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FOOD AND DRUG REGULATION IN NIGERIA: EVALUATION OF ROLE AND OPINION OF HEALTHCARE WORKERS

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ABSTRACT

The challenges with Substandard Spurious Falsely-Labelled Falsified Counterfeit Medical Products (SSFFCS) are Global which calls for intensification of regulation of foods and drugs. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) needs to collaborate with agencies like the Pharmacists Council of Nigeria (PCN) and others to realize its mandate. Healthcare Workers are significant stakeholders that must comprehend and identify their starring roles in regulatory affairs for the safety of patients and the public. 480 Semi-structured questionnaires were administered to healthcare providers; Pharmacists, Medical doctors, Nurses, Laboratory scientists and a few others in Plateau State, Nigeria. A total of 313 questionnaires were returned completed. 92% of respondents are aware of the policy that established NAFDAC, 70% believe that NAFDAC cooperates with other agencies to enable it function. 96.2% look out for NAFDAC registration/ listing number before using foods/ drugs. 82.1% believe that political pressure influences food and drug regulatory decisions in Nigeria, 77% affirm that the problems arising from food and drugs to have decreased within the past ten years, 49.2% think that adverts of drugs in the media is only sometimes observed. Only 28.4% have ever been involved in drug recall, only 25.6% have ever been involved in pharmacovigilance reporting, 35.8% will use a non NAFDAC registered orphan drug in the absence of the registered one. It was concluded that most Healthcare providers are not informed about their roles in regulation

of foods and drug recalls, pharmacovigilance, alert information updating and need to be taught.

KEYWORDS: Healthcare-workers, Regulatory affairs, Food and drugs.

INTRODUCTION

A study to establish the factors responsible for the preponderance of counterfeit drugs in Nigeria despite existing laws was undertaken, it was gathered that implementation of existing laws was the major problem. There were ineffective task forces whose responsibilities were inhibited by corruption, communication gaps, poor funding and logistic problems.[1] In another multi-country study of drug regulation to compare, contrast and synthesize country experience based on data collected in 1998-1999 in ten countries. It was noted that in as much as data collection is static, food and drug regulation is highly dynamic.[2] Therefore, a changing environment affects regulatory activities and consequently, the regulatory agency. Nigeria like every other country in the world is facing the global health problem, substandard and counterfeit medicines affects Africans and Asians on a large scale.[3] The Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) is faced with the task of overcoming the numerous challenges. These impediments can be noted from the persistence of spurious and forged drug and food products in Nigeria despite its popular efforts, poor drug recall, and other deficiencies. Most laws in Nigeria including drug laws are only partially implemented or completely busted without the appropriate punitive measures taken. The illegal dealers in Food, Drugs and Cosmetic activities often have political or economic influence of which they utilize anyway. This is partly encouraged by a negligent judicial system. In the past, NAFDAC has suffered resistance from especially politicians and other stakeholders that benefit directly from the chaotic drug markets as they attempt to raid the markets.[4] The Nigerian Pharmaceutical sector is also regulated by the Pharmacists' Council of Nigeria (PCN) especially managing the training and practice of Pharmacy including issuance of licenses to qualified Pharmacists and patent medicine vendors (PMV) in addition to giving annual permits to Pharmacy Technicians.[5,6] A notable setback to the implementation of drug laws in Nigeria is understood in the poor distribution network of pharmaceuticals whereby medicines are significantly handled by non-Pharmacists in the supply chain and quackery is common.[7] This is contrary to the National Drug Policy (NDP) which stipulates that the distribution, supply, sale and dispensing of medicines is an area to be exerted by the authority of Pharmacists at all points.[8]

The healthcare providers usually have vital roles to play in food and drug regulation ranging from pharmacovigilance reporting[9], clinical studies, drug recall, health inspection, registrations and so on. Healthcare providers and those who deal with medicines can also help in identifying counterfeit medicines by the use of Mobile Authentication Service (MAS).[10] These healthcare workers can educate patients and other medicine consumers how to use the MAS. If healthcare givers can detect food or drug products with compromised quality or efficacy, and they report and decline the use of such products, it will meaningfully contribute in weakening the activities of perpetrators counterfeiting and producers of substandard foods and medicines.

