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Critical Evaluation Of Drug Package Inserts In Maharashtra.

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ABSTRACT

Drug package inserts are the most important written information about the drug for patients, hence it should be simple, precise, understandable and according to section 6.2 and 6.3 of schedule D of ''Drug and Cosmetic Act 1940" and "Drug and Cosmetic Rules 1945." To analyze package inserts whether they include complete data according to the act and the rule or not. To assess the completeness of drug package inserts which are currently in use. 600 Drug package inserts of allopathic drugs from various medical pharmacists and doctor's sample from private doctor outpatient department were collected in duration of one month. Out of which 400 were repeated, so only 200 were analysed for the completeness of data. We found that out of 200 package inserts, all were having section on indications and generic names. 95.5% were having adverse effects mentioned. However only 30% mentioned the references. Also drug strength of 21.5% package inserts was missing and frequency of 20% package inserts was not mentioned. Although package inserts in India have improved over the years still it need to be more precise and simpler for understanding point of view of patients who are the end users of it.

Keywords: Drug information, critical evaluation, package inserts, printed drug leaflet

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INTRODUCTION

Patients Package Inserts (PPI's) are the printed leaflet containing the information based on regulatory guidelines for the safe and effective use of a drug. Statutory information for patients is provided as 'patient information leaflet' included as an insert in the medicine package. They should inform patients about the drugs completely and improve the treatment to be successful and in particular, safety of the drug should be increased [1].

The World Health Organization states that product information leaflet must help patients and other users to understand the medication well [2]. The patients receiving information from their health care providers in the form of verbal medication information is incomprehensive, deficient, tends to be easily forgotten, misunderstand or not understand [3]. This may be due to lack of time and more patient's burden to the health care provider. Most of the time it is seen that the patients who read the patients package inserts are more likely to obey the instructions, especially if the information in the PPI's coincides with the instructions of the health care providers and or pharmacists [4].

In India, the concept of package inserts is governed by Section 6.2 and 6.3 of "Drug and Cosmetic Act 1940 and Drug and Cosmetic Rules 1945 [5, 6]. This Rule does not specify the users of package inserts but it appears to be directed to the healthcare professionals. Also the text in' schedule Y' of the rules does refer to the package inserts as prescribing information [7]. Even though it is an important source of information of drugs, several studies from different countries have shown a need to improve the content and readability of the patients package inserts [8].

Different studies have concluded that the patients package inserts because of their easy availability to everyone, can produce an important impact on patient's compliance and thus on the ultimate effectiveness of the drug use [9]. However, with the growth of the science of Pharmacology and Pharmaceutics, patients package inserts which is an effective tool for providing timely and accurate prescribing guidance has now become more of a legal formality [10].

Taking this into consideration, this study was carried out for complete analysis of the patients package inserts to explore important points which can be useful for increasing knowledge in doctors and patient as well.

MATERIALS AND METHODS

The study was started from the collection of package inserts from doctor's sample provided to doctor's outpatient department and pharmacists from various cities of Maharashtra mostly from Akola, Aurangabad and Pune.

Table 1: Points included in section 6.2 and 6.3 of Drug and Cosmetic Act and Rule 1945.

Contraindications	Indications
Special warnings and precautions	Posology and method of administration
Interactions with medications	Shelf Life
Pregnancy and Lactation	Instruction for use
Effect on ability to drive and use machines	Pediatric and Geriatric group
Undesirable effects	Contraindications and dosage
Antidote for overdosing	Nature and specification of the container
List of excipients	Storage conditions
Drug dose	

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The ethical committee approval was taken. A total of 600 package inserts were obtained, out of which 400 package inserts were repeated hence only 200 package inserts was being thoroughly analysed for most important points mentioned in the Drug and Cosmetic Act 1940 and Drug and Cosmetic Rule 1945, whether they are present or not followed by the scrutiny of the information included under the heading and some extra points were included. These points are mentioned in the table.

If such information was present under the relevant heading or elsewhere in the package insert, it was scored one. Otherwise a score of zero was assigned. After each of the selected package inserts had been scored, the total scores for each heading were calculated by totalling the scores from the individual package inserts. The total scores were expressed as absolute numbers and percentages. Some important extra points are also commented in the results below.

RESULT

600 package insert obtained for this study. Out of which 400 duplicates were excluded from the study. The 200 package inserts studied included 110 oral, 34 injectable and 56 topical preparations. Table no.2 shows the formulation wise distribution of package inserts in details and figure no.1 shows its percentage wise distribution.

