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MARKET RESEARCH AND RECOMMENDATION ON PACKAGING AND LABELING OF VARIOUS OTC (OVER THE COUNTER) DRUGS AVAILABLE IN BANGLADESH

ABSTRACT

The aim of present study was to find out whether or not the pharmaceutical companies of Bangladesh are providing all the necessary information and instructions in the packaging materials of OTC (Over the Counter) Drugs which are available in Pharmaceuticals of Bangladesh and can be bought without prescription by anybody from drug or chemist store. For this purpose 250 brands from 55 generics were selected from different pharmaceutical companies and collected from different drug stores in Dhaka city. Then 16 different regulatory and 12 clinical parameters were thoroughly checked in the packages of selected products. Some lacking was found in the packaging information (both regulatory and clinical) of selected products. The findings as well as some recommendations regarding the OTC drugs packaging are discussed in this article.

KEY WORDS: Brands, Generics, Labeling, Leaflet, OTC drugs, Packaging, Prescription

1. INTRODUCTION:

Non prescription drugs are drugs that are sold over the counter, which means they are sold without a prescription from a doctor. These drugs are sold directly to the consumers as compared to prescription drugs, which require a prescription. They are also referred as the over-the-counter (OTC) drugs. Increasingly, consumers are using medications without medical supervision as more drugs that were once available only by prescription are sold over-the-counter (OTC), and consumers are relying more on self-care for many medical problems. Such a trend makes it critical that sufficient information be made easily accessible to ensure that the medication is safely and effectively used. The consumers are changing world over. Today they are more informed, use more gadgets, lead a fast life and thereby face higher stress. Environmental changes in the form of ever increasing pollution, heavy road traffic leading to increasing commuting time, stressful workplace ,environment and fast changing technology put continuous pressure to adapt and adjust changing lifestyle with smaller living space, less exercise (sedentary jobs), taking junk food, consuming addictive products to stay awake on the job for longer hours and eating on the run put more stress on the body which get expressed in the form of psychosomatic disorders like frequent headache, allergy, common cold, constipation, backache, acidity, chronic fatigue etc. which they are trying to manage with Over The Counter (OTC) drugs [1].

Over time, often 3–6 years, drugs that prove themselves safe and appropriate as prescription medicines may be switched from prescription to OTC. An example of this is diphenhydramine (Benadryl), which once required a prescription but now is available OTC nearly everywhere. Diphenhydramine is an anti-histamine. More recent examples are cimetidine and loratadine in the United States, and ibuprofen (Herron Blue/Nurofen) in Australia [2].

1.1. Possible benefits

- Increased access
- Decreased frequency of visits to physicians, leading to lower healthcare costs
- Improved education of consumers
- Increased autonomy of patients
- Decreased cost to third party players

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1.2. Possible risks

- Inaccurate diagnosis
- Delay in obtaining needed therapy
- Use of suboptimal therapy
- Drug resistance
- Increased costs to patients
- Failure to follow label instructions (Adverse effects, Drug interactions)
- Perceived loss of control by physicians [3].

1.3. Physicians Role [4, 5]

Due to the high prevalence of OTC medication use, physicians need to stay abreast of the trends in OTC usage patterns as well as the risks associated with incorrect use and storage of OTC drugs. Physicians need to participate in efforts to prevent adverse events, therapeutic errors, misuse, and unsupervised pediatric ingestions of OTC medicines.

i) Routinely document OTC use in the medical history:

- to detect incorrect use,
- to detect potential drug-drug interactions, and
- to identify therapeutic duplication.

ii) Discuss with patients the potential risks of the OTC medications they have disclosed during history taking.

iii) Provide alternative medication choices if you suspect misuse of an OTC medication.

iv) Teach patients how to read package labeling with special emphasis on the sections “Warnings” and “Directions” (dosage instructions).

v) Teach parents and caregivers about the use of OTC medications in children.

vi) Emphasize the importance of heeding the dosage instructions of the package labeling.

vii) Teach parents and caregivers about the handling and storage of OTC medications.

