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Evaluation of Completeness of Package Inserts in South India

Dr. A Sudhamadhuri
Assistant Professor,
Department of pharmacology,
Mantralayam Road,
Navodaya Medical College, Raichur, INDIA
allellisudhamadhuri@gmail.com

Dr. Vishal Kalasker
Associate Professor,
Department of Biochemistry,
Mantralayam Road,
Navodaya Medical College, Raichur, INDIA
vishalkalasker83@gmail.com

Abstract:

Aim: to assess the completeness of currently available package inserts in allopathic medicine in South India

Materials & Methods: 120 package inserts accompanying allopathic drugs were collected and analyzed for the completeness of information with reference to the heading given in 'section 6.2 & 6.3' of schedule D, Drug and Cosmetic Act 1945. If the information was present under relevant heading it was scored as one, otherwise a score of zero was assigned. Total score for each heading was calculated by adding the score from the individual package inserts.

Statistical analysis: The results were expressed as absolute numbers and percentage.

Results: 120 package inserts were analyzed in the study. None of the reviewed package insert contained all the sections as required by the Drugs and Cosmetic Act. Among 120 package inserts, only 24 and 3 were found to be complete according to the section 6.2 & 6.3 respectively.

Conclusion: This study showed that very few package inserts were complete as per Indian regulatory guidelines. Package inserts are one of the most frequently used source of drug information. The government should make strict rules to ensure that the information in the leaflet be adequate and follow a standard format.

Keywords: *package inserts, allopathic medicine, Drug and Cosmetic Act, South India*

1. INTRODUCTION

Package insert is a document approved by the administrative licensing authority which is provided with the package of a drug. A package insert primarily directed at the prescribers is intended to provide information for the safe and effective use of the respective drug. It is also known as prescription drug label, prescribing information etc [1] . Regulatory requirement for drug package inserts or leaflets vary across nations. In India regulation for package inserts are provided under section 6.2 and section 6.3 of Drug and Cosmetic Act (1940) Rules (1945) [2].The final amendment had been enforced in 1986. The Drugs and Cosmetic rules do not specify the user of package insert but it appears to be directed to health care professional and the text in schedule(Y) of the rules does refer to package inserts as prescribing information [3].

Section 6.2 mandates that package insert must be in English and must include information on therapeutic indications, posology and method of administration, contraindications, special warning and precautions, drug interactions, contraindications in pregnancy and lactation, effect on ability to drive and use machines, undesirable effect and antidote for over dosing.

Section 6.3 mandates pharmaceutical information on list of excipients, incompatibilities, shelf life as packaged, after dilution or reconstitution or after first opening of the container, special precautions for storage, nature and specification of container and instructions for use / handling.

Studies have shown that the package inserts because of their easy availability can produce important impact on patient compliance and thus ultimate effectiveness of drug use [4, 5]. Package inserts helps bridge the gap between the health care provider and patients and enhances patients knowledge about medication [6, 7]. They also serve as reliable and accurate source of drug information for health professionals [8]. This study was aimed to assess the completeness of package inserts of allopathic drugs marketed by pharmaceutical companies in India.

2. MATERIALS & METHODS

120 leaflets accompanying allopathic medicine marketed by pharmaceutical companies in India ware provided by 6 pharmacies on request. Selection was done to ensure the drugs covered different therapeutic indication (n=10) different pharmaceutical form (capsules, tablets, syrups, injections, lotions, ointments) from different manufacturers (n=32). The study was conducted over a period from Aug-2014 to Dec-2014.

The clinical information included in the package insert was analyzed according to the heading mentioned in section 6.2 & 6.3 of Schedule D of Drugs and Cosmetic rules 1945. If a heading was not present in a package insert the entire insert was checked for presence or absence of information relevant to the concerned heading. If the information was present under relevant heading (or) elsewhere in the package insert it was scored as one, otherwise a score zero was assigned. After each of the selected package insert had been scored, the total score for each heading were calculated by totaling the scores from the Individual package inserts. The total scores were expressed as absolute numbers and percentage.

3. RESULTS

120 package inserts were evaluated in this study. The 120 leaflets studied included 92 oral (56 tablets, 32 capsules and 4 syrups), 17 injections, 11 topical preparations (9 creams and 2 lotions) marketed by 32 different pharmaceutical companies in India.