The regulatory framework of foods does not permit adequately the regulation of the non-formal section. Most foods are consumed by this sector and the food laws are restricted.[11] The difference in cultures with respect to foods, the practice of agricultural routines, and manner of food production further makes it more difficult. Unwholesome, unhygienic or substandard foods can result to cholera, diarrhoea, typhoid fever, Lassa fever and so on.[12]

Healthcare providers' role here is immense ranging from health education to prevention interventions at different stages.

This study seeks to reveal how much professionals directly facilitating the consumption of foods and drugs intended for treatment, prevention and health improvement can contribute in ensuring that their clients do not come to be targets of Substandard Spurious Falsely-Labelled Falsified Counterfeit Medical Products (SSFFCS).

METHODOLOGY

Questionnaires were distributed all across Plateau State, Nigeria and administered to healthcare professionals (Pharmacists, Doctors, Nurses, Laboratory scientists and relevant healthcare providers) with respect to concerns of the knowledge and attitude of health workers to food and drug regulation and related matters. The distribution was significantly done by trained healthcare professionals by convenience to reach their colleagues, thus in the distribution, the most proximate healthcare workers were reached. This was done mainly in hospitals and pharmacies to individual respondents selected across fourteen of the seventeen local government areas of Plateau State. A significant number of healthcare providers practice in Jos metropolitan area, which is inhabited by Jos North, Jos South, a part of Jos East and a part of Bassa Local Government Areas. While the number of Nurses is well

distributed across the State, Medical Doctors, Pharmacists, and Laboratory Scientists are not. They have a concentration in the State capital area. Two of the omitted local Government areas (Riyom and Kanke) do not have functional secondary or tertiary health care facilities yet but under construction that one can find a Medical Doctor, a Pharmacist or a Laboratory Scientist. The third omitted (Langtang South) has Pharmacists, Medical Doctors, Nurses and Laboratory Scientist from the tertiary health facility (Jos University Teaching Hospital {JUTH}) of whom the staff are deployed to the comprehensive health centre. They are posted in and out from time to time. It was most convenient contacting them in Jos and Gindiri. The questionnaires distributed across Plateau State were 480. However, 313 questionnaires were returned completed. 28 were returned not completed. The remaining 139 were not recovered. The first part of the questionnaire is data on personal information which included introduction of the interviewer, occupation of respondent, sex, age, place of work and duration of work. The other parts consisted of the questions relevant to the research. In any case, names and identity of respondents were not disclosed on the questionnaires.

RESULTS

Table 1: Respondents Demographic Information.

Variable	Frequency	Percentage (%)
Sex		
Male	195	62.3
Female	118	37.7
Total	**313**	**100.0**
Profession		
Medical Doctor	66	21.1
Pharmacist	71	22.7
Nurses	132	42.2
Laboratory Scientist	27	8.6
Others	17	5.4
Total	**313**	**100.0**
Age of Healthcare Provider (Respondents) (years)		
20-29	33	10.5
30-39	101	32.3
40-49	114	36.4
50-59	62	19.8
60-69	3	1.0
Total	**313**	**100.0**
Work Duration of Healthcare Provider (years)		
1-5	69	22.0
6-10	78	24.9
11-20	99	31.6
21-30	39	12.5
31-40	28	8.9
Total	**313**	**100.0**

Table 2: Healthcare Providers' Knowledge of NAFDAC Authorization and Policy Formulation.

