Texila International Journal of Public Health
ISSN: 2520-3134
DOI: 10.21522/TIJPH.2013.11.01.Art013

Pictorial Representation on Non-Steroidal Anti-Inflammatory Drugs Product Package and its Influence on Self Medication among Adults in Alimosho LGA, Lagos State, Nigeria

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Abstract

The purpose of this study is to determine the influence of pictorial representation on product packs of NSAIDs on their self-medication among adults in Alimosho Local Government Area (LGA) of Lagos State. The study is a descriptive inferential cross-sectional study that involved the collection of data from adults and secondary data from a regulatory authority. The data collected from questionnaires administered to adults who were randomly selected across the LGA was analyzed to evaluate the association between pictorial representation on product packs and the practice of self-medication. A time series analysis was conducted with secondary data obtained from the National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria's medicine regulatory agency, to determine the possible changes or trends that may have occurred with the availability of NSAIDs with pictorial representation. The respondents who participated in the research were adults who were 18 years and above. Of the 652 respondents, 50.8% were males, and 49.2% were females. Demographic profiles, Information sources, and pictorial influence on product packs of NSAID were tested for association with self-medication. Among respondents, 80.6% admitted that they are self-medicated, and 50.6% of them responded that pictorial representation influenced their decision to purchase NSAIDs. A binary logistic regression was performed to ascertain the association between demographic profile and the influence of pictorial representation on product packs of NSAIDs. The overall model was statistically significant, χ^2 (9) = 33.097, $p < 0.005$. The model explained 1.05% (Nagelkerke R^2) of the variance in a pictorial representation and correctly classified 62.3% of cases.

Keywords: *Alimosho, Attitude, Knowledge, NSAID, Perception, Self-medication.*

Introduction

Nigeria is the most populous country in Sub-Saharan Africa, with wide use of NSAIDs as the drug of treatment for pain and other associated illnesses. Self-medication is a serious health problem in Nigeria due to the frequency of use of NSAIDs in the country. This has a serious negative epidemiological impact due to self-medication practices of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). The challenge of self-medication has become of growing concern as several studies have shown the growing tendency to self-medicate prescription-only NSAIDs. Although the WHO has supported some level of self-medication in developing countries due to poor access to healthcare services and unavailability of trained medical personnel, the issue of risk of self-medication, especially for NSAIDs, call for concern [1]. Patients have been known to experience adverse side effects of NSAIDs and in some cases, face allergic reactions due to issues of contraindication in pregnancy and certain immunocompromised patients. They are

Received: 21.11.2022 ***Accepted: 07.12.2022*** ***Published on: 30.03.2023***
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also known from studies to have self-medicated NSAIDs due to various information sources such as through access to already used product's leaflets, friends, neighbours, unqualified personnel, the internet, and online platform and from other sources [2-4].

The additional burden of graphic pictorial representation on product packs of NSAIDs has led to the disclosure of product indications for self-medication. This study aimed at understanding the health behavior of respondents in the population towards self-medication and to understand or determine if pictorial representation on products pack can influence self-medication of NSAIDs. There are several studies on the determinants, knowledge, awareness, and practice of self-medication of drugs and NSAIDs, but there is no study known to the researcher that speaks to the issue of the influence of pictorial representation on product packs on self-medication of NSAIDs.

The author has used a descriptive quantitative and inferential cross-sectional study to determine the demographic factors and the influence of pictorial representation on self-medication among adults in Alimosho Local Government Area, Lagos State, Nigeria. Several studies have highlighted the increasing trend of inappropriate use of NSAIDs, and this may be attributed to increasing accessibility to prescription-only NSAIDs, availability of information for self-care, easy accessibility to online health information, advertisement, neighbors, friends and family advice, unaffordable cost of conventional healthcare and advise from non-professionals. The ease of accessibility to prescription NSAIDs can lead to multiple drug use with the consequent adverse drug reaction and drug-drug interactions [2, 3]. This can be accentuated by the availability of graphic pictorial representation that describes the indication of the NSAID. For this reason, Section 16b of the NAFDAC Drug Labelling Regulation [4-6] prohibits the inclusion of pictures on the packs of POMs as this may advertise the product to the patient, thereby increasing the exposure of prescription NSAIDs to the patient and lead to serious consequences resulting from Chronic use without doctors advise. This study attempts to understand the relationship between the pictorial representation of pain on use of NSAIDs.

