**Journal of Science and Practice of Pharmacy**
December 2018; 5 (2): 256-266 Available at http://www.jsppharm.org
**ISSN:** 2449-0458 (print); 2449-0466 (electronic)


**Original Research Article**

# Development of an updated version of NAFDAC drug labelling regulation: Perspective of healthcare providers in Lagos, Nigeria

**Rametu O Momodu[1]*, Waka A Udezi[2]**

[1]Drug Evaluation and Research, NAFDAC Office Complex, Isolo Industrial Estate, Isolo, Lagos, [2]Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy, University of Benin, Benin City

*For correspondence: *Email: momodurametu@yahoo.com. Tel: +234803315977*

## Abstract

**Purpose:** The general objective of this study was to demonstrate how responses from stakeholders can be used to update regulations that affect healthcare. Specifically, we aim to measure the level of satisfaction of healthcare practitioners with the elements in the current NAFDAC drug labelling regulations and propose an expanded version as an update of the regulation for use by NAFDAC in Nigeria.

**Methods:** Two structured questionnaires were developed from NAFDAC labeling check list used in vetting manufacturers' proposed product labels and from items that are not part of the current NAFDAC regulations but have been listed by WHO and other international regulatory bodies as essential elements in protecting the health of the public. These instruments were then used to collect data from healthcare providers in Lagos, Nigeria. A Likert scale of 1-5 was used to measure how satisfied respondents will be in having any of the items as part of NAFDAC labeling regulation. Cronbach's alpha, factor loading and summary mean scores that indicate level of satisfaction for a specific item were computed. A score ≥3.0 was interpreted as having a high level of satisfaction or acceptance with the implication that such items should be part of the labeling regulations. Inferential analysis was done and values of $P<0.05$ were interpreted as significant.

**Results:** The satisfaction score for the current NAFDAC labeling regulatory items ranged from 4.02 to 4.67 and 3.47 to 4.51 for proposed items to be added. Thus giving a range of 3.47 to 4.67 for an expanded or updated labeling regulation. Stating the direction for reconstitution on labels on bottles of dry powder medications for reconstitution had the highest satisfaction score of 4.67 ± 1.03 for the current NAFDAC regulations. 'Ensuring adequate font size' had the highest mean score in the updated version (4.51 ± 0.79). Doctors seemed to significantly have a higher level of satisfaction for the updated regulations in all the extracted components except in components which deal with drug compounding and safety where pharmacists had the greatest level of satisfaction $p<0.05$.

**Conclusion:** The current NAFDAC drug labeling regulation is found to be satisfactory, and an expanded version of the regulation that contains new labeling elements to eliminate some of its limitations was also highly rated by healthcare providers.

**Keywords:** Satisfaction, drug label, regulation, NAFDAC

**Indexing:** Index Copernicus, African Index Medicus

## Introduction

All drugs are poisons and a lot of dangers are associated with their use. The labeling of a medicine provides useful information about its identity, safety and uses. However, adverse drug events (ADE) have been reported to frequently occur either due to inadequate or ineffective systems of medicine labeling [1]. This often comes as a consequence of errors in adherence with instructions which are usually contained in the label. Patients often misunderstand drug information which consequently results in ADE [2]. ADE and medication errors are a leading cause of death, accounting for over 100,000 American deaths annually [3]. The drug safety system relies on pharmaceutical companies to provide accurate and complete information on

warnings and contraindications to physicians and patients. Frequently, however, this safety information is not effectively communicated to those who prescribe, administer or take the medications. Medicine label provides information on description and identification of a medicinal product and in addition, prevents medication errors by providing detailed therapeutic instructions. These together with information on proper storage and inventory, help in proper dispensing which is crucial in assuring rational drug use [4,5]. Any error can lead to wrong drug, wrong dose, and wrong advice; therefore, it is important that sufficient drug information is presented to aid accurate dispensing [6]. Most medication errors are reported when the drug label does not have proper warning signs [7]. Another drug labeling factor that could lead to medication errors is illegible labeling, inadequate font size and writing style. This could prevent patients from reading the information in the label leading to medication errors [8].

Drug information received by both the consumers and the providers of medicines (health professionals, caregivers, patients and members of the public) has a significant influence on rational drug use. The accuracy and appropriateness of provided information is generally inadequately monitored, and the effectiveness of the existing regulatory framework is uncertain [9]. A major concern of drug labeling regulation and control is improving the quality and scope of the information presented to the prescriber, and other healthcare professionals since drug labels are used as a source of drug information [10-12].

An effective regulatory system plays a significant role in promoting and protecting public health. In preventing or limiting exposure to unsafe products, regulations must seek to provide the scientific basis for ensuring that food and medicinal products are safe, efficacious, and properly labeled [13]. Public health and safety concerns have caused governments to intervene in the activities of the pharmaceutical sector with respect to regulation of medicines [9]. To forestall the occurrence of public health disasters, a proactive, rather than reactive global public health regulatory framework should be developed [13].

