, cancer, sickle cell anaemia, respiratory tract infections such as with the current COVID -19 pandemic. The use of herbal medicines in the world, vary and is dependent on location, economy of such country, nearness to/availability of quality health care services, historical, psychosocial and cultural beliefs [7].

Abuja, is the Federal Capital Territory of Nigeria, housing the headquarters of many international corporations, ministries and regulatory agencies. In Nigeria, herbal medicine products are most often found in formal markets comprised of pharmacies, Islamic herbal pharmacies and retail stores and Informal markets also called open markets. Herbal medicine products (HMPs) are also often hawked, peddled in carts often called “wheel barrows” on the streets especially in the suburban part of the state. The formal or “closed markets” as termed in this study are often controlled by an existing legal frame work while the informal/open markets carry out their practices based on traditional and cultural practices passed on from generations [8]. The informal market serves quite a number of people in the state especially the suburban parts of the country. The National Agency for food and Drug Administration (NAFDAC) regulates registration of manufacturers, registration of products, labelling and advertisement of products in Nigeria.

It is hypothesised that the proliferation of herbal medicine products (HMPs) and patronage to herb sellers in the country is on the increase especially due to the COVID-19 pandemic. As the proliferation of herbal medicinal product (HMPs) increases so too do the occurrence of products that do not meet up to regulatory requirements and statutes [9, 10]. Knowledge of the products currently stocked in the market and the requisite indications of such product along with documentation of how well the products meet regulatory expectations may help regulatory agencies determine what disease areas need immediate surveillance. Such may provide interventions for improving positive social changes by bringing up stricter but more amiable government policies to ensure a win-win situation for both consumer and producer. The knowledge may also help relevant stakeholders to design appropriate interventions towards encouraging collaboration between herb sellers and scientists whilst also improving standardization of herbal medicines, causing a shift from the dispensary of crude drugs and herbal preparations towards promoting the development of high-quality products.

In this study, we surveyed herbal medicine products (HMPs) sold in retail stores, pharmacies and open markets in three states of the country especially the Federal Capital Territory, Abuja with the aim to study to examine and document the retailed HMPs. Specific objectives were to determine the percentage of packaged herbal medicine products vis-à-vis crude drug/extemporaneous preparation present in the markets under study, determine range of costs of herbal medicines, document herbal products stocked in the markets; investigate the extent to which herbal medicine products (HMPs) comply with regulatory provisions on registration and labelling.

Methodology

2.1. Study Design, Respondents, Sampling method and Setting

This study involved the assessment of herbal medicine products (HMPs) sold in the Federal Capital Territory, Niger and Nassarawa states. The study was carried out April and December, 2021. Study sites included pharmacies, supermarkets, stores, herbal pharmacies and Islamic stores studied as closed markets while herb sellers in markets, cart/truck pushers, hawkers were studied as open markets. Major areas in the states were surveyed (Figure 1). A target of 1000 products (covering open and closed markets) by random sampling was set with a minimum number of 142 sites. Responses were obtained on a voluntary basis and refusal rate was documented.

Determination of sample size.

The minimum study sample size (143) was determined to obtain a representative study population. The number was statistically derived using

$$N = \frac{Z_{1-\alpha/2}^2 [P(1-p)]}{d^2}$$

Where N = Minimum number of products

Z_1 = the value of the reference normal distribution for the desired confidence level: 1.96

α = Level of significance (degree of tolerable error): 0.05 (=95% CI)

$Z_{1-\alpha/z^2} = (0.05/1.96)^2$ (from z table), a constant

$P = 0.76$ (the prevalence of herbal medicine use 75.78%, was calculated by the average of reported prevalence from 5 studies across the country).