Materials and Methods

The study was conducted in Alimosho Local Government Area (LGA) of Lagos State. Alimosho LGA is the largest LGA in Lagos State with coordinates of 6^0 36'38" N 3^0 17'45" E is made up of a population of 2,047,026 people (1,099,656 males and 947,370 females). It is majorly a sub-urban district in Lagos that occupies a 183 km² area and a population density of 14,812/km². The population in this LGA is a mix of various professionals, artisans, businesspersons, and students from various ethnic groups. Alimosho LGA is the Largest Local Government Area in Lagos State within the Ikeja Division. The Yoruba and English languages are the most spoken language, while Islam and Christianity are the two major religions practiced in the area. Alimosho LGA is surrounded by Ogun State in the Northwest and Western area, Ifako-Ijaiye in the Northeast, Agege, Ikeja, and Oshodi-Isolo on the East, and Amuwo-Odofin and Ojo LGAs in the South. The LGA is sub-divided into six Local Community Development Areas (LCDA), namely Egbeda/Akowonjo LCDA; Ikotun/Igando LCDA; Egbe/Idimu LCDA; Ayobo/Ipaja LCDA; Mosan Okunola LCDA; Agbado/Oke-odo LCDA [7, 8].

Study Design and Study Population

This study is a descriptive, inferential form cross-sectional study with a population comprising of residents selected randomly using purposive sampling from various Enumeration Areas within the six LCDAs in the LGA.

The inclusion criteria for the study would be:

1. Those who gave consent to participate.
2. Those who are 18 years and above.

3. Those who have resided within the area for one year or above.
4. Those who have used any type of NSAID.

The Exclusion Criteria:

1. Those who declined to participate.
2. Those who are below 18 years.
3. Those who have not resided in the area for up to one year.
4. Those who have not used NSAIDs.

Sample Size Determination

The primary data were derived from a sample size determined using the Kish Leslie formula as prescribed by the EpiInfo for descriptive studies, which is n= Z^2 Dp (1-p)/e^2. This involved the use of the 95% Confidence Interval, which falls within Z, corresponding to 1.96 standard deviations for 5% alpha error and to produce a conservative sample size within a precision (e) of 5%. The estimated proportion or prevalence within the target population prevalence (p) was set at 0.5. A complex sampling design that is made of clusters of LCDAs was adopted, and as such, to correct for the difference in design and loss of sampling efficiency, a design effect (D) of 1.5 was assumed [9,10].

$$n = \frac{Z^2 Dp(1-p)}{e^2}$$

n= estimated sample size.

D = design effect.

p = the estimated proportion or prevalence within the target population at the time of the first survey. Because of the nonavailability of such, 0.5 is used.

$Z_{1-\alpha}$ or Z = Describes the level of uncertainty in the sample mean or prevalence as an estimate of the population mean or prevalence. This is put at1.96 (for 95% confidence level) and,

e = precision at 0.05.

$$n = \frac{\{(1.96)^2 \times 1.5 \times 0.5(1.05)\}}{(0.05)^2}$$

$$= \frac{\{(3.8416 \times 1.5 \times 0.25)\}}{0.0025}$$

$$= \frac{1.4406}{0.0025} = 576.24$$

Sampling Technique

In this study, a probability sampling technique was used that considered equal allocation across the six LCDAs that constitute Alimosho LGA. The National Population Commission (NPC) was contacted to provide the list of Enumeration Areas (EAs) which was based on the 2006 National Population Census conducted by the NPC. The list of EAs obtained was used in determining the various communities/enumeration areas from which select EAs would be visited. LCDAs were paired in twos depending on proximity, and each of the pairs were broken down into fifteen EAs each. A total of 45 EAs were purposively sampled with a sample size per EA as 15 per EA. Adult listing per LCDA was used by trained Research Assistants, disaggregating the list by Gender and Enumeration Areas (EAs). Respondents at EA levels were selected based on the inclusion and exclusion Criteria.