The National Agency for Food and Drug Administration and Control (NAFDAC) has specified the content of a medicine label [14] in line with its statutory role. However, it should be noted that the need to draft or review a regulation may be triggered by public health incidences, recommendations from stakeholders, regulatory officers or observations from international health agencies. These observations are written out as a proposed regulation that is circulated electronically amongst the standards and regulation committee(SRC)members of NAFDAC for comments; when the comments are incorporated it becomes a draft regulation which is then posted on the NAFDAC website for 3 months. At this point stakeholders and sectorial groups are expected to make inputs which the SRC uses to update the draft regulation and it becomes a provisional regulation. This is sent to the NAFDAC council for consideration and endorsement, then to the honorable minister of health for approval and to the federal ministry of justice for legal drafting. Finally, it goes to the federal printing press for printing and gazzeting. The gazetted regulations are distributed by the registration directorate of NAFDAC.

This process of developing or updating a regulation appears to have some perceived limitations (especially in the passive 3 months period). Internet penetration in Nigeria is low and expensive and most stakeholders may not even be aware that such a process is going on or that there is a document that requires their input online. This is likely to reduce the robust participation of healthcare practitioners in the process. It is important that the Drug labeling regulation is adequate in scope to ensure that drug information presented in labels are accurate, unbiased and factual with strong active participation from local stakeholders (healthcare professionals and members of the public whose health will be directly impacted by the regulation).

Therefore, the general objective of this study was to demonstrate how survey responses from healthcare providers who are local stakeholders can be used to update regulations that affect healthcare. Specifically, we aimed to measure the level of satisfaction of healthcare practitioners with the elements in the current NAFDAC drug labelling regulations and propose an expanded version that contains locally evaluated elements as an update of the regulation to meet best global practice for use by NAFDAC in Nigeria.

## Methods

### *Setting*

This study was carried out in Lagos, Nigeria. It has twenty (20) local government areas and is often described as one of the fastest growing cities in the world with a population of 24million. About 65% of the population is between15-35years. Lagos has many hospitals, medical facilities as well as registered pharmacies. The Lagos healthcare system is generally divided into public and private sectors which provide medical services at the primary, secondary and tertiary levels.

### *The instruments*

Each of the instruments used in this study was a two part questionnaire. The first part was used to collect demographic data such as age, gender, profession and years of experience. The second part of the first questionnaire consisted of 24 items taken from NAFDAC labeling check list used in vetting submitted manufacturers' labels. In the second questionnaire, the second part consisted of 14 items which are currently not part of the NAFDAC regulations but have been listed by WHO and other international organizations. These 14 items have not been previously evaluated in Nigeria. Some of the items in the two questionnaires were then negatively worded to prevent mechanical responses and used in constructing a likert scale to measure how satisfied respondents will be in having the items as part of NAFDAC regulation. The response stem was as follows: 1= strongly dissatisfied, 2 = dissatisfied, 3 = undecided, 4= satisfied and 5 = very satisfied.

### *Sample*

The sample used in the study consists of healthcare providers (Doctors, Nurses and Pharmacists) who are practicing in Lagos metropolis and have given their consent to participate in the study. Sample size was determined with the aid of Raosoft sample size calculator to be 500 at 95% confidence interval with a margin of error of 4.33% for an unknown population.

### *Data collection*

A list of all the Pharmacists, Doctors and Nurses, registered in the previous year, residing in Lagos was obtained from their professional bodies with their practice addresses. Using a lottery technique, a list of those to approach for participation was drawn up. The workplace of the selected participant was then visited to administer the questionnaire. Where consent was not granted the next in the list was approached for recruitment. It was a self-administered questionnaire and effort was made to ensure completion of the items at the point of administration. Where immediate response was not possible several attempts were made to collect the questionnaire within the following two months.

### *Data analysis*

The returned questionnaires were coded and typed into Microsoft Excel after reversing the scores of negatively worded items. It was then cleaned and sorted before calculation of mean, standard deviation and percentages. The data was then loaded into SPSS 21.0 (SPSS Inc., Chicago, IL) for calculation of Cronbach's alpha and factor loading. A Likert type summation of scores was employed in the second section of the two questionnaires. The mean scores of each of the 24 and 14 items were calculated on a scale of 1.0 to 5.0 in the computation of level of satisfaction; hence, a score greater than 3.0 was interpreted as having a high level of satisfaction or acceptance with the implication that such items should be part of the labeling regulations.

All such items from the two instruments were then combined to form an expanded regulation for further analysis. The combined items' internal consistency (38) was explored by the computation of Cronbach's alpha. Principal component analysis employed Varimax rotation with Kaiser Normalization of commonalities and listwise deletion of missing data. None of the items loaded below 0.4 hence none of the selected regulatory items was deleted since they contributed adequately to the summary scores.

Possible association between levels of satisfaction with the expanded version of the labeling regulation with demographic variables was further investigated using student's t-test or one-way analysis of variance where applicable with the aid of GraphPad Instat 3.0 that reports exact P-values. Values of $P < 0.05$ were interpreted as significant.

# Results

Six hundred questionnaires were distributed of which 521 usable responses were returned giving a response rate of 86.8%. Of the 521 participants, 280 (53.7%) were males. The rest were females (47.3%). A majority of the subjects were doctors 250 (48%) while pharmacists were 200 (38.4%); the rest were nurses.

About 48% of the participants were aged 35-54 years and about 25% (132) and 24% (123) of respondents had 5-9 years and greater than 20 years' experience respectively. See Table 1.