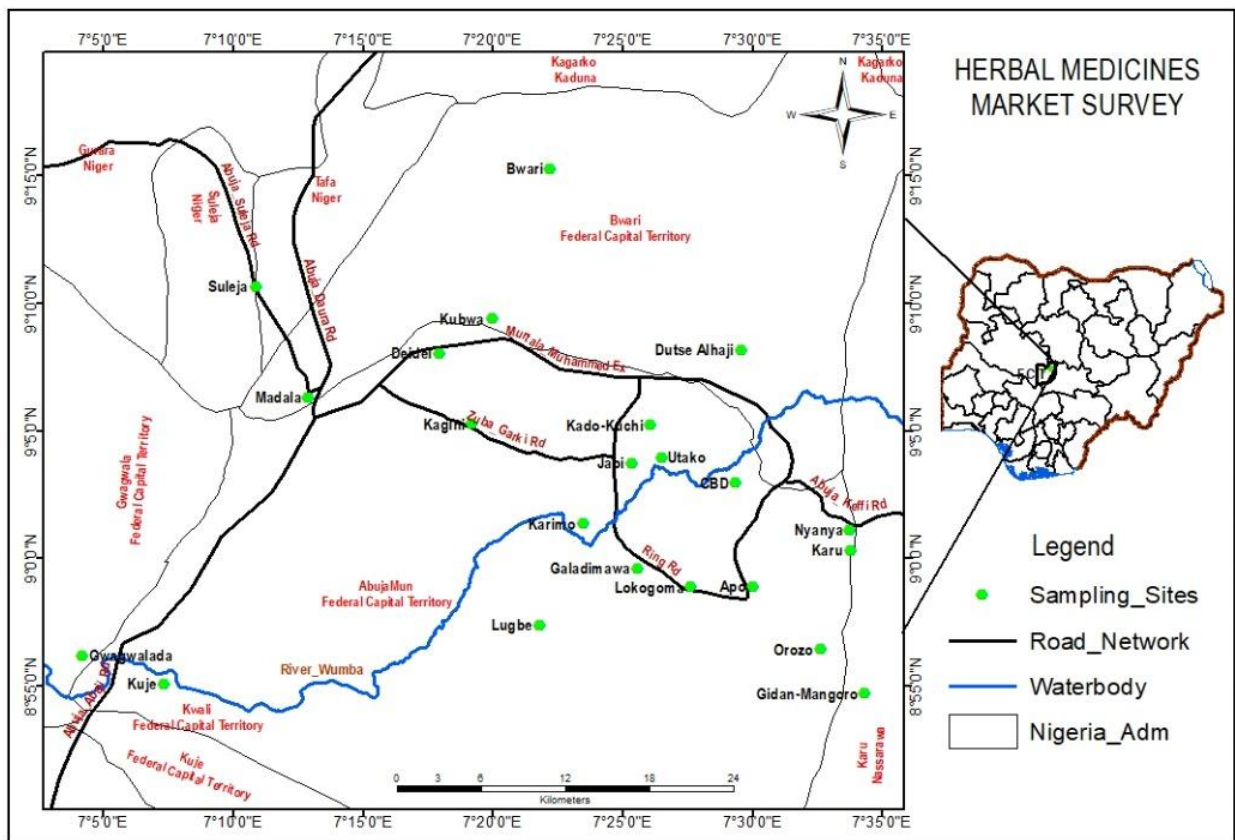


Figure 1: Mapping showing areas that were sampled

Questionnaire design, study variables, deployment and data collection

A cross sectional study using open ended–semi structured questionnaires was employed. A draft questionnaire and data collection tool was developed and passed through multiple rounds of review. Qualitative content validity was evaluated by a panel of 8 experts, who reviewed the questionnaires and data collection tool with emphasis on the objectives, ease to getting cooperation and accurate responses from respondents and easy comprehension/ complexity of the questionnaire, appropriateness of questions and eventual relevance. Content validity was also evaluated quantitatively wherein content validity index (CVI) for relevancy and clarity were tested for each item. If CVI was greater than the criterion of the Lawshe's table for each item. An acceptable I-CVI of items higher than 79% was considered appropriate, between 70 and 79% revised, whilst items having I-CVI of less than 70% were eliminated. Questions for this survey were in two (2) categories: (1) Open ended questions for TMPs and herb sellers in open markets (2) Data collection tool documenting information on herbal medicine products (HMPs) in relation to retail store/pharmacy or open market. Information covering name, cost, indication, source of herbal medicines and other information expected to be on labels of herbal medicine products was documented. All personnel involved were trained on objectives data collection was carried out using interviewer-administered questionnaires.

Compliance to regulation on Labelling

Each product was evaluated for compliance to regulation on labelling as recommended by the National Agency for Food and Drugs Administration and Control (NAFDAC). Information such as brand name, indication, side effect/adverse reaction/contraindication, manufacturing/expiry date, batch/lot number, manufacturers address, registration or listing number. The level of compliance (%) by the population of HMPs studied was evaluated (NAFDAC, 2013).

