Original Article

Safety warnings and first aid instructions on consumer and pharmaceutical products in Nigeria: has there been an improvement?

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Abstract

Objectives: To investigate the adequacy of safety warnings and first aid instructions on the labels of pharmaceutical and consumer products in Nigeria.

Methods: A market basket method (total collection of all available samples) was used to investigate the adequacy of safety warnings and first aid instructions on the labels of 600 pharmaceutical and consumer products in Nigeria.

Results: The results showed that 69.8% of the products had adequate warnings whereas 385 (64.1%) of the products screened had legible product warnings. Only 52 (8.7%) of the total number of products had appropriate first aid instructions while only 25 (4.12%) of the products described symptoms and full treatment of poisoning by the product and 319 (53.2%) products surveyed recommended calling a health professional. A total of 31 (5.2%) products had labels that were considered too technical (non English). Of the 600 products, 386 (64.3%) had dosage instructions that were considered adequate while 538 (89.6%) had adequate storage instructions. About 68% of the products had partially correct warnings while 44 or 7.3% had partially correct first aid instructions. Some products had neither warnings nor first aid instructions.

Conclusion: This study suggests a not too impressive improvement in the correctness and appropriateness of label information (JPMA 60:801; 2010).

Introduction

Labels with special instructions regarding how a prescription medication should be taken or its possible side effects are often applied to pill bottles.[1] Explicit, well-publicized drug warnings can change the prescriber's behaviour.[2] Special instructions regarding how a prescription medication should be taken or its possible side effects are often applied to medication bottles in the form of auxiliary labels. These labels typically include small illustrations that are intended to enhance comprehension. World Health Organisation specifies that advertisements should contain side effects and major adverse drug reactions; precautions, contraindications, and warnings; major interactions; and reference to scientific literature where appropriate. Pharmaceutical labels must provide critical instructional information to people with different experiences and education levels. Patients are faced with the responsibility of converting declarative information into procedural application, resulting in a substantial risk of errors.[3]

Orisakwe 1992[4] had surveyed the adequacy of safety warnings and first aid instructions on consumer and pharmaceutical products in Nigeria with a call and recommendation for improvement and establishment of poison control centres. The thrust of the follow up investigation is to ascertain degree of improvement in correctness and adequacy of safety instructions or precautionary warnings on even greater number of pharmaceutical and consumer products in Nigeria.

Materials and Methods

A total of 600 products made up of prescription drugs, over-the -counter medications, injections and intra-venous fluids, antiseptics and disinfectants, detergents and washing fluids, household items, insecticides and consumables in the Niger Delta Area of Nigeria were screened for the labelling requirements from July to September 2007 using the under listed criteria Orisakwe 1992:[4] A market basket method (total collection of all available samples) was used in the sample collection using two big pharmacy shops. The following factors were checked:

1. Are the first aid instructions or warnings appropriate and correct?

2. Is the print size of the warning legible and strategically located on the product pack?

3. Correctness or otherwise of the warning.

4. Is the description of signs and full treatment of poisoning, e. g gastric lavage, induction of emesis, use of activated charcoal as oral adsorbent, haemoperfusion and specific antidotes, stated.

5. Is the referral to a medical professional or poison control centre for consultation in the event of poisoning appropriately written.

6. Is the appropriate dosage and storage instructions for various products properly displayed.

The total number of products that satisfied these requirements or criteria and those that did not were checked and their percentages were calculated.

Results

In all 413 (69.8%) of the products had warnings that were considered adequate for the products whereas 385 (64.1%) of the products had strategically located and legible product warnings on their labels. Only 52 (8.7%) products had appropriate first aid instructions while only 25 (4.1%) described symptoms and full treatment of poisoning by the product and 319 (53.2%) products surveyed, recommended calling a health professional. Thirty one (5.2%) had labels that were too technical and confusing since it was in a foreign language and not English. Of the 600 products, 386 (64.3%) had adequate dosage instructions while 538 (89.6%) had adequate storage instructions. Only 408 (68%) of the products had partially correct warnings while 44 (7.3%) had partially

Table-1: Label review.

Parameter	Products meeting requirements	Percentage of products
Are the warnings correct and appropriate for the product?	413	68.9
Are the first aid instructions correct and appropriate for the product?	52	8.7
Are these warnings and first aid instructions easily located on the label and is the print size legible?	385	64.12
Are the warning instructions partially correct?	408	68
Are the first aid instructions partially correct?	44	7.3
Are the warnings and first aid instructions incorrect?	5	0.83
Does the label also describe signs and full treatment of poisoning by the product?	25	4.12
Does the label recommend consulting a health professional?	319	53.16
Number of products not having warning instructions`	381	63.5
Number of products not having first aid instructions	12	2.0
Are the warnings and first aid instructions too technical and confusing?	31	5.16
Are the dosage instructions for the product adequate?	386	64.33
Are the storage instructions for the product adequate and appropriate?	538	89.6

Table-2: Summary of products surveyed.

Items	Number	Percentage
Tablets, capsules, and ovules	214	35.7
Topical preparations, creams, lotions and powders	99	16.5
Syrups, antihistamines, antitussives and multivitamins preparations	142	23.7
Instillations: eye/ear drops, lotions, and ointments	34	5.7
Injectables-injections, intravenous fluids, etc	80	13.3
Insecticides- raid, mobil, baygon etc	7	1.2
Consumables-Gauze bandage, plasters, syringes, etc	9	1.5
Household items- soaps, perfumes, antiseptics	15	2.5

correct first aid instructions. Some products had neither warnings nor first aid instructions Table-1.

