Research Article

Assessment of Label Compliance of Internal Liquid Preparations as per US FDA Guidelines in a Community Pharmacy

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ABSTRACT

The safe use of all medicine depends on users reading the labelling and packaging carefully and accurately to assimilate and act on the information presented. In most countries of the world, there exist no official guidelines highlighting labelling requirements for pharmaceutical formulations. The objective of the study was to do a study on liquid preparations, to assess whether primary labels have adequate information for the patient to make proper self-medication choices. A total of 105 liquid preparations were selected from a community pharmacy. The labels were carefully assessed based on US FDA guidelines. The study shows that 100% of the liquid preparation's labels mentioned the active ingredient(s) along with their strength,87.6% mentioned storage conditions, 83.8% mentioned label type, 77.1% mentioned inactive ingredients, 66.9% mentioned drug category, 46.7% mentioned either use or indications of the drug, 44.8% mentioned warnings related to drug interactions/ contraindications/ overdosages/ precautions, 43.8% mentioned directions including how much to be taken, dosage interval, maximum dose allowed per day and the dose for children, 41.9% mentioned keep out of reach of children, 34.3% used label font correctly,13.3% mentioned use in special population and none of the preparations mentioned warnings related to pregnancy and breast-feeding. It is legal requirement that each dispensed medicine is labeled with clear-cut laid down guidelines for their complete labeling to ensure that each patient gets sufficient drug information and counseling so as to make a responsible decision for rational utilization and assist the patient to organize their medication routines by themselves.

Keywords: Community Pharmacy, FDA guidelines, Label, Liquid Preparations, Primary labelling.

INTRODUCTION

Labelling is the norm that provides comprehensive and concise statement of drug's Quality, Safety and Efficacy. The safe use of all medicine depends on users reading the labelling and packaging carefully and accurately to assimilate and act on the information presented. In most countries of the world, there exist no official guidelines highlighting labelling requirements for pharmaceutical formulations.[1,2]

Liquid preparations are intended for oral uses are an indispensable part of the health care system. Although liquid preparations are supposed to be relatively safe, readily available and consumed by the patients, it is very important that the label should provide sufficient information to make the patients adhere to their medications. Hence the label of liquid preparations plays an important role in conveying valuable information to the patient. All pharmaceuticals are thus, labelled under21 CFR 201.56(d) and 201.57as per US FDA guidelines 2013 including India.[6] The FDA, issuing these guidelines to provide recommendations for developing labelling for new prescription drugs and revising labelling for already approved prescription drugs. The containers of all the drugs, particulars should either printed or written in indelible ink and should appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed.[1] The liquid preparations for internal use are listed under the Schedule H and G must contain the following mandatory texts on the label. -

"WARNING: To be sold by retail on the prescription of a Registered Medical Practitioner only & CAUTION: It is dangerous to take this preparation except under medical supervision" respectively.[5]

OBJECTIVE

The objective was to do a study on liquid preparations, to assess whether primary labels have adequate information for the patient to ensure the rational use of the drugs.

METHODOLOGY

A total of 105 liquid preparations were randomly selected covering all the internal liquid preparations in a community pharmacy nearer to our Medical College. The labelling of the medicines were then carefully assessed based on the 21 CFR 201.56(d) and 201.57 as per US FDA guidelines-2013, for Human Prescription Drugs and Biological Products labelling. The proposed labelling includes various components like active ingredients with their strength, drug category, general warnings, storage conditions etc.; and they were studied as specified by FDA standard labelling format.[4]The results obtained were tabulated and analysed.