Statistical analysis

All data were analysed using Microsoft Excel 2016 and SPSS© version 23 (IBM Corp., Armonk, NY, USA). Categorical variables such as data obtained from the herbal medicine products were expressed in form of frequencies and percentages, while continuous variables were reported as means \pm standard deviations (SDs). Cross tabulation to evaluate and compare the number of registered products in relation to countries or states of origin was carried out.

Ethical Considerations

Ethical approval (FHREC/2021/01/92/09-08-21) was obtained from the Health Research Ethics Committee, Federal Capital territory (FCTA). The participation of TMPs/herbsellers/retail stores/pharmacies was strictly voluntary. Personal data/information of the participants were not reported and the privacy of respondents along with the names of their stores/pharmacies was preserved in the study.

3.0 Results

A total of 926 samples were examined and documented from 155 sites. Among these, 647 samples formed the final sample size of the study due to exclusion of 279 entries. Repeated mentions were excluded.

A. Sampled sections and Response Rate

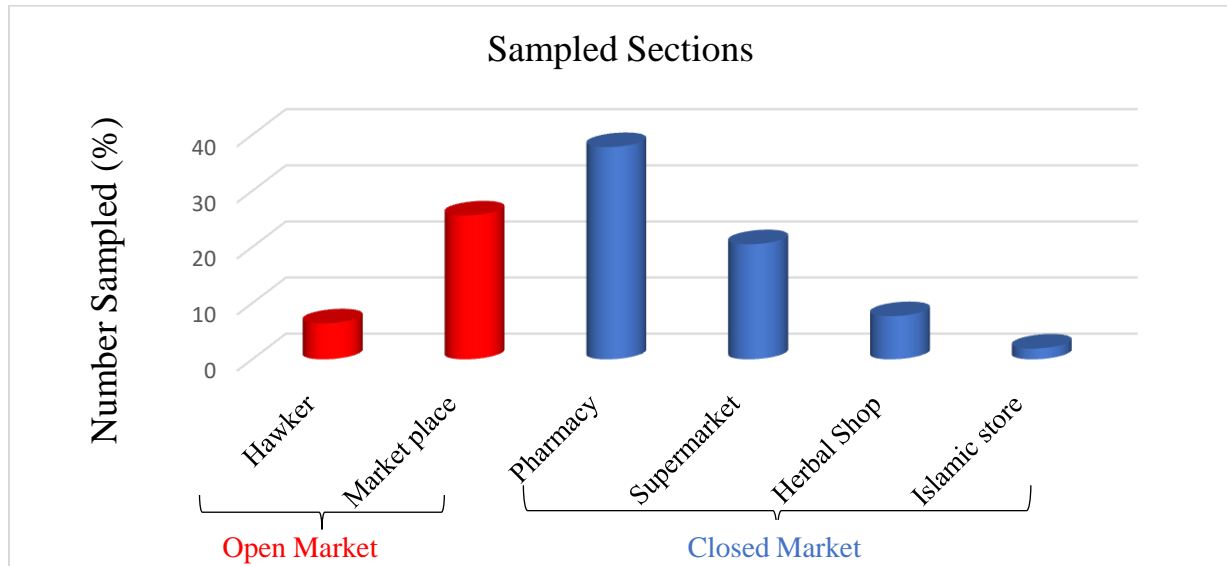


Figure 2: Number of each sampled section during the survey

Table 1: Presence of Herbal Medicine Products (HMPs) and Compliance to expected information on Product label

Responses	Presence of herbal medicine products in open markets (%)		
Yes	26.1		
No	73.9		
	Presence of extemporaneous preparations in open markets (%)		
Yes	82.6		
No	17.4		
	Presence of crude drugs in open markets (%)		
Yes	95.7		
No	4.3		
	Presence of herbal medicine products in closed markets (%)		
Herbal medicine products	100		
Crude drug/extemporaneous preparation of herbal drugs	0		
Compliance to expected information on herbal medicine product (HMP) label.			
S/No	Expected information	Frequency (Yes)	Percentage (%)
1.	Name of Product	637	98.5
	unbranded "other" names (open market)		83.5
	unbranded "other" names (closed market)		23.3
2.	Indication	550	85.0
3.	Direction of use	591	91.3
4.	Side effect/ ADR	149	23.0
5.	Composition	636	98.3
6.	Composition (%)	242	37.4
7.	Lot/Batch number	432	66.8
8.	Manufacturing/Expiry date	524	81.0
9.	Address	608	85.3
10	NAFDAC number	254	39.3