- Tell your patients to put the entire container up, away, and out of sight after every use.
- Tell your patients to correctly replace the child-resistant caps on all medicines.

viii) Refer patients to Internet educational resources

1.4. Bangladesh perspective:

Since 1982, Bangladeshi Pharmaceuticals Manufacturers have adopted the trend of excelling in

- the manufacturing processes
- new dosage formulations
- introduction of new molecules

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- packaging adoption of marketing
- principles customer focus

According to BMI (Business Monitor International) report (December 18, 2010) Bangladesh placed 14th position among 17 regional markets, placed below Vietnam and above SriLanka. Globally Bangladesh**:** placed 67th position among 83 market-strong pharmaceutical universes. According to IMS 3Q 2011 Pharmaceutical market of Bangladesh was estimated about 8000 Cr. taka with a growth rate of 24.64 %. The top ten brands in Bangladesh Pharma market are Seclo, Losectil, Napa, Neoceptin-R, Neotack, Pantonix, Cef-3, Ciprocin, Zimax, Xeldrin etc. Top Ten Generics in Bangladesh are Omeprazole , Calcium, Colecalciferol, Cefexime, Ascorbic acid, Ranitidine, Azithromycin, Ciprofloxacin, Paracetamol, Pyridoxime etc. Most of these drugs are OTC.

There are about 257 Pharmaceutical companies in Bangladesh with few multinational companies. But The Pharma maret is mainly dominated by local companies. Top 10 local companies meet about 67% of local demands of drugs. The rest of the demand is fulfilled by others companies and by some multinational companies.

A product is not correctly formulated unless it is properly packaged, and in some cases the major part of the formulation process may be concerned with selecting the right package for the product [6]. So a pack is the economical means of providing for a product presentation, protection, identification/information, convenience / containment/compliance until the product is used or administered, paying due attention to any relevant environmental issues. Type of pack can refer to either the basic materials employed, i.e. glass, plastic, metal, etc. or the pack style/type, e.g. bottle, tube, sachet, blister. Packs may provide single (non-reclosable) use, or multi-use (reclosable). Both groups have influences on the product and have to be considered in terms of the material characteristics and the total packaging concept involving such factors as product compatibility, functional and aesthetic design, production performance, material costs, production costs and user convenience. The choice of packaging material will depend upon:

- The dosage form desired,
- The degree of protection required.
- compatibility with the dosage form,
- presentation and aesthetics,
- customer convenience e.g. size, weight of dosage form,
- filling method,
- sterilization method to be employed and cost.

There are three types of packaging. The primary or immediate pack which consists of those materials that are in direct contact with the product. The secondary pack and sometimes tertiary components enable the product to be stored, transported and displayed, and possibly assist use. Tertiary components may include ancillary components, e.g. leaflets or inserts, separate dispensing spoons and measures.

The pack must afford protection against the following primary hazards:

• **climatic,** i.e. those associated with the surrounding atmosphere

•**biological**—these involve microbiological (bacteria, moulds and yeasts) and biological factors (insects, rodents, human

pilferage, etc.)

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•**mechanical,** i.e. physical hazards associated with storage, carriage, etc.—general handling

•**chemical**—aspects of interaction and exchange between product and pack, i.e. compatibility, ingress and egress, and

Combinations of these and the factors above

•**use**—professional and patient, including any possibilities of misuse or abuse.

1.5. CPMP Notes for Guidance III/9163/90; SmPC [7]

Immediate packaging must contain product name, active ingredients, pharmaceutical form and contents, list of excipients, method and route of administration, special warnings, expiry date, special precautions, name and address of authorization holder, authorization number, manufacturing batch number, instructions for use for self-medication product. All products must contain a patient leaflet unless all the information can be conveyed on the outer packaging label. The content of the leaflet and order of presentation are defined in Directive 92/27 and must be as follows.