Responses	Frequency No.	
a. Healthcare worker is aware of the policy (decree/law) that empowers the National Agency for Food and Drug Administration and control (NAFDAC) to carry out its duties		
Yes	298	95.2
No	6	1.9
Don't know	9	2.9
Total	**313**	**100.0**
b. NAFDAC has been cooperating with relevant agencies effectively that relate to food and drug regulation as opinion		
Yes	219	70
No	61	19.5
Don't know	33	10.5
Total	**313**	**100.0**
c. Healthcare worker is aware of laws/legislations that concerns health care provider's handling of drugs and foods		
Yes	272	86.9
No	23	7.3
Don't know	17	5.4
Total	**312**	**97.7**
No Response	**1**	**0.3**
Total	**313**	**100.0**
d. The laws are adequate		
Yes	155	49.5
No	105	33.5
Don't know	53	16.9
Total	**313**	**100.0**

Table 3: Healthcare Providers' Knowledge of Regulatory Rules.

Responses	Frequency No.	Percentage (%)
• **Drugs/medicines need regulation**		
Yes	311	99.4
No	2	0.6
Total	**313**	**100**
• **Foods need regulation**		
Yes	309	98.7
No	4	1.3
Total	**313**	**100.0**
• **Herbs/ Herbal products need regulation**		
Yes	307	98.1
No	6	1.9
Total	**313**	**100.0**
• **Cosmetics need regulation**		
Yes	306	97.8

No	7	2.2
Total	313	**100.0**
• **Healthcare worker looks out for NAFDAC registration/ listing number before using a drug/ food product**		
Yes	301	96.2
No	10	3.2
Don't know	2	0.6
Total	**313**	**100.0**
• **The presence of NAFDAC number on foods/ drugs indicate that the product is effective for human consumption**		
Yes	191	61
No	103	32.9
Don't know	19	6.1
Total	**313**	**100.0**
• **The presence of NAFDAC number on foods/ drugs indicate that the product is Safe for human consumption**		
Yes	192	61.3
No	101	32.3
Don't know	20	6.4
Total	**313**	**100.0**
• **Healthcare worker will stock or use a product NOT registered with NAFDAC if the registered equivalent is not available**		
Yes	53	16.9
No	250	79.9
Don't know	10	3.2
Total	**313**	**100.0**
• **NAFDAC makes registration of products difficult**		
Yes	116	37.1
No	126	40.3
Don't know	**71**	**22.7**
Total	**313**	**100.0**
• **Healthcare worker thinks that political pressure influences food and drug decisions in Nigeria**		
Yes	257	82.1
No	32	10.2
Don't know	24	7.7
Total	**313**	**100.0**

Table 4: Healthcare Providers with Media Regulation and Regulatory Impact.

Responses	Frequency No.	Percentage (%)
1. The problems arising from food and drugs have decreased within the past ten years		
Yes	241	77.0
No	43	13.7
Don't know	29	9.3
Total	**313**	**100.0**
2. Healthcare worker considers adverts on the media to comply with the laws		
Yes	112	35.8
No	47	15.0
Sometimes	154	49.2
Total	**313**	**100.0**
3. Healthcare worker considers adverts of drugs in the media as adequate		
Yes	72	23.0
No	79	25.2
Sometimes	162	51.8
Total	**313**	**100.0**
4. Healthcare worker considers adverts of drugs in the media as appropriate		
Yes	100	31.9
No	47	15.0
Sometimes	166	53.0
Total	**313**	**100.0**
5. Healthcare worker considers reports of admissions due to drug related problems /quality to have decreased within the past ten years		
Yes	203	64.9
No	64	20.4
Don't know	46	14.7
Total	**313**	**100.0**

Table 5: Recall and Pharmacovigilance Regulatory Involvement.

Response	Frequency No.	Percentage (%)
1. Healthcare worker have been involved in product recall in Nigeria		
Yes	89	28.4
No	214	68.4
Don't know	10	3.2
Total	**313**	**100.0**
2. Healthcare worker believes drug recall is very effective in Nigeria		
Yes	71	22.7
No	167	53.4
Don't know	75	24.0

Total	**313**	**100.0**
3. There is task force in practice area of healthcare worker		
Yes	125	39.9
No	111	35.5
Don't know	77	24.6
Total	**313**	**100.0**
4. Healthcare worker have been involved in pharmacovigilance reporting		
Yes	80	25.6
No	219	70.0
Don't know	14	4.5
Total	**313**	**100.0**
5. Healthcare worker considers pharmacovigilance reporting to be effective within their practice area		
Yes	116	37.1
No	123	39.3
Don't know	73	23.3
Total	**312**	**99.7**
No Response	1	0.3
Total	**313**	**100.0**

Table 6: Decisions Healthcare Providers Take With Respect To Orphan Drugs.