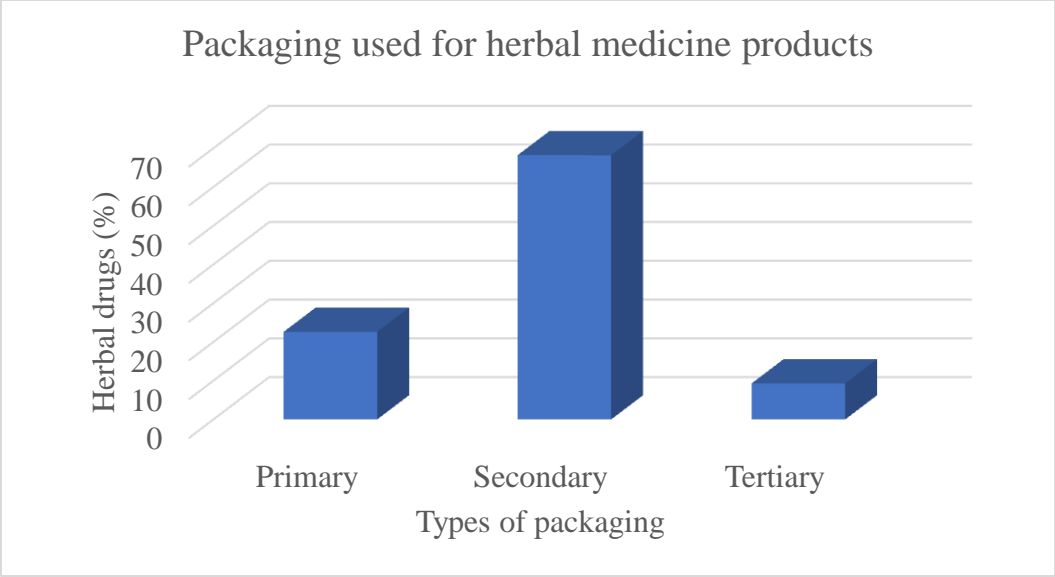


Figure 3: Packaging used for herbal medicine products (HMPs)

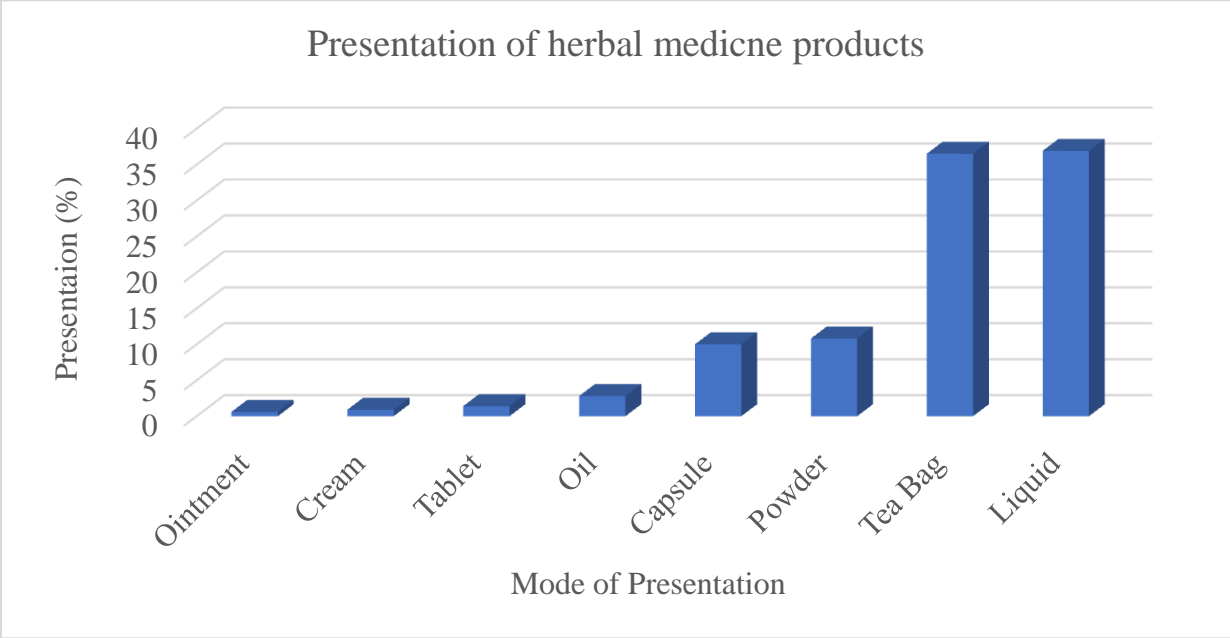


Figure 4: Presentation of herbal medicine products (HMPs)