- Identification of product.
- Name of product, statement of active ingredients, pharmaceutical form, pharmaco-therapeutic group, name and address of authorization holder.
- Therapeutic indications.
- Information needed for taking the product.
- Contra-indications, precautions for use, interactions, special warnings, including use in pregnancy, elderly, effect on ability to drive vehicles and details of any excipients which may be important for the safe and effective use of the product.
- Instructions for use.
- Dosage, method and route of administration, frequency of administration, duration of treatment where limited, action to be taken in the case of an overdose or lack of dosing and risk of withdrawal effects where possible.
- Undesirable effects.
- Effects that can occur under normal use of the product and action to be taken.
- Expiry date.
- Warning against use of the product after the date, appropriate storage precautions and warning against visible signs of deterioration.
- Date on which package leaflet was last revised.

The leaflet must be written in clear, understandable terms, be legible and be in the official language of the member state. Inclusion of symbols or pictures is permitted if in compliance with the SmPC. Since this is a user leaflet the language must be understandable to the lay person. The above information relates to a package insert designed for the patient, but in some cases further information is required for use by the doctor, dentist or nurse in supplying or administering the product. To cover this need a professional user leaflet may be included provided it is within the scope of the SmPC, but even if the product is administered by a professional a patient insert must also be provided.

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2. MATERIALS AND METHODS

For this research work 250 different brands were selected from 55 generics which are available in Bangladeshi Pharma market and which can be bought without prescription. These products were collected from different dispensary or drug store from Zigatola, Kolabagan, Rayer Bazar, Dhanmondi-15 no and thoroughly examined. We also include some antibiotics in our survey though they are not OTC drugs. The justification is that these antibiotics are sold without prescription in Bangladesh. In this survey primary packages such as strips, blister, bottles, flexible tubes, collapsible tubes etc; Secondary packages such as inner cartoons, paper bags etc; and literature or inserts were examined. The selected generics are mentioned in Table-01

Among these 255 brands different dosage forms such as oral solid, oral liquid, semisolid for topical application, ophthalmic products, parenteral products were included. Sixteen regulatory and general parameters and twelve clinical parameters were evaluated for survey work. Regulatory parameters includes trade name, generic name, name of manufacturer, manufacturing date, expiry date, batch no, manufacturing license no, product license no (DAR no.), price, mailing address of the company, sterility statement, insert, packaging quantity, no of products, bilinguality, dosage form. The clinical parameters includes composition, indication, mechanism of action, side effects, contraindication, dosage and administration, instruction for use, storage condition, overdose, drug interaction, instruction for pediatric or geriatric use, use in pregnancy and lactation etc. Firstly samples were collected from drug store and then thoroughly examined against these parameters. For accuracy samples were reexamined by another person. The results were then recorded and presented in a tabular form.

3. RESULT AND DISCUSSION

First of all findings are shown in tabular form and then discussed where the dissimilarities or lackings of packaging information among the companies. Few pictures are given here to compare one package with a standard one (Table-02, 03).

According to survey it was found that regulatory parameters were more available than the clinical informations such as over dose, instruction for paediatric or geriatric use, drug drug interactions, use in pregnancy and lactation in the packages of OTC drugs. Since OTC drugs are taken by the patients without prescription, this information should be available in inserts or on the secondary packages to reduce the accidental misuse of drugs and for the safety of patients.

It was observed that bar code was absent in case of most of the pharmaceutical companies. But in modern age it is an essential parameters for a standard packaging. It is read by optical scanners to find out the necessary information within a fraction of second [8]. It is also required when a product is exported to other countries (Figure-01).

Another mentionable issue is mailing address. It was not found on most of the packages. It is required to communicate with company if necessary. Few companies mentioned their mailing id with their address (Figure-02).