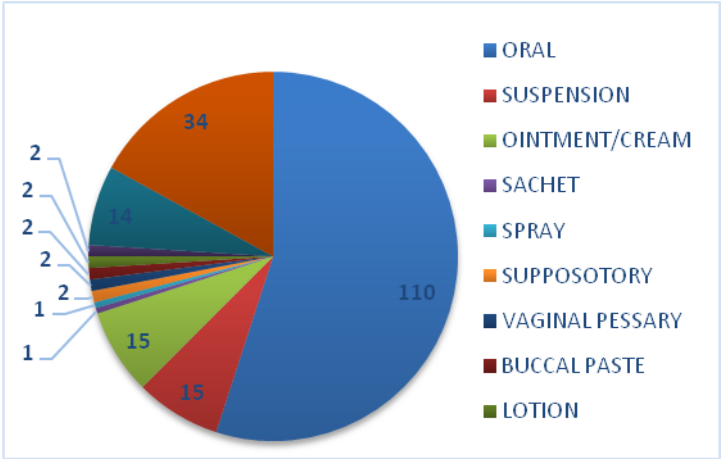
Table 2: Formulation wise distribution of Package Inserts

ORAL SOLIDS	110	VAGINAL PESSARY	2
ORAL LIQUIDS	15	BUCCAL PASTE	2
OINTMENT/CREAM	15	LOTION	2
SACHET	1	EYE DROP	2
SPRAY	1	GEL	14
SUPPOSITORY	2	INJECTABLE	34

In general it was difficult to locate all the information given in package inserts due to lack of common layout and headings. Generic names and therapeutic indications were mentioned in all the package inserts. Contraindications and precautions were mentioned in more than 95% of package inserts.

However effect on ability to drive and use machine, also date on which package inserts was updated was mentioned in very few inserts i.e., 23% and 31% respectively. Retail price was not mentioned in any of the package inserts. Also strength of the drug was missing in 21.5 % of the package inserts and frequency of dose was not mentioned in 20 % of the package inserts.

Figure 1: Formulation wise distribution of drug package inserts



In studied leaflets, mention of generic name of other ingredients was 44% whereas 80.5% of the drug interactions mentioned was mostly drug-drug interactions and only 5% inserts included drug food interactions.

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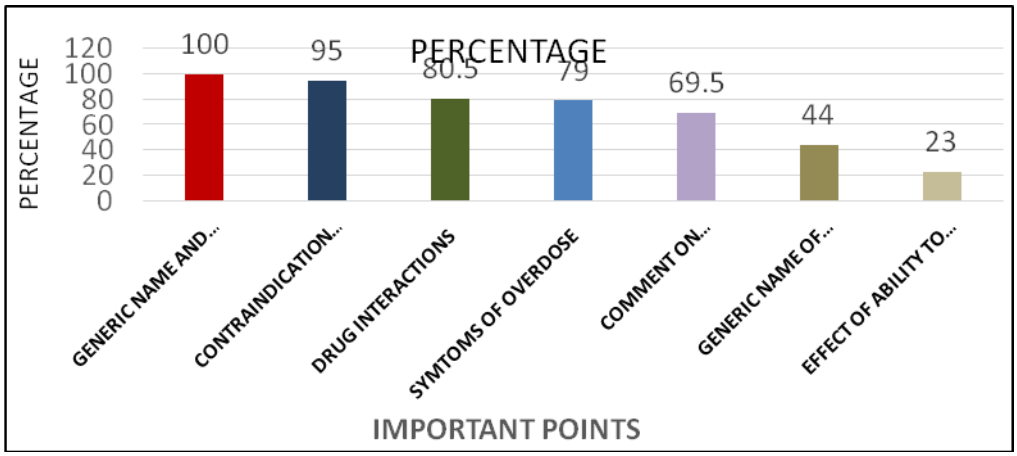
A comment on pregnancy and lactation along with paediatric and geriatric conditions was 76.5% and 69.5% respectively.

Comment on symptoms of overdose of drug was mentioned in 79% of the package inserts but only 9% were having treatment for overdose. Figure no.2 shows the percentage of important points mentioned in the package inserts studied.

Figure 2: Important points mentioned in drug package inserts



DISCUSSION

Complete, accurate and precisely specific information is required for safe and efficient use of the drug. This information can help to minimize the adverse effects due to incorrect method of taking drug and can avoid self-medication. Patients package insert is one such reliable information, which requires prior approval by the respective administrative authority, and which, if used effectively can be a reliable tool for minimization of the medication errors.

From our study nearly about 80 % compliance was found regarding the presence of important data in the sections 6.2 and 6.3 of schedule D of Drug and cosmetic rules 1945. Up to 95 % of package inserts mentioned adverse drug reaction but none of the leaflets included life threatening adverse drug reactions.

The study of Shivkar in 2009 indicated that the information relevant for the safe and effective use of medication was not uniformly mentioned in the package inserts analysed [7]. When compared to the findings from the study by Lal and Seth in 1996 [11], there has been an overall increase in the information given in the leaflets.

However there is still a need to further refine the contents of the circulated package inserts, to make them more complete, reliable and up to date.

According to our study, only 31% of package inserts reveals last date of updated package inserts which is very important to increase regular monitoring of implementation of guidelines and new information to be added. Also 19.5% of the package inserts are difficult to read and understand due to its small font size, which is essential point to be noted.

Almost 85% of the package inserts does not mentioned reference which is important to check its validity. Improvements such as adoption of Indian guidelines regarding inclusion of relevant information, could greatly enhance quality and clarity, and appeal to end users. Lastly the address and name of manufacturer should be in less space to accommodate other important information.

CONCLUSION

The package inserts are the good and reliable source of information for the patients in addition to the

information given by the doctor. It is better to review the package inserts before taking any new medication to avoid any medication errors. Hence there is need to produce the package inserts in simpler language and accurate information with the headings for well understanding of the user.

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