**Table 1:** Demographic factors of respondents (N=521)

| Variable | Number responding | Percentage |
|---|---|---|
| **Profession** | | |
| Doctor | 250 | 48.0 |
| Pharmacist | 200 | 38.4 |
| Nurse | 71 | 13.6 |
| **Age (years)** | | |
| <25 | 57 | 10.9 |
| 25-34 | 168 | 32.2 |
| 35-44 | 143 | 27.4 |
| 45-54 | 105 | 20.2 |
| ≥55 | 48 | 9.2 |
| **Years of experience (years)** | | |
| <5 | 108 | 20.7 |
| 5-9 | 132 | 25.3 |
| 10-14 | 92 | 17.7 |
| 15-19 | 66 | 12.7 |
| ≥20 | 123 | 23.6 |
| **Sex** | | |
| Male | 280 | 53.7 |
| Female | 241 | 46.3 |

The reliability of the questionnaire as determined by Cronbach's alpha was 0.87 (24 items), 0.860 (14 items) and 0.892 (38 items) for the current regulation, proposed regulatory items to be added to the current regulation and the proposed updated regulation respectively. None of the items loaded less than 0.4 showing that each item contributes adequately to summary scores. The range (factor loading) for all three was 0.4-0.9 (See Tables 2, 3 and 4).

The satisfaction scores for the current NAFDAC labeling regulatory items ranged from 4.02 to 4.67. For the proposed items included into the current labeling regulations the satisfaction score ranged from 3.47 to 4.51 while the proposed updated regulation had a satisfaction score range of 3.47 to 4.67. Items that dealt with disposal of hazardous/toxic medicines, not having a label that imitates that of another similar product and having a blank space for labeling on the product packs to improve legibility had mean scores of 4.43 ± 1.01, 4.50 ± 0.98 and 4.26 ± 0.91 respectively (see Table 4).

The question, "Pictorials on prescription only medicines is not okay" appears to be the item with the lowest score of 3.59 ± 1.25 while 'writing the direction for reconstitution on the labels of bottles containing powders' had the highest satisfaction score of 4.67 ± 1.03 for the current NAFDAC regulations. Declaring all excipients used in the drug had the lowest satisfaction score in the updated version of the regulation (3.47 ± 1.20). Component 4 of the updated regulation which had items that had to do with storage, use in pregnancy and font size to allow for easy reading of label had the highest satisfaction score of 4.57 ± 0.77. The extracted components (1-10) of the proposed expanded regulation were significantly different ($P < 0.0001$).

In the updated regulation, those aged 45-54years appear to be more satisfied with aspects of the regulation that require excipients and sweetening agents to be declared (component 10 in Table 4) compared to other respondents ($P=0.038$) while those who are aged 25-54 years old with 10years work experience were more likely to be dissatisfied with statements like 'more powerful drugs' on labels and more satisfied with the inclusion of direction for reconstitution of powdered syrups on labels (component 9; $P=0.0186$). Women appeared to be more satisfied with aspects that help to trace the source of drugs and contra-indication (component 8) compared to men ($p=0.0083$). In general, doctors seemed to significantly have a higher level of satisfaction for the updated regulations in all the components shown in Table 10 except components 5 and 10 (which deals with drug compounding and safety) where pharmacists had the greatest level of satisfaction at $p<0.05$.