Responses	Frequency No.	Percentage (%)
1. Healthcare worker will insist on the use of a NAFDAC registered product if in need of an orphan drug		
Yes	244	78.0
No	68	21.7
Total	**312**	**99.7**
Missing system	1	0.3
Total	**313**	**100.0**
2. Healthcare worker will utilize a non NAFDAC registered orphan drug in the absence of a registered one		
Yes	112	35.8
No	200	63.7
Total	**312**	**99.7**
Missing system	1	0.3
Total	**313**	**100.0**
3. Healthcare worker will utilize anyone orphan drug available without strict scrutiny if in need		
Yes	49	15.7
No	263	84.0
Total	**312**	**99.7**
Missing system	1	0.3
Total	**313**	**100.0**
4. Any good orphan product does not matter		
Yes	70	22.4
No	243	77.6
Total	**313**	**100.0**

Table 7: Healthcare Providers' observation of Regulation and Treatment failure.

Responses	Frequency No.	Percentage (%)
1. Healthcare worker ever observed treatment failure due to defect in quality of NAFDAC registered drugs/ medicines		
Yes	150	47.9
No	138	44.1
Don't know	25	8.0
Total	**313**	**100.0**
2. Healthcare worker took the drug sample to a drug analyst for content analysis to identify quality		
Yes	17	5.4
No	296	94.6
Total	**313**	**100.0**
3. Healthcare worker did dissolution analysis/ bioequivalence studies to identify failed product		
Yes	8	2.6
No	305	97.4
Total	**313**	**100.0**
4. Healthcare worker identified treatment failure based on patient's poor response		
Yes	128	40.9
No	185	59.1
Total	**313**	**100.0**
5. Healthcare worker ever handled a product then realized it was counterfeit		
Yes	143	45.7
No	148	47.3
Don't know	22	7.0
Total	**313**	**100.0**

Table 8: Listing Recalled Products by Healthcare Providers and Frequency of Involvement.

Serial No.	List of Products The Healthcare Provider Was Involved In Its Recall	Frequency (No) (%)
1	Mist magnesium trisilicate suspension	2 (0.64)
2	Paracetamol syrup e.g My pikin, Pfizer etc	23 (7.35)
3	Chloroquine injections	7 (2.24)
4	Teething powder/Infant gripe water	5 (1.60)
5	Analgin injection	8 (2.56)
6	Intravenous infusions e.g. 5% Dextrose water, 5% Dextrose saline and Normal saline for different companies from Dana, Bioflex and so on	21 (6.71)
7	Gentamycin 280mg injection	29(9.27)
8	Artesunate + Amodiaquine/ Artemisinin antimalarial drug	2 (0.64)
9	Frusemide injection	1 (0.32)
10	Griseofulvin tablets	2 (0.64)
11	Unspecified cosmetic agents	1(0.32)

12	Tablets Stavudine	1 (0.32)
13	Tabs Amoxicillin	1 (0.32)
14	Procaine Penicillin	1 (0.32)
15	Pur clear cream	1 (0.32)
16	Daonil tablets	1 (0.32)
17	Paracetamol tablets	1 (0.32)