The data regarding the presence of important sections described in the leaflets is provided in table 1. Classification of drug package inserts according to the indication given in table 2. In general the Presentation of clinical information was complete though it was difficult to locate and retrieve information easily due to lack of a common layout and headings, indications, contraindications and side effects were mentioned in almost all Package inserts. Posology and method of administration were mentioned in 90% package inserts, Precautions for use present in 80% inserts, Pediatrics and geriatric use were mentioned in 38% and 40% of inserts. Although adverse effects were mentioned in all package inserts only 30% of inserts categorized the Adverse Drug Reactions organ or system wise and 20% mentioned the frequency of various Adverse Drug Reactions. Only 8% leaflets highlighted the series of adverse drug reactions associated with the products which included drugs with hypoglycemic effect, and hypersensitivity .The information on antidote in case of overdose and effect on ability to drive and use medicines were present in 20% of package inserts.

Pharmaceutical section had many deficiencies the list of excipients, incompatibility, storage instructions were mentioned in 40%, 48% and 62% respectively. While special precautions for storage, nature & specification of container and instructions for use was mentioned in 62%, 76% and 30% respectively.

4. LIST OF TABLES

Table1. *Results of Analysis of drug package inserts*

Sl. No.	Section 6.2	Positive scores	Percentage of positive scores
1.	Therapeutic indication	120	100%
2	Posology and method of administration	108	90%
3	Contraindications	120	100%
4	Special warnings and precautions for use	96	80%
5	Interaction with medication and other interaction	110	92%
6	Pregnancy and lactation if contraindicated	115	96%
7	Effect on ability to drive and use medicines if contraindicated	24	20%
8	Undesirable effects / side effects	120	100%
9	Antidote for over dose	24	20%
	Section 6.3		
10	List of excipients	48	40%
11	Incompatibility	58	48%
12	Shelf life in the medical product package for sale	0	0

13	Shelf life after dilution / reconstitution according to direction	0	0
14	Shelf life after opening the container	3	2%
15	Special peculations for storage	74	62%
16	Nature & specification of container	91	76%
17	Instruction for use	36	30%

Table2. *Classification of drug package inserts according to the indication (Total number =120)*

Sl. No.	Class	Number	Percentage (%)
1	Antibiotic drug	26	21.66%
2	NSAIDS and analgesics	22	18.33%
3	Anti diabetic drugs	17	14.16%
4	Antiemetic drug	13	10.83%
5	Anti asthmatic drug	12	10%
6	Antifungal drug	08	6.66%
7	Anti tussive drug	08	6.66%
8	Anti hypertensive drug	06	05%
9	Anti platelet drugs	05	4.16%
10	Anti hyperlipidemic drugs	03	2.5%

5. DISCUSSION

The safe and efficient use of drugs requires that accurate, complete, specific and timely information be disseminated to the prescribers and users in a readily comprehensible manner. Package insert is one such reliable source of information which receives prior approval by the respective administrative authority and which if used effectively can be a reliable tool for the minimization on of medication errors [9]. This study showed that package inserts are inadequate in many aspects, dosage instructions were missing from 15% of package inserts. Information on pediatric and geriatrics was missing from many package inserts. This could be of concern as a study from northern India has shown that more than 56% of hospital admissions due to adverse drug events occurred in people aged over 60 years [10]. Information about the shelf life was not present in any Package Insert. Information on shelf life is important as the drug that has passed its shelf life might be safe for consumption but its quality cannot be guaranteed [11]. Excipients which have been known to cause drug interactions were mentioned in 40% of the package inserts [12]. Among 120 package inserts, only 24 and 3found to be complete according to the section 6.2 & 6.3 respectively. It was however noted that there has been an overall improvement in the percentage of inserts containing information as compared to previous studies [13, 14].

Information included in the package insert is necessary for both prescriber and the patients. Currently in India the structure and content of information on the inserts is geared towards prescribers only. In Indian scenario due to inadequate doctor patient ratio, the accessibility to trained prescribers is difficult and physicians are not able to spend enough time with their patients. This gives rise to self medication, medication errors and adverse drug reactions. All these issues indicate the need for patient oriented package inserts [15]. As package inserts are one of the most frequently used source of drug information, approaches to optimize them should be explored as soon as possible.

6. CONCLUSION

This study showed that very few package inserts are complete as per regulatory guidelines. To avoid medication errors due to deficits in the current package inserts, the government should make strict rules to ensure that the information in the leaflet be adequate follow a standard format and displayed in a way that the essential be easily picked.

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AUTHORS' BIOGRAPHY

Dr. Sudhamadhuri has completed her MBBS and MD (Pharmacology) from the prestigious Gandhi Medical College, Hyderabad. Presently she is working as assistant professor in Navodaya Medical College Raichur, Karnataka

Dr. Vishal Kalasker has completed his MBBS from Vijayanagara institute of Medical Sciences, Bellary and MD (Biochemistry) from the JJM Medical College, Davanagere. Presently he is working as associate professor in Navodaya Medical College Raichur, Karnataka