In most of the plastic bottles Plastic Resin Identification Code was absent. Some companies mentioned this code in right form, but it is a matter of great sorrow that some companies mentioned this code in wrong way.This code is important to select the plastic or polymer for recycling, product pack compatibility, drug stability and patient safety. It should be mentioned carefully on the bottom of the bottle (Figure-03,04).

In most cases insert was present inside the secondary packages, but the information was not present on the out side package. But few companies mentioned this information on the secondary packages (Figure-05).

To make the use of drugs easier some sign were found on the packages such as heart, stomach, lung etc. But most of the cases these sign were absent. If it would be used it will be helpful for all kinds of patients to identify the drugs. In case of OTC drugs it is an essential criteria since patients buy the drugs without prescription and it will help to reduce the accidental misuse of drug (Figure-06).

Some exceptional information were found which includes the name of days or no of drugs on the blister strips to help the people to take the drugs in time. In case of OTC drugs this information plays a vital role in proper use of medication. Some companies provided

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the directions how to open the packages. Some companies also provided the instructions what should be done before taking the medications, how many times the drugs should be taken and the divided of the doses according to age (Figure-07).

3.1. Recommendations

- According to the result of this survey some recommendations are:
- OTC drugs must be tamper resistants to prevent any unauthorized access.
- Child resistant features should be added to prevent any accidental misuse of drugs by children within a specific time periods,since OTC drugs are kept anywhere in houses and is used by any persons,which can influenced the children to use inabsence of adults.
- Directions for the opening of bottles should de added or shown on the closures.
- Every company should mention their Mail ID on secondary packages.
- Plastic resin identification code should be mentioned correctly to facilitate further recycling process
- Inserts should be given in each package.
- Bar code should be given in each package.
- Instructions for use should be highlighted both in English and Bengali so that every patient can read it easily.
- Alarming system (Alarm Clock) can be included with packets for unconscious patients
- No of drugs or name of the days can be mentioned on strips or blisters to help the patients specially older patients to take the drugs in time.
- Storage conditions must be mentioned on the package.
- Over dose, precautions, use in pregnancy and lactations, side effects, contraindications must be mentioned in inserts.

Table-01: The Generics and No. of Brands Selected for Research

Therapeutic Class	Generic Name	No.of Brands	Dosage form
Gastro intestinal	Omeprazole	05	Tablet, Capsule, Suspension, Syrup, Injection etc.
	Esomeprazole	06	
	Pantoprazole	05	
	Antacids	05	
	Ranitidine	05	
Analgesic and antipyretic	Aspirin	03	Tablet, Capsule, Injection

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	Paracetamol Ibuprofen Pathedine Naproxen Diclofenac Sodium Aceclofenac	06 06 01 06 08 07	
Antitussive	Dextromethorphan Ambroxol	04 05	Syrup, Suspension
Sedatives and Hypnotics/ Tranquilizer/Anxiolytics/ Antipsychotics	Diazepam Chlorpromazine HCL Lorazepam Nitrazepam Flurazepam Amitriptyline Doxepin	05 04 03 04 06 07 02	Tablet, Capsule, Injection
Nausea, vomiting, vertigo	Cinnarizine Promethazine Prochlorperazine Maleate	04 05 07	Tablet, Syrup
Sedating Antihistamine	Chlorpheniramine Maleate Diphenhydramine HCL	05 05	Tablet, Capsule
Non Sedating Antihistamine	Cetirizine Loratidine Desloratidine	06 06 05	Tablet, Capsule

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Skin Preparation	Diphenhydramine HCL Mepyramine maleate Calamine 15 gm Tetracycline Gentamycin Ketokonazole Tioconazole	03 04 04 05 03 05 02	Ointmants
Anti-Diarrhoeal Drugs	Cotrimoxazole Nalidixic Acid	04 03	Tablet, Capsule
Antibiotic	Penicilin Cloxacillin Fluxacillin Ampicillin Amoxicillin Cephalexin Cephadroxil Cephradine Cefaclor Cefuroxime Tetracycline Azithromycin Chloramphenicol	05 03 03 04 07 04 04 05 06 03 04 05 05	Tablet, Capsule, Injection
Vitamins	Vit-C,Vit-D,Follic Acid	05	Tablet