**Table 2:** Factor loading and mean current regulation score for healthcare professionals (N=521)

| Item | Factor loading | Mean ± SD |
|---|---|---|
| **Component 1** | | |
| It is important that the side effects are clearly written in the insert or leaflet (paper inside the packet) | 0.531 | 4.61 ± 0.82 |
| It is important to state the pharmacological action of the drug (what the drug does in the body) | 0.663 | 4.36 ± 1.02 |
| It is important to have a patient information leaflet on all medicines to explain the characteristics of the drug to patients in simple language. | 0.622 | 4.02 ± 1.32 |
| It is important to indicate the volume strength i.e. total quantity in total volume (mg/ml) in the inner and outer label. | 0.674 | 4.45 ± 0.90 |
| It is important that the name of the drug, strength and pharmaceutical form should appear on the blister. | 0.672 | 4.38 ± 0.96 |
| Sub-mean total | | 4.36 ± 1.00 |
| **Component 2:** | | |
| The brand name of a drug product does need to be clearly stated. | 0.740 | 4.41 ± 1.06 |
| It is important to have the name/ address of the distributor/ local company on the outer package | 0.471 | 4.28 ± 1.22 |
| It is necessary to state the pharmacological class of the drug. | 0.642 | 4.32 ± 1.11 |
| Pictorial on prescription only medicine is not okay | 0.636 | 3.59 ± 1.25 |
| Sub-mean total | | 4.15 ± 1.16 |
| **Component 3:** | | |
| The Batch No. , date of manufacture and expiry date should be clearly stated. | 0.771 | 4.56 ± 1.08 |
| All drugs should have package inserts or leaflet | 0.495 | 4.55 ± 0.92 |
| It is important to have information on symptoms of overdose and management of overdose on the leaflet | 0.737 | 4.45 ± 1.12 |
| Sub-mean total | | 4.52 ± 1.04 |
| **Component 4:** | | |
| The drug should not have a package/label that looks like another drug's package/label | 0.701 | 4.50 ± 0.98 |
| It is important to state clearly the active constituents and strength of the drug | 0.634 | 4.49 ± 1.15 |
| It is important to have the name of the manufacturer on the package. | 0.412 | 4.39 ± 1.56 |
| Sub-mean total | | 4.46 ± 1.23 |
| **Component 5:** | | |
| It is important to include a calibrated spoon or measuring cup in the packet of liquid preparations. | 0.696 | 4.36 ± 1.18 |
| The mark for the quantity of water to be added for reconstitution should be indicated on the label or bottle | 0.777 | 4.35 ± 1.26 |
| The direction for reconstitution is necessary on the label on the bottle | 0.564 | 4.67 ± 1.03 |
| Sub-mean total | | 4.46 ± 1.16 |
| **Component 6:** | | |
| The information on how to store the drug should be stated. | 0.772 | 4.57 ± 0.77 |
| It is important to state special warnings such as use during pregnancy, lactation and other special population | 0.756 | 4.63 ± 0.75 |
| Sub-mean total | | 4.60 ± 0.76 |
| **Component 7:** | | |
| It is necessary to have the NAFDAC Reg. No. on the blister pack or ampoules | 0.729 | 4.35 ± 1.23 |
| The information on caution or warnings are important | 0.722 | 4.27 ± 0.94 |
| Sub-mean total | | 4.31 ± 1.09 |
| **Component 8:** | | |
| It is important to have the name/address of the manufacturer on the paper inside the packet of the medicine. | 0.542 | 4.54 ± 0.97 |
| It is important to have information on conditions when the drug should not be taken (contra indications) | 0.799 | 4.58 ± 0.97 |
| Sub-mean total | | 4.56 ± 0.97 |

**Table 3:** Factor loading and mean proposed regulation score for healthcare professionals (N=521)

| Item | Factor loading | Mean ± SD |
|---|---|---|
| **Component 1** | | |
| The font size used for labeling should be big enough to allow easy reading. | 0.400 | 4.51 ± 0.79 |
| The name of the product should appear on at least 3 non-opposing faces of the pack to aid accurate identification of the drug; lead-face of the pack, front face and side face should have the name of the product. | 0.743 | 4.16 ± 1.05 |
| It is important that product packs (Prescription Only Medicine) should have a blank space for the dispensing label or a color on the pack that will not interfere with the legibility of the dispensing label. | 0.790 | 4.26 ± 0.91 |
| It is important that calendar packs for tablets/capsules taken as a single dose or twice daily be supplied in blister packs of 7 and labeled with the days of the week. | 0.821 | 4.03 ± 1.10 |
| Sub-mean total | | 4.24 ± 0.96 |
| **Component 2:** | | |
| It is important to include information like the name of the product in Braille on the packaging so that Blind or partially sighted persons can read it | 0.630 | 3.74 ± 1.08 |
| The leaflet approval date and version should be stated | 0.640 | 4.18 ± 1.14 |
| It is important to include on labeling the contact details of place to report any adverse effects on the labeling. | 0.586 | 4.32 ± 1.03 |
| It is important to state any special disposal conditions for hazardous/toxic medicines e.g. anticancer, radiopharmaceuticals. | 0.701 | 4.43 ± 1.01 |
| Sub-mean total | | 4.17 ± 0.96 |
| **Component 3:** | | |
| It is important to include in the label of injections, eye drops and topical medicines (oral, nasal, rectal, vaginal, inhalations) the other substances in the medicines apart from the active ingredient in (with recognized action) | 0.592 | 3.96 ± 1.38 |
| It is important that the name or logo of the marketing authorization holder should appear on the blister. | 0.751 | 3.80 ± 1.32 |
| It is important to have the name/address of the distributor/local company on the label on the blister/primary pack | 0.533 | 4.06 ± 1.28 |
| Sub-mean total | | 3.88 ± 1.35 |
| **Component 4:** | | |
| Statement like “more powerful drug” or “best for you” or “we make better drugs” on labels is not acceptable | 0.900 | 4.18 ± 1.08 |
| Sub-mean total | | 4.18 ± 1.08 |
| **Component 5:** | | |
| It is important to declare all the excipients used in the drug | 0.791 | 3.47 ± 1.20 |
| It is important to declare any sweetening agent used in syrups | 0.773 | 3.70 ± 1.34 |
| Sub-mean total | | 3.59 ± 1.27 |