RESULTS AND DISCUSSION

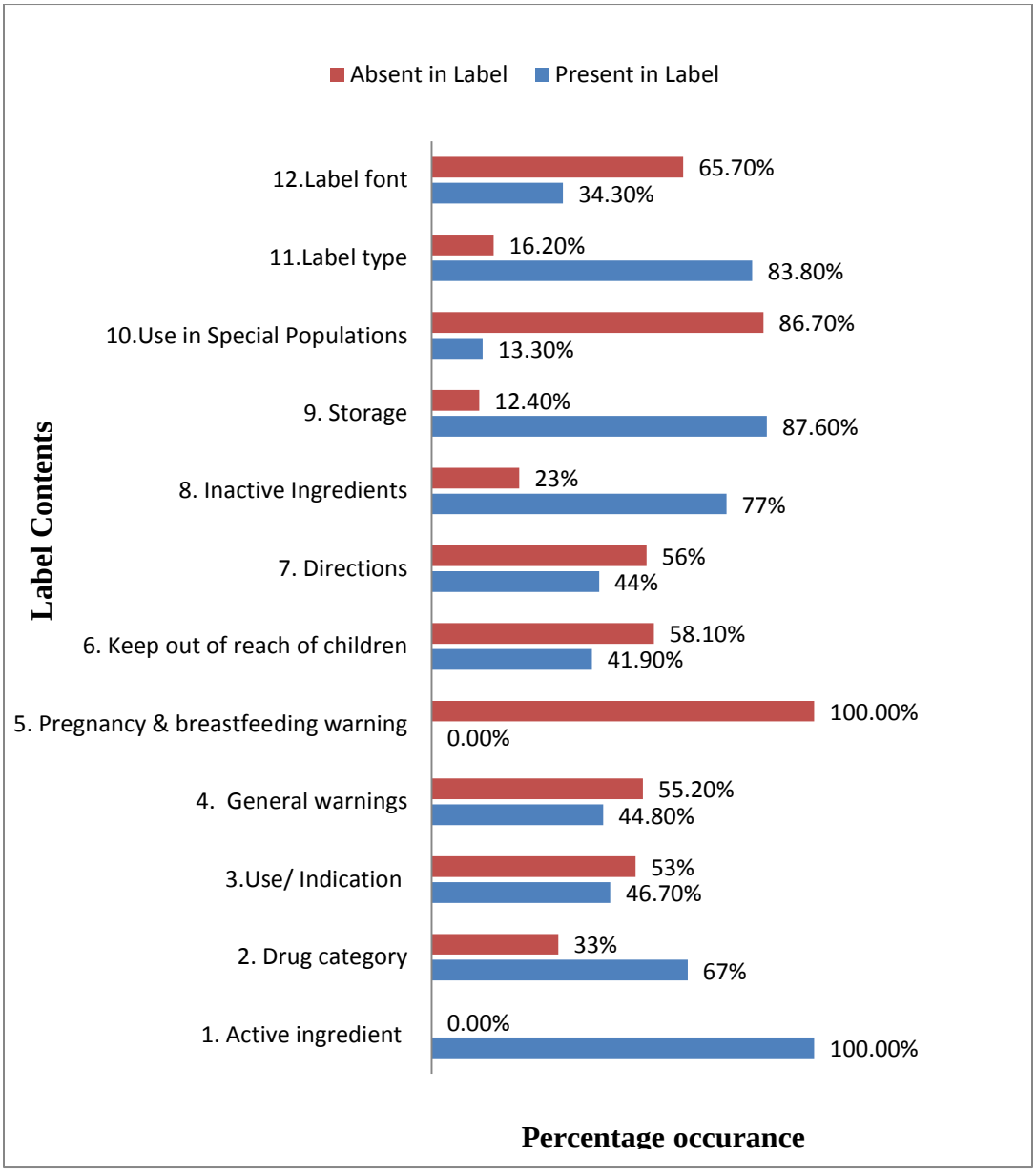
A total of 105 liquid preparations were selected. About 100% of the liquid preparation labels mentioned the active ingredient(s) along with their strength, 66.9% mentioned about the drug category of the drug, 46.7% mentioned about the Use/Indication of the drug, 44.8% mentioned about the warnings of the drug, 41.9% mentioned 'Keep out of reach of children', 43.8% mentioned about proper directions to take the drug including how much to be taken, dosage interval, maximum dose allowed per day and the dose for children, 77.1% mentioned about the product's inactive ingredients to help avoid ingredients that may cause an allergic reaction, 87.6% mentioned about the drugs storage conditions, 13.3% mentioned about the product's use in special populations, 83.8% of the liquid preparations correctly mentioned label type, 34.3% of the label correctly used the label font and none of them mentioned about warning related to pregnancy and breast-feeding of the drug.

The current study revealed that most of the patients coming to the study set up are either low socioeconomic back ground people or fall below poverty line, of which a majority of them are found to be of geriatric population. The major challenging factors faced by the medical fraternity while curing an ailment is socio-economic factors, rural community and aged population.Hence, the pharmacist-based educational interventional programme to the patients may overcome this situation to an extent and thus, provides treatment at minimum cost with maximum benefit and betterment of pharmacist-patient care services.[3]

The pharmacists are in unique position to improve medication adherence. They actually demonstrate the use of the medication to the individual patients as well as their caregivers, providing all necessary information either verbally or in written individualized information about their disease and treatment plan in the local language especially in post-discharge patients. Thus, Pharmacists helps in making a responsible decision for rational utilization of prescribed drugs and assist the patient to organize their medication routines by themselves.[2,3] They also play a major role in simplifying therapeutic regimen especially in geriatrics, encouraging patients to discuss their concerns, eliciting patient perception of illness. Hence, providing long-term support and continuity of care to the patient.

Table 1: Distribution of the studied parameters as per the Guidelines for Liquid Preparations

SL NO	PARAMETERS STUDIED	PERCENTAGE(%)
1	Active Ingredient with Strength	100
2	Drug Category	66.9
3	Use/Indications of the drug	46.7
4	General Warnings	44.8
5	Warnings related to Pregnancy & Lactation	0
6	Keep Out of Reach of the Children	41.9
7	Directions	43.8
8	Use in Special populations	13.3
9	Inactive Ingredients	77.1
10	Storage Conditions	87.6
11	Label Type	83.8
12	Label Font	34.3



The bar diagram represents the distribution of studied parameters as a plot of Percentage occurrence Vs. Label contents

CONCLUSION

The present study revealed that the required information provided on the liquid preparation labels are quite insufficient for the patient for ensuring safe, effective and rational use of the medication. In the present scenario, it is legal requirement that each dispensed medicine should be labelled with clear-cut laid down guidelines for their complete labelling so as to ensure each patient gets sufficient drug information and counselling.

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