% HERBAL MEDICINAL PRODUCTS

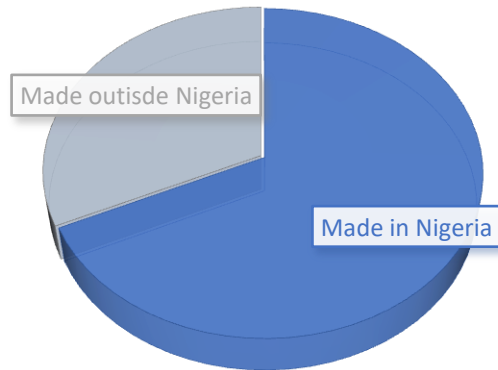


Figure 5: Distribution of source of herbal medicine products (HMPs)

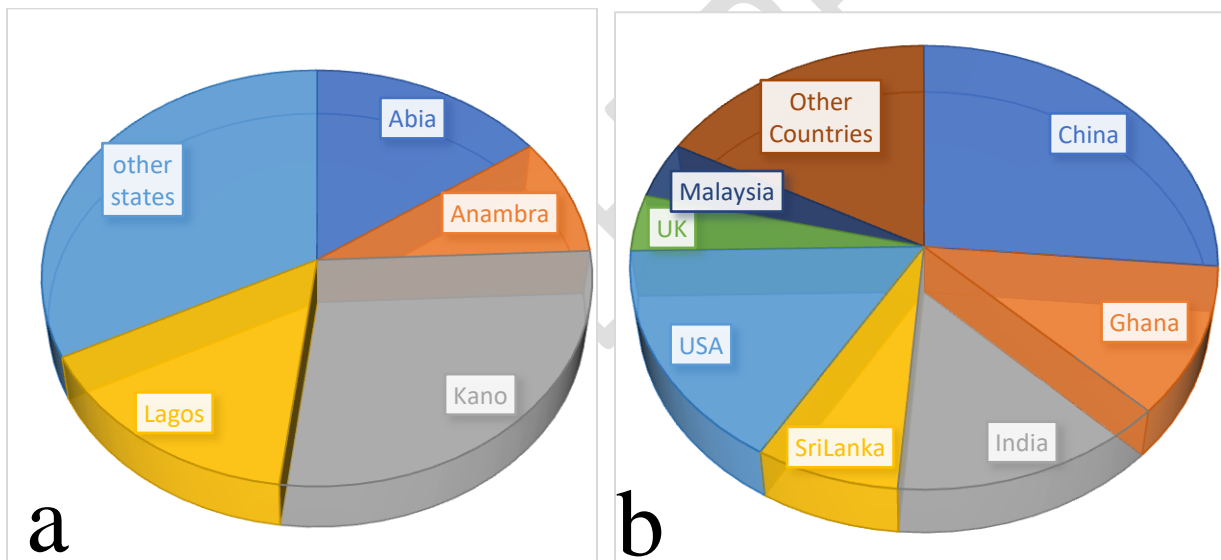


Figure 6: Distribution of source of herbal medicine products (HMPs) made within (a) and outside Nigeria (b)