Instruments and Measures

An approved standardized questionnaire was used to elicit information from randomly selected respondents. The questionnaire was used to quantify the demographic characteristics, the knowledge, attitudes, and practices of use of NSAIDs, associated risks of self-medication, and adverse reactions to NSAIDs. It was also used to elicit information on the information sources for patients, purchase, and determine the influence of pictorial representation on product pack and self-medication. This survey involved the use of smartphones that had CSEntry downloaded and installed on them. The software called CSpro (Census and survey Processing system) for Laptop/desktop and an App CSEntry (Phone App) was developed by the United States Census Bureau and ICF international. The CSEntry App was downloaded as a user-friendly and easy-to-use free software for data entry, editing, manipulation, tabulation

dissemination, and thematic and Global Positioning System (GPS) mapping [11, 12].

Data Collection and Analysis

The CSPro was used to elicit responses from eligible respondents randomly selected from the sampling frames in the LGA. Potential participants were screened to determine how eligible they were to participate in the study. An explanation was made to those who are not eligible on why they were not selected. The eligible respondents received information from the Participant Information Sheet on confidentiality and were asked to sign the Informed Consent form, which would then be retained by the researchers [13]. The RAs were divided into three groups of five assistants, inclusive of a Team Leader to cover two LCDAs during the period. The LCDAs were divided into already existing communities using the National Population Commission Enumeration List. The RAs were instructed to spread across each town to collect data. They were made to randomly select households with a spread monitored by the GPS monitoring application on the CSPro.

Time series of secondary data obtained from the National Agency for Food and Drug Administration and Control on identified violation records of NSAIDs with pictorial representation were analyzed to observe changes or trends that may have occurred over the period of three years. This helped determine if the trend over time of the availability of NSAIDs with pictorial representation was significant or due to chance. The survey data obtained from field activities and stored in the cloud server (Dropbox) were cleaned and edited and then read into SPSS version 25.0 for analysis.

Chi-squared tests and non-parametric descriptive analysis were employed for the evaluation of the association between demographic characteristics and knowledge, attitude, and practice of self-medication. Also, a binary logistic regression analysis was used to model relationships between respondents' demographic, literacy and socio-economic variables and pictorial representation on products pack [13].

Ethical Consideration

Necessary ethical approval (s) were obtained from the Institutional Review Board based in the Nigeria Institute of Medical Research for the study. Beneficence, informed consent, privacy, and the right to voluntarily withdraw from the study by participants were respected during the research. Respondents were given a Participant Information Sheet to read and properly informed and briefed on the nature of the study, their rights to confidentiality, Informed Consent, and completion of the questionnaire. Each respondent was given an Informed Consent Form before the administration of the questionnaire, and high priority was given to respondents' confidentiality [13].

Results

The respondents who participated in the research were adults who were 18 years and above. Of the 652 respondents, 50.8% were males, and while 49.2% were females. Twenty-seven percent (27%) of the respondents were between 18-25 years, 53.2% were between 26-49 years, 15.2% were between 50-64 years and 4.4% were above 64 years of age. The majority of the respondents were of the Christian Religion (72.9%), Islamic Religion made a 24.8%, Traditional Religion were 1.1% and the remaining respondents made up 1.3% of the respondents. Fifty-five percent (55.8%) of the respondents stated that they were married while 39.3% were singles while 5% of the respondents were either widowed, separated or co-habiting with sexual partners. Fifty seven percent (57%) of respondents had their highest educational attainment as secondary education while 27.5% had one form of tertiary education or the other. Eleven percent (11%) had primary education while 3.8% had no formal education.