DISCUSSION

Knowledge of NAFDAC empowerment and policy formulation

It is apparent that more of the Healthcare Providers believe that they are aware of the law establishing NAFDAC. 95.2% of Healthcare Providers are aware, and only 1.9% of them are not aware while 2.9% don't know. The law establishing NAFDAC is the Decree No. 15 of 1993 which was amended in 1999 as decree 19 and included in law of Nigeria in 2004.[13] The law comes with the mandate of NAFDAC. The Healthcare Providers believe that NAFDAC has been cooperating with relevant agencies effectively that relate to food and drug regulation at 70% response. NAFDAC is supposed to cooperate with several organizations especially the Pharmacist Council of Nigeria for effective food and drugs regulatory activities.[13] Healthcare Providers should not be left out in this collaboration in consideration of their own role. For foods, the general hygiene is required for Healthcare Providers just like the general public. However, Healthcare Providers are more conversant with the need for hygiene and have the knowledge of organisms that cause illnesses. They have a role of informing and aiding the public about hygiene. For handling of drugs, there are drug laws and the National Drugs Policy[8] which up till date has not been fully implemented especially with respect to drug distribution, use of Healthcare Providers and many more. 49.5 per cent of Healthcare Providers think the laws concerned with handling of food and drugs are adequate, while 33.5 per cent think they are not adequate. The numbers of Healthcare Providers that do not know (16.9%) when combined with those that gave negative response shows that less than halve of the population actually have confidence in the laws that affect food and drugs.

Knowledge of regulatory rules

The Healthcare Providers significantly affirmed that Drugs/ Medicines, Foods, Herbs/ Herbal products, and Cosmetics need regulation. There are laws that support the regulation of all of the items however not with equal strength. The product that does not have stringent regulatory force is cosmetics because according to Ross[14] in a view, and in an older publication by Weissler[15] since 1974, it is believed that the harmful substances are already known so caution is already taken by the manufacturers. For herbal products, the regulatory

principles have only recently been strengthened in some countries. There are lots of restrictions in regulation of herbal products across the Globe, howbeit; they differ from Country to Country.[16,17] They may be mild in some and a little more stringent in others. Yet still, there is general restriction to the enforcement of laws on herbs and herbal products since they fall under the category of dietary products. The regulation of herbal products in Nigeria is based on the 'Guidelines for Registration and Control of Herbal Medicinal Products and Related Substances in Nigeria'. They are into three classes and four categories. Extemporaneous herbal preparations are only listed and not advertised or registered but events following the listing through assessment or monitoring should be reported, while large scale production of herbal products locally or introduced from other countries are duty-bound for registering and all advertisements must be approved by NAFDAC prior to marketing. Homeopathic medicinal products are also required to be registered with approval of advertisement messages by the regulatory authority before marketing. Both large scale herbal products and homeopathic medicinal products should undergo post-registration evaluation/monitoring.[18] It is apparent that Healthcare Providers look out for NAFDAC registration/listing number before using drug/ food products at a 96.2% affirmative response. This is attributed to the effort of NAFDAC in Public awareness campaign and its activities in confiscating and destroying unwholesome products[19], media communication to the public about utility of only registered products and many other activities account for the confidence not only from Healthcare providers, but the public in general. Although a majority of respondents affirmed to the effectiveness of NAFDAC registered products at 61%, still the 32.9% that said no to this is considered noteworthy. There has been laboratory analysis of NAFDAC registered products in the past that were actually not effective.[20] For safety of NAFDAC registered products, there has been intense effort to maintain regulatory services like the use of MAS to avoid counterfeiting; the Healthcare Providers agree to that at 61.3%. However, many still have the perception that the products may not be safe at 32.3% negation. For stocking of non-NAFDAC registered products in the absence of a registered equivalent; the Healthcare Providers in the majority did respond that they will not stock. In actual sense this condition requires a critical decision because there must be a balance between safety and emergency. One may be compelled under these circumstances to decide in what may favour the life of a patient. The condition attached to the question is that the product does not have a registered equivalent or it is not just available. Healthcare providers could find themselves under this condition and they need to act rationally and may go against the rule if it will count in saving the patient's life. 79.9% of Healthcare Providers claimed they will not use a non-