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	Vit-C	04	
Oral Contraceptive	Levonorgestrel Oestrogen+Progesteron	04 05	Tablet

Table-02: Percent occurrence of Regulatory and general parameters

Regulatory and general parameters	% 0ccurrence
Trade Name	100
Generic Name	100
Name of Company	100
Mailing ID	20
Mfg. Date	100
Exp. Date	100
Batch No.	100
Mfg. Lic. No	100
Product Lic. No.	100
Price	100
Sterility Statement	90% for liquid dosage form
Insert	92
No.of product	100
Dosage Form	100
Packaging Quantity	45
Bilinguality	95

Table-03: Percent occurrence of selected clinical parameters

Clinical Parameters	% Occurrence
Composition	100
M/A	96
Indication	100
Dosage and Administration	98
C/I	95

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S/E	99
Instruction for Use	95
Storage Cndition	89
Precaution	95
Overdose	76
Drug Interaction	81
Instruction for pediatric/geriatric	75
Use in pregnency and Lactation	79

Figure-1: Bar code

Figure-2: Mailing ID

Figure-03:Correct code.

Figure-04:No code is present.

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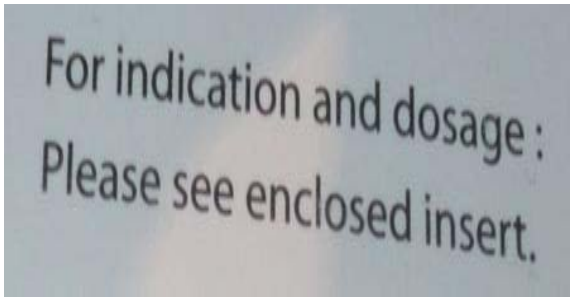

Figure-05: Direction to see the insert inside the secondary packages.

Figure-06:The sign of stomach indicates that the drug is for gastritis

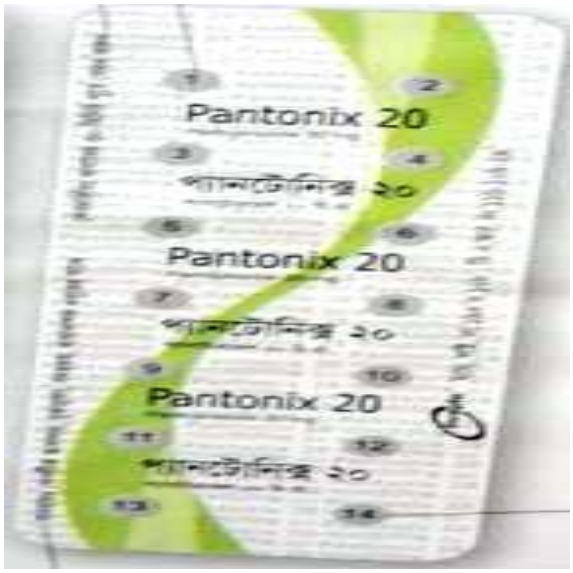

Figure-07:No of drugs shown on strip

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CONCLUSION

The present survey and our data indicate that the packaging information of various OTC drugs from various companies in pharmaceuticals market of Bangladesh is not sufficient. Since OTC drugs can be bought without prescription in anytime, anywhere and by anybody, so the packaging information (regulatory and clinical) of OTC drugs should be specific, reliable, clearly printed in both English and Bengali and important information should be highlighted. Pharmaceutical companies as well as Drug Regulatory Authority, Drug Administration, Ministry of Health and Family Welfare should be careful and take necessary steps regarding the packaging of OTC drugs for the safety of patients and improve the healthcare system of Bangladesh.

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