54% were businesspersons, 21.6% were artisans, 15.5% were students, 6.4% were civil servants, and 2.5% unemployed. Ninety-four percent (94%) of the respondents have stayed at least a year in the Local Government Area. Eighty-six percent (86%) of respondents indicated that they knew what NSAIDs were with 81.7% stating that they took painkillers. Sixty-two percent (62%) of those who knew and took NSAIDs responded that they did not take NSAIDs based on a doctor's prescription. In this study, 59.5% of the respondents are aware that NSAIDs can cause side effects with 62.3% experiencing side effects and 56.6% experiencing one level of side effect or the other. To understand the attitude of respondents towards self-medication, several questions were asked the respondents, and 78.2% of respondents agree it is always necessary to consult a medical professional before taking any medicines for ailments. When asked about awareness of the hazards of self-medication, 81.9% accepted that they knew that it was risky to practice self-medication.

On pictorial representation, 95.6% of respondents admitted that they had seen NSAIDs with pictorial representation. Twenty-one percent stated that they were ignorant that pictorial representation was not accepted on prescription NSAIDs. When asked if pictorial representation influenced their decision to purchase the product, 50.6% stated that pictorial representation influenced their decision to purchase NSAIDs. Fifty-five percent (55.5%) of those who accepted that pictorial representation influenced their decision to purchase NSAIDs stated that they made the decision to purchase because, with the pictorial representation, they knew the use of the medicine, while 19.4% stated that the pictorial representation appeals to them due to their attractiveness. Despite knowing that pictorial representation is not allowed on NSAIDs, 65.3% responded that they would still purchase the products.

Responses by the participants showed that 23% of respondents used as a pain killer followed by Ibuprofen which accounted for 20% of respondents, and then Diclofenac which accounted for 19% of consumption. The time series analysis showed Diclofenac as the highest imported NSAID within the period under review.

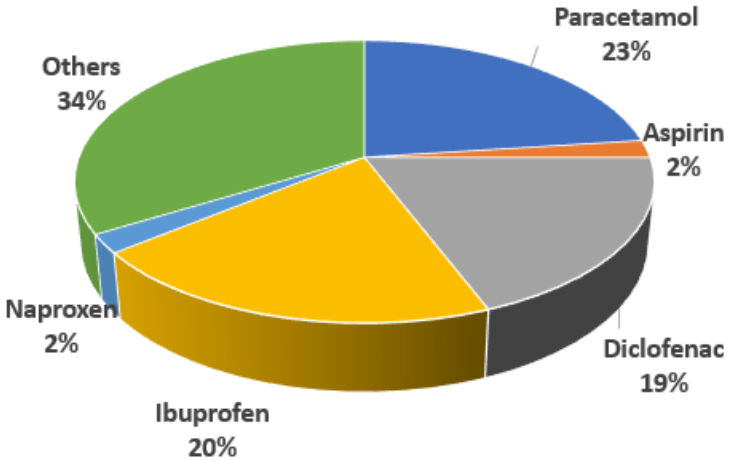

Figure 1. Response of Participants on Self- medication of NSAIDs

Table 1. Demographic Characteristics of Respondents

Gender			**Age**			**Religion**			**Marital Status**		
Variables	**Frequency**	**Valid Percent**	**Variables**	**Frequency**	**Valid Percent**	**Variables**	**Frequency**	**Valid Percent**	**Variables**	**Frequency**	**Valid Percent**
Male	331	50.8	**18 - 25 years**	177	27.1	**Christianity**	475	72.9	**Single**	256	39.3
Female	321	49.2	**26 - 49 years**	347	53.2	**Islam**	162	24.8	**Married**	364	55.8
Total	652	100	**50 - 64 years**	99	15.2	**Traditional religion**	7	1.1	**Divorced**	7	1.1
			65 and above	29	4.4	**No religion**	7	1.1	**Widowed**	16	2.5
			Total	652	100	**Others (Pls specify)**	1	0.2	**Separated**	4	0.6
						Total	652	100	**Cohabiting with sexual partners**	5	0.8
									Total	652	100