**Table 4:** Factor loading and mean combined regulation score for healthcare professionals (N=521)

| Item | Factor loading | Mean ± SD |
|---|---|---|
| Component 1 | | |
| It is important to state the pharmacological action of the drug (what the drug does in the body) | 0.508 | 4.36 ± 1.02 |
| It is important to include information like the name of the product in Braille on the packaging so that Blind or partially sighted persons can read it | 0.477 | 3.74 ± 1.08 |
| The leaflet approval date and version should be stated | 0.603 | 4.18 ± 1.14 |
| It is important to include on labeling the contact details of place to report any adverse effects on the labeling. | 0.539 | 4.32 ± 1.03 |
| It is important to state any special disposal conditions for hazardous/toxic medicines e.g. anticancer, radiopharmaceuticals. | 0.674 | 4.43 ± 1.01 |
| It is important to have a patient information leaflet on all medicines to explain the characteristics of the drug to patients in simple language. | 0.604 | 4.02 ± 1.32 |
| It is important to indicate the volume strength i.e. total quantity in total volume (mg/ml) in the inner and outer label. | 0.452 | 4.45 ± 0.90 |
| Sub-mean total | | 4.21 ± 1.07 |
| **Component 2:** | | |
| The name of the product should appear on at least 3 non-opposing faces of the pack | 0.712 | 4.16 ± 1.05 |

| | | |
|---|---|---|
| to aid accurate identification of the drug; lead-face of the pack, front face and side face should have the name of the product. | | |
| It is important that product packs (Prescription Only Medicine) should have a blank space for the dispensing label or a color on the pack that will not interfere with the legibility of the dispensing label. | 0.701 | 4.26 ± 0.91 |
| It is important that calendar packs for tablets/capsules taken as a single dose or twice daily be supplied in blister packs of 7 and labeled with the days of the week. | 0.808 | 4.03 ± 1.10 |
| It is important that the name of the drug, strength and pharmaceutical form should appear on the blister. | 0.500 | 4.38 ± 0.96 |
| Sub-mean total | | 4.21 ± 1.01 |
| **Component 3:** | | |
| The brand name of a drug product needs to be clearly stated. | 0.677 | 4.41 ± 1.06 |
| It is important to have the name/address of the distributor/local company on the label on the blister/primary pack | 0.510 | 4.28 ± 1.22 |
| It is necessary to state the pharmacological class of the drug. | 0.532 | 4.32 ± 1.11 |
| Pictorial on prescription only medicine is not okay | 0.658 | 3.59 ± 1.25 |
| It is important to include in the label of injections, eye drops and topical medicines (oral, nasal, rectal, vaginal, inhalations) the other substances in the medicines apart from the active ingredient in(with recognized action) | 0.417 | 3.96 ± 1.38 |
| Sub-mean total | | 4.33 ± 1.20 |
| **Component 4:** | | |
| The information on how to store the drug should be stated. | 0.786 | 4.57 ± 0.77 |
| It is important to state special warnings such as use during pregnancy, lactation and other special population | 0.738 | 4.63 ± 0.75 |
| The font size used for labeling should be big enough to allow easy reading. | 0.690 | 4.51 ± 0.79 |
| Sub-mean total | | 4.57 ± 0.77 |
| **Component 5:** | | |
| The Batch No. , date of manufacture and expiry date should be clearly stated. | 0.754 | 4.56 ± 1.08 |
| It is important to have information on symptoms of overdose and management of overdose on the leaflet | 0.719 | 4.45 ± 1.12 |
| It is important that the side effects are clearly written in the insert or leaflet (paper inside the packet) | 0.462 | 4.61 ± 0.82 |
| Sub-mean total | | 4.54 ± 1.01 |
| **Component 6:** | | |
| The drug cannot have a package/label that looks like another drug's package/label | 0.663 | 4.50 ± 0.98 |
| It is important to state clearly the active constituents and strength of the drug | 0.528 | 4.49 ± 1.15 |
| All drugs should have package inserts or leaflet | 0.517 | 4.55 ± 1.32 |
| Sub-mean total | | 4.51 ± 1.15 |
| **Component 7:** | | |
| It is important to have the name of the manufacturer on the package. | 0.400 | 4.39 ± 1.56 |
| It is necessary to have the NAFDAC Reg. No. on the blister pack or ampoules | 0.735 | 4.35 ± 1.23 |
| It is important that the name or logo of the marketing authorization holder should appear on the blister. | 0.630 | 3.80 ± 1.32 |
| The information on caution or warnings are important | 0.512 | 4.27 ± 0.94 |
| Sub-mean total | | 4.20 ± 1.26 |
| **Component 8:** | | |
| It is important to have the name/address of the manufacturer on the paper inside the packet of the medicine. | 0.515 | 4.54 ± 0.97 |
| It is important to have information on conditions when the drug should not be taken (contra indications) | 0.780 | 4.58 ± 0.97 |
| It is important to have the name/address of the distributor/local company on the label on the blister/primary pack | 0.533 | 4.06 ± 1.28 |
| Sub-mean total | | 4.39 ± 1.07 |
| **Component 9:** | | |
| Statement like “more powerful drug” or “best for you” or “we make better drugs” on labels is not acceptable | 0.452 | 4.18 ± 1.08 |
| It is important to include a calibrated spoon or measuring cup in the packet of liquid preparations. | 0.628 | 4.36 ± 1.18 |
| The mark for the quantity of water to be added for reconstitution should be indicated on the label or bottle | 0.724 | 4.35 ± 1.26 |
| The direction for reconstitution is necessary on the label on the bottle | 0.548 | 4.67 ± 1.03 |
| Sub-mean total | | |

| | | |
|---|---|---|
| **Component 10:** | | |
| It is important to declare all the excipients used in the drug | 0.690 | 3.47 ± 1.20 |
| It is important to declare any sweetening agent used in syrups | 0.735 | 3.70 ± 1.34 |
| Sub-mean total | | 3.59 ± 1.27 |