NAFDAC registered product, perhaps they may not have been in such a dilemma in real life. 16.9% answered 'yes' in support of utilizing non-NAFDAC registered product under the circumstances of non-availability of a registered one. There was almost a balanced distribution in the response as yes (37.1%) and no (40.3%) in support or against the opinion that NAFDAC makes registration of products difficult. This question is best answered by those with the experience of registration of products. There are however guidelines in place for registration of products in the best interest of public safety.[13] There is the general believe that political pressure influences food and drugs decision in Nigeria at 82.1% in support of that. This is widely known especially from the past experience of the chaotic drug markets in Onitsha, Anambra State, in Kano, Kano State and other places.[4,19]

Media regulation and regulatory impact in ten years

Healthcare Providers in their majority (77%) perceived that the problems arising from foods and drugs within the past ten years have decreased. NAFDAC needs to be more Supervisory in the area of media adverts because in all cases of complying with the law, the adverts being adequate, and the adverts being appropriate, the healthcare providers that think it only happen sometimes are in the majority. The advertisement of pharmaceuticals can come in form of providing product information, its chemical constituents and how it's used. Secondly, it can be in form of publicizing for increased sale. The laws that regulate advertisements of foods and drugs include 'the National drug formulating and the essential drug (EDL) list Act' which states that a drug must be in the list to be displayed for sale, advertised, imported, sold or manufactured in Nigeria. The NAFDAC Act says it may prohibit the advertisement of some drugs. The food and drug Act says drugs used for treatment and prevention of diseases in the first schedule should not be advertised. Food, drugs and related products (Registration, etc.) Act specifies that only foods and drugs registered with NAFDAC can be advertised. The counterfeit and fake drugs and unwholesome processed food (miscellaneous provisions) Acts did not mention advertisement as a word but restrains against display for sale any product in the category.[21] The response to the last variable on the table says 'yes, reports of admissions due to drug related problem and quality to have decreased within the past ten years at 64.9%. However, with an improvement in technology and Science, increase in training and number of Healthcare Providers or expertise could also account for such an improvement. Also, with the collective collaboration of Healthcare Providers as a team can also influence changes positively.

Recall and Pharmacovigilance Regulatory Involvement

The Health workers as low as 28.4% have been involved in recall of products. With respect to common products recalled, the Healthcare Providers stated; Gentamycin 280mg injections (9.27%), Paracetamol syrup (7.35%), Chloroquine injections (2.24%), Teething powder (1.60%), Analgin injection (2.56%), intravenous infusions e.g. Bioflex and Dana (6.71%), and others found in Table 8. Gentamycin at high single dose is known to cause ototoxicity.[22] This was publicized amply that many health care providers stopped its use. However, the lower doses of gentamycin injection are still in use. Similarly, chloroquine was stopped as a first line drug in the treatment of malaria because of resistance especially that caused by *Plasmodium falciparum*. Healthcare providers need to know that NAFDAC maintains an alert website which they should access to know of unwholesome products currently in place. The problem is that the healthcare providers may not find access to internet within their work domain. 53.4% of the respondents believe that drug recall is not effective in Nigeria. Some of these products were rather banned than recalled and are not compensated so many people hide those products and sell the products to people according to reports by the Healthcare Providers on oral responses. Such people that buy may not be aware of alert notices. Alerts may include herbs which people think they are safe. There is evidence of serious harm from herbal products currently on NAFDAC alert site.[13] For the presence of task force in healthcare provider's practice area, 24% do not Know if there is task force or not. Most task forces are limited to only state capitals. Most times, they are not active due to insufficient funding or lack of logistics as it was the problem since 2000 according to Erhun *et al.*[1] Only 25.6% of the healthcare providers have been involved in pharmacovigilance reporting and 70% have never been involved. This is delicate as there is gross under-reporting of adverse drug events. The comments of Healthcare Providers about pharmacovigilance include, lack of information, or the Healthcare Provider thinks it is not his or her responsibility. The deficiency in information is partly due to lack of training or understanding. Many healthcare facilities have benefited from the antiretroviral drug programs as the staff have received training on pharmacovigilance reporting, new pharmacovigilance units have been setup. There are comments that pharmacovigilance training was initiated through the HIV/AIDS program (not shown here) but on oral interviews. One can deduce with only 37.1% in support of pharmacovigilance reporting that is it highly under-reported. Pharmacovigilance reporting is a responsibility of Healthcare Providers and even patients.