Table 2. Demographic Characteristics of Respondents

Monthly Income			**Educational Attainment**			**Occupation**			**Length of Stay**		
Variables	**Frequency**	**Valid Percent**	**Variables**	**Frequency**	**Valid Percent**	**Variables**	**Frequency**	**Valid Percent**	**Variables**	**Frequency**	**Valid Percent**
N 0 - 100,000	422	64.7	No formal Education	25	3.8	Student	101	15.5	less than 1 year	40	6.1
N 101,000 - 500,000	122	18.7	Primary Only	74	11.3	Artisan (Hand work like carpenter)	141	21.6	1-4 years	231	35.4
N 501,000 - 1 million	4	0.6	Secondary Only	372	57.1	Civil Servant	42	6.4	5-9 years	156	23.9
N 1 million & above	2	0.3	Tertiary Education	179	27.5	Businessman/woman	352	54	10-15 years	106	16.3
Decline to say	102	15.6	Others (Pls specify)	2	0.3	Unemployed	16	2.5	15 years & above	119	18.3
Total	652	100	**Total**	652	100	**Total**	652	100	**Total**	652	100

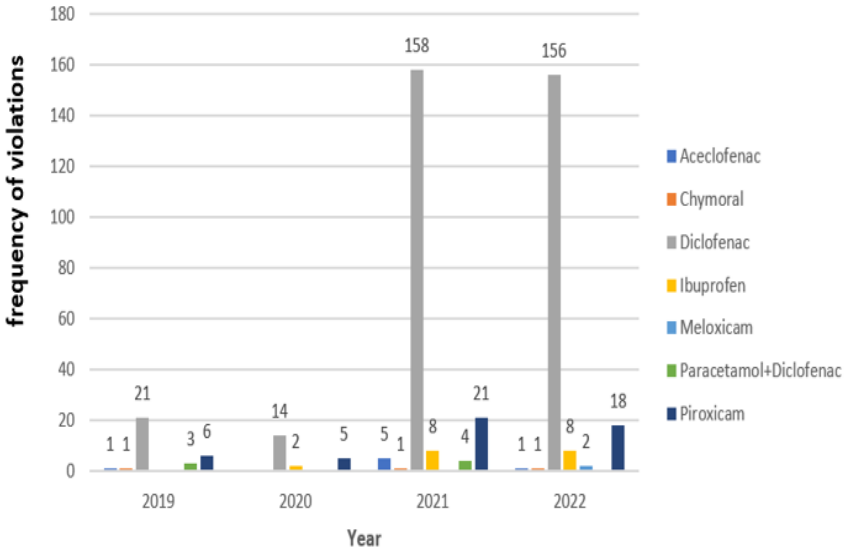

Figure 2. Annual Data on Importation of NSAIDs with Unapproved Pictorial Representation

Chi Square Test

The result of the Chi-square test showed that self-medication had no significant relationship at 5% significance level with pictorial representation (χ^2 =1.774, df=1, p=0.183) therefore, we can accept the null hypothesis (H_o) that there is no significant relationship between pictorial representation on NSAIDs and self-medication of NSAIDs. There was no significant relationship at 5% significance level with product packs (χ^2 =13.423, df=4, p=0.09) therefore, we can accept the null hypothesis (H_o) that there is no significant relationship between product packs and self-medication of NSAIDs.