**Table 5:** Relationship between demographic factors and combined labelling regulation for healthcare professionals

| Variable | Frequency | Components' Score ± SD | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
| **Sex** | | | | | | | | | | | |
| Male | 280 | 4.14 ± 0.71 | 4.19 ± 0.80 | 4.04 ± 0.81 | 4.59 ± 0.59 | 4.52 ± 0.75 | 4.47 ± 0.79 | 4.16 ± 0.82 | 4.34 ± 0.91 | 4.33 ± 0.82 | 3.6 ± 0.94 |
| Female | 241 | 4.24 ± 0.66 | 4.23 ± 0.82 | 4.10 ± 0.78 | 4.53 ± 0.67 | 4.57 ± 0.78 | 4.56 ± 0.66 | 4.23 ± 0.75 | 4.53 ± 0.69 | 4.35 ± 0.82 | 3.5 ± 0.93 |
| P-Value | | 0.0691 | 0.5740 | 0.3915 | 0.2776 | 0.4567 | 0.1628 | 0.3127 | 0.0083 | 0.7814 | 0.2740 |
| **Age (yrs)** | | | | | | | | | | | |
| <25 | 57 | 4.30 ± 0.66 | 4.11 ± 0.86 | 3.88 ± 0.93 | 4.43 ± 0.84 | 4.55 ± 0.88 | 4.43 ± 0.85 | 4.12 ± 0.67 | 4. 50 ± 0.77 | 4.11 ± 0.92 | 3.3 ±0.97 |
| 25-34 | 168 | 4.22 ± 0.75 | 4.23 ± 0.83 | 4.17 ± 0.76 | 4.55 ± 0.67 | 4.58 ± 0.66 | 4.51 ± 0.80 | 4.15 ± 0.91 | 4.52 ± 0.70 | 4.30 ± 0.86 | 3.5 ± 0.89 |
| 35-44 | 143 | 4.29 ± 0.63 | 4.29 ± 0.76 | 4.14 ± 0.78 | 4.58 ± 0.55 | 0.51 ± 0.82 | 4.53 ± 0.73 | 4.29 ± 0.75 | 4.52 ± 0.70 | 4.30 ± 0.84 | 3.5 ± 0.95 |
| 45-54 | 105 | 4.10 ± 0.66 | 4.07 ± 0.79 | 3.95 ± 0.76 | 4.62 ± 0.58 | 4. 4 ± 0.86 | 4.54 ± 0.60 | 4.21 ± 0.72 | 4.38 ± 0.75 | 4.48 ± 0.67 | 3.8 ± 0.96 |
| ≥55 | 48 | 4.13 ± 0.76 | 4.28 ± 0.81 | 3.97 ± 0.86 | 4.65 ± 0.54 | 4.65 ± 0.60 | 4.52 ± 0.65 | 4.20 ± 0.70 | 4.26 ± 0.83 | 4.56 ± 0.70 | 3.5 ± 0.88 |
| P-Value | | 0.1885 | 0.2068 | 0.0001 | 0.3529 | 0.6397 | 0.9177 | 0.4071 | 0.1329 | 0.0186 | 0.0381 |
| **Profession** | | | | | | | | | | | |
| Doctor | 250 | 4.39 ± 0.07 | 4.43 ± 0.78 | 4.37 ± 0.74 | 4.56 ± 0.60 | 4.58 ± 0.82 | 4.60 ± 0.82 | 4.48 ± 0.61 | 4.64 ± 0.65 | 4.42 ± 0.76 | 3.42 ± 0.81 |
| Pharmacist | 200 | 4.03 ± 0.65 | 4.05 ± 0.67 | 3.79 ± 0.71 | 4.62 ± 0.60 | 4.59 ± 0.65 | 4.47 ± 0.61 | 4.13 ± 0.68 | 4.27 ± 0.78 | 4.35 ± 0.80 | 3.77 ± 0.10 |
| Nurse | 71 | 4.09 ± 0.74 | 3.87 ± 1.02 | 3.77 ± 0.85 | 4.44 ± 0.66 | 4.25 ± 0.82 | 4.31 ± 0.71 | 3.43 ± 1.02 | 4.39 ± 0.72 | 4.00 ± 0.98 | 3.42 ± 1.07 |
| P-value | | 0.0001 | 0.0001 | 0.0001 | 0.0991 | 0.0082 | 0.0001 | 0.0001 | 0.0001 | 0.0001 | 0.0001 |
| **Years of Experience (yrs)** | | | | | | | | | | | |
| <5 | 108 | 4.12 ± 0.07 | 4.14 ± 0.82 | 3.98 ± 0.80 | 4.41 ± 0.87 | 4.43 ± 0.86 | 4.29 ± 0.97 | 3.97 ± 0.91 | 4.44 ± 0.76 | 4.16 ± 0.86 | 3.46 ± 0.99 |
| 5-9 | 132 | 4.23 ± 0.73 | 4.18 ± 0.84 | 4.11 ± 0.82 | 4.61 ± 0.55 | 4. 59 ± 0.68 | 4.57 ± 0.66 | 4.20 ± 0.79 | 4.48 ± 0.71 | 4.22 ± 0.94 | 3.60 ± 0.92 |
| 10-14 | 92 | 4.34 ± 0.63 | 4.35 ± 0.74 | 4.21 ± 0.78 | 4.62 ± 0.52 | 4.50 ± 0.82 | 4.58 ± 0.75 | 4.38 ± 0.77 | 4.58 ± 0.69 | 4.33 ± 0.80 | 3.57 ± 0.86 |
| 15-19 | 66 | 4.23 ± 0.73 | 4.34 ± 0.78 | 4.07 ± 0.80 | 4.54 ± 0.50 | 4.57 ± 0.80 | 4.57 ± 0.62 | 4.24 ± 0.79 | 4.58 ± 0.63 | 4.54 ± 0.61 | 3.64 ± 0.10 |
| >20 | 123 | 4. 11 ± 0.66 | 4.12 ± 0.80 | 3.10 ± 0.78 | 4.64 ± 0.58 | 4.60 ± 0.71 | 4.57 ± 0.58 | 4.25 ± 0.62 | 4.32 ± 0.79 | 4.52 ± 0.70 | 3.66 ± 0.91 |
| P-value | | 0.0464 | 0.1374 | 0.0001 | 0.0443 | 0.4235 | 0.0130 | 0.0049 | 0.0622 | 0.0008 | 0.5057 |