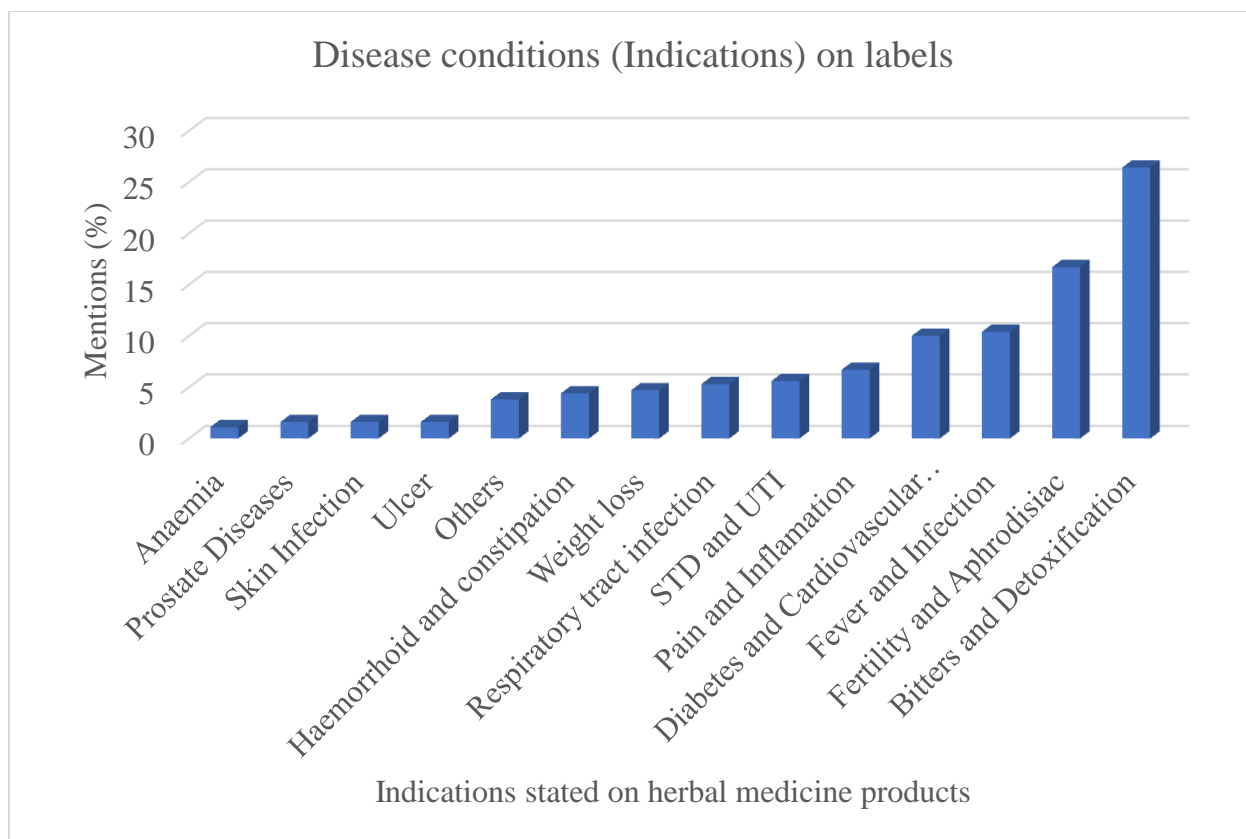


Figure 7: Indications of herbal medicine products (HMPs)

Indications classified as “others” included: memory loss, convulsion, stretch marks, lactogenic, ulcer, cancer and allergies.

Some results from verbal communications during survey

Reasons for not packaging and putting out herbal medicines in labelled and/or packaged forms

1. I will need to register it and NAFDAC and its regulatory considerations are too difficult and expensive
2. It is cheaper to import the foreign made than to produce and package here in Nigeria
3. It will increase my cost of production and current cost of medicine
4. I am too old for that now my children will continue with that
5. I am afraid to collaborate to get my preparations to such level as we are often cheated and our knowledge is taken away
6. People don't need us to package and put any requirements on any package. When it works, they always come back.
7. Unavailability of medicinal plants due to seasonal differences, distance to points/states of collection, urban development and farming practices affect the eventual cost of herbal medicines.

DISCUSSION

The study documented commonly sold herbal medicine products (HMPs) in the Federal capital territory with major emphasis on the presentation of the herbal medicines and compliance to regulatory requirements. A response rate of 86.5% was achieved covering 155 sites and 647 HMPs. In this study, herbal medicine products (HMPs) were regarded as finished and packaged herbal products in one herbal dosage form or the other, consisting of one or more herbal preparations made from one or more herbs containing no synthetic active substances. From the open markets studied, only 26.1% of the open market sites studied had HMPs. The open market sites had crude drugs (95.7%) and herbal preparations which were already prepared or freshly made as extemporaneous preparations (82.6%) and HMPs (26.1%) (Table 1).