Decisions healthcare providers take with respect to orphan drugs

As many as 78% will insist on a NAFDAC registered product if in need of an orphan drug. A hesitation may come if someone needs a drug for rare disease or neglected diseases in which, it may not be readily available, taking decisions may be difficult. That explains why as much as 35.8% frankly responded that they will utilize a non-NAFDAC registered orphan product in the absence of a registered one. Many companies are not interested in producing orphan drugs because they may not be economically wise for the fact that only a few people may need the drugs at a time period.[23] In such a situation, such drugs may not be available in Nigeria and importation may be necessary for a single patient that may need it for disease treatment or management of ailment. Healthcare providers should be allowed to make rational decisions or be given the liberty to decide in favour of their patients. These require rational decisions based on the prevailing circumstances.

Regulation and treatment failure

A majority of Healthcare Providers believe that they have observed treatment failure due to defect in quality of NAFDAC registered drugs/medicines. The Healthcare Provider was expected to pick which link(s) were/was responsible for the treatment failure to establish that the treatment failure was due to the drug product. This is with respect to the fact that treatment in failure can result from other flaws for instance wrong diagnosis made or wrong drugs given to a patient or the patient takes sub-optimal dose, or drug resistance or non-adherence from the patient or drug interactions and so on. The first two links are (1) taking the drug sample to a drug analyst for content analysis and (2) doing dissolution/ bioequivalence studies of the drug product. These first two are more reliable than the third which is basing it on the patient's poor response for reasons already mentioned above. There was almost no affirmative response for the first two while there was a high affirmative response for basing the treatment failure on the patient's poor response. What did affect this result was that every respondent that answered "no" for 'Have you ever observed treatment failure due to defect in the quality of NAFDAC registered drugs/medicines?' a "no" will mean that the respondent will not fill in questions concerning the link. It was filled in as 'no' automatically when imputing the data. 45.7% have ever handled a counterfeit product, 47.3% never did while 7% do not know. There is thus evidence that counterfeit products come into the hands of healthcare providers often unwittingly. Common comments about action taken upon realizing a counterfeit product were that the Healthcare Provider did not use the product, it was thrown away, it was discarded, and it was returned to the place of purchase

and so on. The Healthcare Providers should have uniformity in action to take upon discovering a counterfeit product. The reason is because discarded products could be refilled or relabelled by counterfeiters as WHO defined it.[24,25]

CONCLUSION

In as much as most healthcare workers said they are aware of the policy that empowers NAFDAC to carry out its duties, most said they are aware of laws/legislations that concerns health care providers' handling of food and drugs, the claims were not supported as many healthcare workers were not aware of their responsibilities as partakers in food and drug regulatory affairs. This is because in practice only few have been involved in recall, pharmacovigilance reporting and other responsibilities in professional practice. Most health care providers have the perception that the food and drug regulatory agency in Nigeria has progressed but still with flaws in the area of communicating information, collaboration, implementation of policies, political pressure, media advertisements, recall supervisions, pharmacovigilance and drug counterfeiting. Healthcare providers should also be allowed to make rational decisions in instances of non-availability of unregistered products or for drugs used in the treatment of neglected or rare diseases. This is because such drugs may not be easily available and when in need, it may be too urgent to consider insisting on registered products. The quality of drugs that Healthcare Providers utilize is in strong terms affected by the unorganized drug distribution network. It affects the practice of Healthcare providers as patient's response to treatment is compromised by substandard spurious falsely-labelled falsified counterfeit medical products or in cases where products lose their potency in the course of transportation or handling. The Food and Drug regulatory authority needs to increase collaboration with healthcare providers through amicable approach and involvement in activities, and relevant agencies and re-strategize in methods that need review to achieve its set goals.

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