# Discussion

Healthcare providers play a critical role as they are established as a source of drug information to patients. Their role in reduction of incidence of medication errors cannot be overemphasized. Proper dispensing promotes rational drug use and labeling has been identified as one of the key factors that affects dispensing. Healthcare providers have been reported to use drug labels as source of drug information and their reliance on labels thus plays a role in their dispensing functions. In avoiding irrational drug use, any error or failure in the dispensing process can jeopardize patient care [15], hence the need to

adequately regulate the quality of information available from drug labels. This study validates the important role played by drug labels in ensuring the efficiency of healthcare providers in the discharge of their roles and patient safety. Regulatory authorities play a vital role in regulating the quality of drug information conveyed in drug labels; a critical evaluation of the current NAFDAC labeling regulations shows that there is a need to include more items in the regulation in other to meet up with international best practices otherwise the new items evaluated would have had scores less than the midpoint. Although, healthcare providers were satisfied with the current regulation, findings from this study strongly favor the inclusion of more items in the regulation to meet global best practices.

Such items to be added include using a standard font size in labels to enable easy reading as supported by findings from literature [16,17] and as indicated by the report of the institute for safe medication practices (ISMP) [18]. This is necessary as majority of respondents complained about the font size of labels being too small for easy reading in some medicines currently in circulation. A review suggested that a standardized label format with understandable font and simple language helps patients understand drug information and directions for use. Information is dynamic and new research findings are being released. It is important that drug information is accurate and up to date. This necessitates the inclusion of leaflet approval date and version on leaflets so that updated versions would convey when new discoveries or updates became available while obsolete information can be deleted. Prescribers need to be equipped with quality and up to date drug information so they can answer questions accurately from patients, regulators and other stakeholders. Apart from reducing medication errors it will also improve confidence in the healthcare system.

Adequate disposal conditions of hazardous/toxic medicines' is beneficial in promoting health and safety. This seemed to justify the level of satisfaction indicated by respondents in this study for the inclusion of this item in the proposed labeling regulation. The role of dispensing in promoting rational drug use has been well established. Having identified labeling as one of the factors affecting dispensing [6]; it seems the inclusion that drug packets of prescription only medicine (POM) should have a blank space for the dispensing label or a color on the pack that will not interfere with the legibility of the dispensing label is a desired requirement. This finding is similar to a previous study [19].

As suggested by Fasting and Grisvold (2002), medicine label provides information that protect patients against medication errors by providing detailed therapeutic and storage instructions that also aid proper dispensing [4]. This element as part of the updated regulation has the potential to reduce dispensing errors. Findings from this study favour the inclusion of contact details or a place to report any adverse effects on the labeling of drug products. This will aid pharmacovigilance which is identifying hazards associated with drug products and minimizing risk of any harm that may affect users of the products. As this is now captured in the proposed updated regulation; if implemented will aid post marketing surveillance activities of pharmaceutical companies and the regulatory authority through reports sent to pharmacovigilance centers. This study also indicates that drug products with look-alike labels should be discouraged. Several case studies exist which discourage look-alike packaging because of the potential for medication errors and fatalities [20,21].

This study used a survey to collect data from healthcare providers in Lagos to update NAFDAC drug labelling regulation. The satisfaction scores appear to confirm that it is a valid way of quickly updating healthcare regulation with the involvement of local stakeholders. In addition, doctors appear to be more satisfied with the proposed expanded regulation in all the extracted components possibly because of their patient oriented training; while pharmacists in line with their training showed more satisfaction with aspects of the regulation that deals with drug manufacturing and safety. This gives the impression that the coverage of the expanded regulation is broad in terms of protecting public health.