Logistic Regression Analysis

A binary logistic regression was performed to ascertain the association between demographic characteristics and the influence of pictorial representation on product packs of NSAIDs. The overall model was statistically significant, χ^2 (9) = 33.097, p< 0.005. The model explained 1.05% (Nagelkerke R^2) of the variance in a pictorial representation and correctly classified 62.3% of cases. The odds of males self-medicating is 20% lower than that of their female counterparts (OR=0.865; 95%CI: 0.566-1.322). It could also be deduced that gender significantly contributed to the model (p<0.05), which predicts being influenced by pictorial representation in the study. Further regression analysis on socio-demographic variables such as age showed that age is not statistically significant. Although the odds of being influenced by pictorial representation for the other independent variables explored in this study are high, these odds are also not statistically significant. None of the demographic characteristics significantly contributed to the model (p<0.05), which predicts the influence of pictorial representation in the study.

Further regression analysis on socio-demographic variables such as Age 18-25 (OR=0.333; p=0.096; 95%CI: 0.091-1.216), Age 26-49 (OR=0.513; p=0.233; 95%CI: 0.171-1.536) were found not to be significant, Similarly, considering the reference category of Never married/Divorced/Separated, the odds for being Singles (OR=0.683; p=0.530; 95%CI: 0.207-2.250), and Tertiary education (OR=1.716; p=0.455; 95%CI: 0.417-7.070) referenced with No formal education revealed that they did not make a significant contribution to predicting the impact of pictorial influence on product packs of NSAIDs on the demographic characteristics.

Table 3. Association between Pictorial Representation and Self-medication

Variables	Odds ratio	95% C.I.	
		Lower	Upper
Gender			
Male	0.865	0.566	1.322
Female	1.000		
Age group			
18-25	0.333	0.091	1.216
26-49	0.513	0.171	1.536
50-64	0.275	0.087	0.868
65 & above (ref)	1.000		
Educational attainment			
No Formal Education (ref)	1.000		
Primary	0.438	0.098	1.951
Secondary	0.665	0.166	2.665
Tertiary	1.716	0.417	7.07
Marital Status			
Singles	0.683	0.207	2.25
Married/cohabiting	0.703	0.252	1.962
Never married/widowed/ divorced (ref)	1.000		

Discussion

This study was conducted in the largest local Government in the Lagos State of Nigeria. Alimosho Local Government Area is one of the seven hundred and seventy-four 774 local governments in Nigeria and a sub-urban metropolitan area. The Local Government Area has a population of people from various tribes in Nigeria but with the Yoruba language as the major language spoken in the area. The lingua franca is English which is generally spoken among the populace. An estimated sample size of 576 people was planned based on the sample size calculation. A total of 652 responses evenly spread across the LGA were received from administered questionnaires using the CSEntry App downloaded on smartphones. The study had responses from both gender and people from various professions, age, and marital status with years of residence above one year. The research participants were slightly more men than women and those who participated were informed of their rights to withdraw from participation at any time during the interview. All the participants who commenced the question session completed it. There were no missed cases as all respondents cooperated adequately.

A set of 15 researchers were recruited to participate in this study. One of the major reasons for the use of NSAIDs is the management of pain as found in other studies. The use of NSAIDs in self-medication for pain has been implicated in many studies, and with the use of NSAIDs comes its adverse effect [14, 15]. Of the 652 responses received, 80.6% admitted that they self-medicated, with 57.6% as males and 42.4% as females. This is considerably high and like the study conducted by [16], which had a 75.5% prevalence rate. The gender prevalence contradicts other studies that reveal that women are more likely to self-medicate than men and that women are more prone to seeking health-related information [17, 18].

NAFDAC as the Nigeria Medicines Regulatory Authority in Nigeria, has

categorized most NSAIDs as Prescription Only Medicines (POM), which should be purchased upon prescription from a physician [19]. Unfortunately, most purchases of NSAIDs are done without a prescription due to the poor medicine dispensing practices in pharmacies and patent medicines store that unethically stock these prescription medicines. The NAFDAC Drug Regulation also requires that no POM should have a pictorial representation that passes the indication and use of such products to the patient or consumer. Although this is bad ethical behaviour between the dispensers and patients, this behaviour has not really changed as most respondents in this study have indicated that they self-medicate NSAIDs and readily access them when they need them. Much has also not been done to prevent the dispensing of prescription NSAIDs to patients by regulators and authorities responsible for enforcing proper ethical practices with regard to dispensing of medicines to patients and consumers. This is compounded by the readily available Prescription NSAIDs with pictorial representation. The study revealed that educational attainment was not statistically significant to self-medication. This also applied to being influenced by pictorial representation.