Table-2 shows the types of drugs/medicaments and consumer products covered in the study. These products range from tablets, capsules, and ovules (35.7%), topical preparations (16.5%), syrups (23.7%), instillations (5.7%), injectables (13.3%), insecticides (1.2%), gauze/bandages/plasters (1.5%), household products comprising of soaps, detergents, perfumes and antiseptics (2.5%).

Discussion

With the exception of the work done by Orisakwe[4] we are not aware of any other study on the safety warnings and first aid instructions on consumer and pharmaceutical products in Nigeria. This follow up study is intended to ascertain the level or degree of improvement over a fifteen year period after the recommendations of Orisakwe.[4] There have been some improvements in product labelling information namely in the area of correctness and appropriateness of information, easily located and legibility of print size and recommendation of consulting of health professional in the present study compared to the lower percentages shown by Orisakwe's work of 1992.[4] This study recorded more products not having either warning or first aid instructions and number of products having incorrect first aid instructions than the 1992 data.[4] There seem to be no improvement in labelling requirement.

Pharmaceutical labels must provide critical instructional information to people with different experiences and education levels. Patients are faced with the responsibility of converting declarative information into procedural application, resulting in a substantial risk of errors.[3] Effective communication is an essential or vital ingredient of good product labelling.[5]

Investigations of the correctness and appropriateness of labels on pharmaceutical and consumer products is non-priority research area amongst health care professionals in Nigeria is evidenced by non-availability of data. The efforts of the regulatory agencies like National Agency for Food Drug Administrative Control, Standards Organization of Nigeria (SON), and Consumer Protection Council (CPC) should be complemented by the similar works from the academia for comprehensive policy guidelines.

This study shows that although there has been some progress in some aspects of the label requirements, there are still gaps left uncovered. Although 68.9% of the total number of products surveyed had appropriate warnings, only 8.7% of the products had adequate first aid instructions and only 4.1% described signs and symptoms of poisoning by the product and prescribed full treatment of such poisoning. This may have grave consequences in rural communities especially in the event of poisoning. Only half of the products recommended seeing a physician, in the event of adverse reactions or poisoning this may be of very little help. Most of the times physicians simply engage in symptomatic management of such cases of poisoning.[6] The absence of poison control centres and good statistical data base for continuous poison information update is a matter of urgent concern. The government should consider upgrading and expanding National Agency for Food Drug Administrative Control, NAFDAC's pharmacovigilance project to include well equipped poison control and surveillance centres. Such poison control centres should design specific therapeutic and intervention modalities for the effective management and treatment of poisoning.

Massey and Shulman[7] on the analysis of the American Association of Poison Control Centres (AAPCC) report of suspected over ingestion of mouthwash by children under age 6 and examine the effect of a 1995 Consumer Product Safety Commission (CPSC) rule requiring child-resistant packaging for mouthwashes containing at least 3 g of ethanol per package suggests that the CPSC rule requiring child-resistant packaging on containers of mouthwash containing 3 g or more of ethanol has been successful in reducing AAPCC's reports of mouthwash over ingestion. Health care providers should take a more active role by informing parents of the dangers associated with accidental ingestion of ethanol-containing mouthwash. Manufacturers should print warnings about the potential hazard of high ethanol concentrations on labels more prominent and they should stop producing mouthwashes with such high concentrations of ethanol. In Nigeria drugs with the warning, keep out of reach of children, should be put in child-resistant packages.

Physicians may not be familiar with the content of some herbal remedies in Nigeria and thus may not be able to adequately handle the problems that may arise from their use.[8] Drug companies especially in developing countries such as Nigeria should resist the temptation of seeing the physician as an encyclopaedia of drug information. This is because very often the physician depends on prescribing information provided by the manufacturer by way of product information

insert or advertisements in relevant journals. The physician may have limited access to other sources of information and journal advertisements are not compelled to provide sufficient and reliable information for appropriate use of drug, as is the case in advanced countries.[9] Although in Nigeria, public advertising of ethical products in the media is not allowed by law, companies still find other avenues such as conferences and clinical presentations to advertise their products sometimes making claims that can hardly be substantiated. There is thus need for effective control over promotions because studies have shown that even physicians who have access to objective sources of prescribing information are still vulnerable to messages in promotional material.[10]

The actual contents of pharmaceutical and consumer products with their stated amounts should be emphasised in labels as one way of improving label information in Nigeria. In the United States, the Food and Drug Administration (FDA) is amending the general labelling provisions for over-the-counter (OTC) drug products to include details of the ingredients.[11] There have been increasing incidences of renal failure in Nigeria, and although the aetiology of this ailment can be multifactorial, it is feared that the condition could have been aggravated by the excessive and non-regulated levels of some of the metals in OTC drug products.

Manufacturers have continued to use technical languages (non English) in their labels as evidenced in 5.2% recorded in the present study as compared with the 4.5% observed in the 1992 study.[4] This is considered a grave oversight considering the low literacy level in Nigeria. Improvement in literacy and by extension of health is advocated. Low literacy has been associated with higher rates of hospitalisations and use of emergency services[12] and poorer understanding of one's medical condition.[13] Poor adherence to medical instructions and worse health outcomes are linked to low literacy.[14] These reports emanate from surveys conducted in developed nations and expectedly the situation may be worse in Nigeria.

Regulatory authorities of countries have the statutory duty to evaluate new medicines in respect of quality, safety and efficacy.[15] Drugs should be accompanied by a summary of product characteristics which includes a statement on the effects of the products on the ability to drive and operate machinery. Any claims or warnings made in this or other respects must be based on data resulting from scientific experiments and will appear in data sheets. Appropriate label warnings may also be required, in some cases imposed by the Labelling Regulations, such as the standard antihistamine warning. The use of package inserts to give further warning to the public is also encouraged.

An improved drug labelling is warranted in Nigeria also.

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