The identity of a product is the first point of reference towards describing product quality and this is also important for registration of the product. The name of a product and some form of branding is central to its identity. A major observation in this study was that 98.5% of HMPs had one form of name or the other. It was observed that some HMPs had seemingly branded names (63.4%) while others (36.6%) had other forms of names. The occurrence of such “other names” was observed more in the open markets (83.5% of products) than closed markets (23.3% of HMPs) as expected (Table 1). These “other names” included HMPs known by means such as the name of the disease they are expected to manage e.g. ulcer tea, antimalarial herbal mixture, STD, gonorrhoea, fibroid remover etc. Some were labelled/called by the medicinal plant(s) they contained e.g “Nigelia”, “Moringa”, “Neem” or both the name of the plant and disease condition e.g “blood pressure tea with moringa”. In some cases, the names were mixed with the degree to which the medicine is perceived to be active e.g “active cold medicine”, “AK-47”, “super bazooka”, “Diabetes bullet”, “fibroid flusher”, “cough go” etc. Some others are named in local languages/lingua such as “kaya mata” or “Jekorigbo”. Hence multiple products exist from different sources with the same names. This poses a huge problem for regulatory bodies as it is difficult to trace such herbal medicines in the event of a reported case toxicity. This data shows the degree of knowledge and/or perception of branding. Perhaps for herbal medicines with such general names in the open market, it is fuelled by the perception that the drug will sell faster if it is just called e.g. antidiabetic tea. This calls for the need to train TMP’s on the need for and importance of proper branding and registration of product names.

A poor level of packaging was observed in the open markets which could affect acceptability and patronage of locally sourced herbal medicines in Nigeria despite the wide availability and possible effectiveness of herbal medicines [11] [12] . Participants during oral interview expressed concerns and reasons for not packaging the herbal medicines. Some of which include, the cost of packaging and possible increase in cost of product after packaging; the lack of remuneration after information is given to natural product scientist towards further development of the crude drug and the difficulty in complying with regulatory obligations once the crude drugs are packaged. Some participants claimed they were too old and would hand over the responsibility of further development to their children. None of the closed markets sold crude drugs nor extemporaneous preparations, all HMPs sold within the closed markets had one form of packaging or the other. The HMPs documented had different forms packaging, 68.2% of

HMPs had secondary packaging while 22.6% had primary packaging and different forms of presentation, 36.9% were liquid, 36.5% in tea bag, 10.8% in powder forms. The least mentioned were ointments (0.6%) and creams (0.9%) (Figure 3&4). Besides increased acceptance, excellent packaging has been known to be a major component of product quality. Inadequately packaged/labelled or unpackaged crude drugs, herbal preparations and herbal medicines are prone to exposure to adverse temperatures, light and humidity which will in turn affect stability and quality of products. A major gap in knowledge and practice was established in the open markets. These results also show that over 70% of the herbal medicine products consumed in the FCT are administered orally. This gives further reason for close monitoring, post market surveillance for microbial load checks and acute toxicity tests.

It is noteworthy that sixty-eight percent (68%) of the HMPs studied were observed to be made in Nigeria against the general notion of the authors that most HMPs will be made outside the country. This study does not take cognisance of the number unpackaged and/or extemporaneous preparations possible. Nigerian traditional medicine practitioners must be encouraged to package on small scale basis their HMPs and collaborate for large scale production. This will in turn boost degree of use of HMPs and economic turn over. Of the HMPs made in Nigeria, 28% were made in Kano, 16% in Lagos and 15.2% in Abia state. Countries mostly represented among imported HMPs were China (26.4%), USA (16.1%), India (14%) and Ghana (10%). On cross tabulation, for HMPs made in Nigeria, the highest number of unregistered herbal products as expected came from Kano state (13%), while others were made in Abia (2%), Enugu (2.0%), Anambra (1.5%). For HMPs made outside the country, the highest number of unregistered products came from China (5.3%), USA (2.8%) Ghana (2.2%), India (1.7%) and Malaysia (1.2%) (Figure 5&6).