This study carried out a time series analysis of the importation of Prescription NSAIDs with pictorial representation, and the results reveal a continuous increase in the importation over the three years and a half and a high volume of import of NSAIDs with pictorial representation when compared to other imported NSAIDs. This was validated by the high consumption of Diclofenac among respondents. This is despite efforts by NAFDAC to discourage this unethical behavior by importers of these products. This constitutes a serious problem as outrageous pictures are placed on the packs of the products that may convey the use of the product and encourage self-medication among users. Access to affordable health services has created challenges in public health, and as such, there is a need to improve accessibility and affordability of medical care to health seekers so that they do not resort to self-medication and medical information from unprofessional sources [20, 21]. Curiously, 65.3% of the respondents said that they would still purchase NSAIDs with pictorial representation when asked if they would, even after knowing that pictorial representation on NSAIDs is not allowed.

The structured questionnaire with closed-ended questions limits the options for responses and the outcomes of the research such that the results may not necessarily represent the actual outcome in a generalizable form. This also limits the determination of causality of analysis and why the population self-medicates NSAIDs [13]. The study did not have the qualitative aspect that would have been more flexible in approach and make provision for further explanation of reasons for responses to questions [13, 22].

Conclusion

This descriptive study has revealed certain challenges with the self-medication of NSAIDs among adults in the Alimosho LGA. The research concludes that most respondents admitted that they self-medicated NSAIDs and the pattern of use shows inappropriateness with the risk of adverse side effects. Analysis of the association of demographic profile with pictorial representation on product pack revealed that the overall logistic regression was statistically significant. Access to unreliable information can be reduced through proper health information dissemination that could help improve healthy behavior among the population [4].

NAFDAC, as a regulatory authority for medicines regulation, control, importation, distribution, sale, and use, should ensure that medicines are properly distributed and available in only locations that have approvals to stock them. Therefore, NAFDAC should further strengthen regulatory interventions that prevent

the importation and distribution of prescription NSAIDs with pictorial representation and ensure that such medicines are not readily available over the counter in pharmacies and patent medicines stores without prescription from certified medical personnel [23].

Recommendations

This study has highlighted the need for response in addressing the issues of self-medication and the influence of pictorial representation on product packs of prescription NSAIDs. The researcher, therefore, recommends that:

1. NAFDAC should strengthen efforts at enforcing strict policies that must be complied with among importers of prescription NSAIDs with pictorial representation into the country.
2. NAFDAC and the Pharmacist Council of Nigeria should collaboratively formulate strategies that would ensure compliance to non-dispensing and sale of prescription-only medicines without written prescriptions. This should involve conducting unscheduled inspections to pharmacies, patent medicines outlets, and even drug hawking locations for the purpose of enforcing compliance and penalties where applicable.
3. Further post-marketing efforts should be conducted to withdraw all non-complying products with pictorial representation from circulation. This would reduce the risk of exposure to the hazards of self-medication by the population.
4. NAFDAC should carry out further research on this work at a nationwide scale to understand the impact of pictorial representation of prescription medicines on the populace. This should cut across all socio-economic and demographic profiles of various communities.

Conflict of Interest

The author declares no conflict of interest.

Acknowledgement

We wish to acknowledge the Institutional Review Board for the approval issued for this study. We cannot thank NAFDAC enough for providing the Import data on products with pictorial representation on NSAIDs product packs. We also want to acknowledge Prof. Samson Babatunde Adebayo for his priceless advice.

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