Therefore, based on the results, the possibility exists that the expanded regulation will contribute in the following areas: Prevention of bias in presenting products' information by eliminating/justifying use of statements like 'more powerful drug', 'best for you' and other unacceptable adjectives used in promoting medicine use, improved presentation of product information to visually impaired patients,

promote dosage adherence when products are supplied in calendar packs and listing of excipients and sweetening agents to reduce the possibility of subjecting patients with hypersensitivity reactions to the declared allergens used as excipients or sweeteners.

## Conclusion

Healthcare provider's level of satisfaction with the current NAFDAC drug labeling regulation was high despite its limited coverage of key labeling elements. An updated or expanded version of the regulation to eliminate the limitations of the current regulation was equally rated highly in terms of satisfaction. Pharmacists had the greatest level of satisfaction for the aspects of the regulation that dealt with drug manufacturing and safety while doctors were satisfied with all the other components of the expanded regulation produced by this study when compared to other healthcare practitioners.

## Conflict of Interest

No conflict of interest is associated with this work.

## Contribution of Authors

Both authors contributed equally in all aspects relating to conception, design, data collection, analysis and interpretation including the final write up of the paper.

## References


1. Vredenburgh AG, Zackowitz IB. Drug labeling and its impact on patient safety. Work. 2009;33(2):169-74.
2. Gandhi TK, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, Seger DL, Shu K, Federico F, Leape LL, Bates DW. Adverse drug events in ambulatory care. New England Journal of Medicine. 2003;348(16):1556-64.
3. Fortescue EB, Kaushal R, Landrigan CP, McKenna KJ, Clapp MD, Federico F, Goldmann DA, Bates DW. Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients. Pediatrics. 2003;111(4):722-9.
4. Fasting S, Gisvold SE. Adverse drug errors in anesthesia, and the impact of coloured syringe labels. Canadian journal of anaesthesia. 2000;47(11):1060.
5. Agrawal P, Sachan A, Singla RK, Jain P. Statistical Analysis of Medication Errors in Delhi, India. Indo Global Journal of Pharmaceutical Sciences. 2012;2(1):88-97.
6. Balzer F, Wickboldt N, Spies C, Walder B, Goncerut J, Citerio G, Rhodes A, Kastrup M, Boemke W. Standardized drug labelling in intensive care: results of an international survey among ESICM members. Intensive care medicine. 2012;38 (8):1298-305.
7. Lisby M, Nielsen LP, Brock B, Mainz J. How are medication errors defined? A systematic literature review of definitions and characteristics. International Journal for Quality in Health Care. 2010;22(6):507-18.
8. Davis TC, Federman AD, Bass PF, Jackson RH, Middlebrooks M, Parker RM, Wolf MS. Improving patient understanding of prescription drug label instructions. Journal of general internal medicine. 2009;24(1):57-62.
9. Smith BJ, Tang KC, Nutbeam D. WHO health promotion glossary: new terms. Health promotion international. 2006;21(4):340-5.
10. Kornfield R, Donohue J, Berndt ER, Alexander GC. Promotion of prescription drugs to consumers and providers, 2001–2010. PloS one. 2013;8(3):e55504.
11. Ball J, Mackert M. Pharmaceutical advertising practitioners' approach to trust and emotion. International Journal of Pharmaceutical and Healthcare Marketing. 2013;7(3):244-64.
12. James Wooten, Susan Sanders, Christy Seigerwall (2012). Sources for drug information medicine 415R : 1-16
13. Patel M, Miller MA. Impact of regulatory science on global public health. The Kaohsiung journal of medical sciences. 2012 Jul 1;28(7):S5-9.
14. NAFDAC - National Agency for Food and Drugs Administration and Control (2005). National Agency for Food and Drug Administration and Control Decree 1993 No.15; Drug Products Labeling Regulations. Available: http://www.nafdac.gov.ng/drugs.html
15. Hogerzeil HV, Ross-Degnan D, Laing RO, Ofori-Adjei D, Santoso B, Chowdhury AA, Das AM, Kafle KK, Mabadeje AF, Massele AY. Field tests for rational drug use in twelve developing countries. The Lancet. 1993;342(8884):1408-10.
16. Malik M, Hussain A, Amin T, Hashmi A. Role of Drug Labeling in Promoting Rational Dispensing: A Literature Review. Journal of Dental and Medical Sciences 2016;15(12):74-78
17. Wogalter M., Vigilante W. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. Ergonomics. 2003; 46(4):327-344.
18. ISMP-Institute for Safe Medication Practices (2014). Principles of Designing a Medication Label for Community Pharmacy and Mail Order Pharmacy Prescription

Packages.http://www.pharmacytoday.org/article/S1042-0991(15)31570-X/pdf. Accessed 01.05.2018.

19. Shrank W, Avorn J, Rolon C, Shekelle P. Medication safety: Effect of content and format of prescription drug labels on readability, understanding, and medication use: A systematic review. Annals of Pharmacotherapy. 2007;41(5):783-801.
20. McCoy L K., Look-alike, sound-alike drugs review: include look-alike packaging as an additional safety check: Jt Comm J Qual Patient Saf. 2005;31(1):47-53. https://www.ncbi.nlm.nih.gov/pubmed/15691210 accessed 01.05-2018.
21. Nandini M Dave. "Look alike" packaging: Do we need a wake-up call? J Anaesthesiol Clin Pharmacol. 2018; 34(1): 133-134.