Herbal medicine products in the F.C.T were observed to have various indications as stated on the labels of the HMPs. The most mentioned was for bitters and detoxification (26.4%) followed by fertility and aphrodisiac (16.7%) and fever and infection (10.4%) which was not significantly different ($p \leq 0.05$) from Diabetes and Cardiovascular diseases (10%) (Figure 7). Considering the law of demand and supply, these products are in high supplies due to a high demand for them. Many studies have shown the involvement of medicinal plants especially bitters in detoxification. Detoxification, a process largely involving the scavenging of free radicals have been implicated in the management of many diseases [13]. A high prevalence in infertility, erectile dysfunction among other sexual dysfunctions have been reported especially in the Northern and Southern parts of Nigeria [14]. A major cause of erectile dysfunction has been attributed to cardiovascular diseases such as hypertension. A study by [15], conducted among Lagos residents reported the most frequently mentioned use as “Agbo Jedi” and “Agbo Iba”. From this study, the products highlighted also had as part of their names or labels, “bitters and or detoxifiers”.

The compliance to laid down requirements on labelling is a fundamental part of HMPs quality as inclusion of information such as product branded name, batch number, net composition etc allows for traceability and shows how genuine product is [12]. It is laudable to note that over 75% HMPs sold in the markets were compliant in ensuring information such as name of product,

direction of use, composition, manufacturing and expiry date, indications, address of manufacturer and lot/batch number are stated on the labels attached to each HMP (Table 1). However, some salient information did not meet up with the expected requirement. It was observed that 23% of HMPs had information on the possible side effect or adverse reaction (if any) labelled on the HMP. Besides the possibility of inadequate documentation of side effects by herb users and TMPs during patient consultation and also a possible lack of information on toxicity of some herbal medicines, herbal medicines are often times thought to be safe and without side effects and can thus be the reason for the lack of information on possible side effects/adverse reactions that could possibly arise from multicomponent HMPs. From the study, only 37.4% of HMPs had composition (%) of the components of each product on the label. This could be as a result of an attempt to keep the formula of the preparation/HMP secret. A few herb sellers in the open market expressed the notion that packaging their herbal preparations with all the details needed by NAFDAC will give out their knowledge and way of livelihood. It was said that their patients always came back due to the effectiveness of the product. Only 39.3% of products had NAFDAC registration numbers. Herb sellers in the open market expressed the notion that the cost and requirement for NAFDAC registration was too high to attain. It is important to make the process of registration of herbal medicine products less cumbersome and affordable for the TMPs. A reorientation of TMPs against the notion that gaining NAFDAC approval is unattainable will also enhance the involvement and cooperation of the TMPs.

Other notions highlighted by TMPs in the open market depicted an increasing cost of herbal medicines due to reasons such as unavailability of crude drugs (some plants are seasonal, some natural products are unavailable from sources where they used to be collected, distance to point of collection), complexity and mode of preparation of the herbal medicine. The cheapest HMP in the open market ranged between 50 - 500 naira for skin infections and fever in babies and children while most expensive ranged between 10,000 - 30,000 naira for infertility in women and mental illness. In the closed market, HMPs were observed to be as cheap as 150-500 naira for fever and infection and as expensive as 15,000 – 50,000 for infertility, diabetes and hypertension.

A report from WHO global survey on National policy on traditional medicine and regulation of herbal medicines stated some essential components needed by every country such as National programme, expert committee, office and policy on TM/CAM, a research institute on TM/CAM or herbal medicines along with regulations governing TM/CAM [5]. In addition to these and to effectively achieve compliance to regulations, national interventions encouraging the standardization of practice, supporting the branding, packaging and registration of safe and efficacious HMPs must be put in place to ensure a transition from crude drugs to well packaged herbal medicines in open markets and the consumption of quality herbal medicines from closed markets. Major limitations experienced during the survey were refusals to participate in survey for reasons such as fear of victimization as herb sellers and store owners assumed that the administrators of the questionnaire were from regulatory agencies and limited time given by store owners to record data needed.

CONCLUSION

Herbal medicine products sold in the FCT Nigeria were surveyed, documented and appraised for their regulatory status. Knowledge and practice gaps have been highlighted. There is a need to educate TMPs on essence of drug development and packaging of products to improve acceptability, national relevance and international recognition. Herbal medicine producers must be further enlightened on registration requirements and to encouraged to register their products.

ABBREVIATIONS

TMPs – Traditional Medicine Practitioners; HMPs – Herbal Medicine products; FCT- Federal Capital Territory; TM/CAM – Traditional Medicine/Complementary and Alternative Medicine; WHO –World Health Organization; NAFDAC- National Agency for Food, Drug, Administration and Control.

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