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Research Article

Analytical evaluation of drug package inserts in India

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ABSTRACT

Background: A drug package insert or prescribing information is a document provided along with a prescription medication to provide additional information about that drug. Drug package inserts are approved by the administrative licensing authority. A package insert is intended to provide information for the safe and effective use of the respective drug. Product information provided by pharmaceutical companies has been determined to be far from adequate and not conforming with requirement of Indian regulatory. Hence, it was decided to conduct a study to assess the presentation and completeness of clinically important information provided in the currently available package inserts in India.

Methods: Package inserts were provided by five pharmacies on request. The package inserts were collected in 10 weeks' period and then they were analyzed for presentation and completeness of clinical information according to heading mentioned in Section 6.2 and 6.3 of schedule D of Drug and Cosmetic Rule, 1945. If the information was present under relevant heading, it was scored as one. Otherwise as score of zero was assigned. Total score for each heading was calculated by adding the score from the individual package inserts.

Results: 70 package inserts were included in the study. None of the reviewed package inserts contained all the sections as required by the Drugs and Cosmetics Act. Total 15 headings were evaluated under both Section 6.2 and 6.3, highest value for the presence of heading were 12 out of 15 heading evaluated. That shows the best value of compliance was 80%.

Conclusion: Accurate drug product information is important for the safe and effective use of medicines. Hence, pharmaceutical companies and regulators should ensure that accurate and up to date product information is provided in the package inserts.

Keywords: Drug package inserts, Drug & Cosmetic Act, Prescribing information

INTRODUCTION

A drug package insert or prescribing information is a document provided along with a prescription medication to provide additional information about that drug.[1] Drug package inserts are approved by the administrative licensing authority. 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.,[2]

Pharmaceutical companies disseminate information regarding marketed products through promotional materials, medical representatives, periodicals, scientific meetings, as well as printed materials, which accompany drug products. Printed information accompanying drug products includes the information on the primary or immediate drug packaging, the external package, as well as that on the inserts or leaflets accompanying drug products. The main aim of the package inserts or leaflets is to provide information essential for the safe and effective use of the drugs and hence reducing the number of adverse reactions resulting from medication errors.[3] Drug package insert is approved by the administrative licensing authority. Regulatory requirements for drug package inserts or leaflets vary across nations. United States-Food and Drug Administration and European Medicines Agency amend their regulations governing the content and format of labeling for drug products from time to time.[4,5]

In India, the concept of package insert is governed by the "Drugs and Cosmetic Act (1940) and rules (1945)." Section D (II) of the rules lists the headings according to which information should be provided in the package inserts. "Section 6.2" mandates that the package insert must be in English and must include information on therapeutic indications, posology and method of administration,

contraindications, special warnings and precautions, drug interactions, contraindications in pregnancy and lactation, effects on ability to drive and use machines, undesirable effects, and antidote for overdosing. "Section 6.3" mandates pharmaceutical information on list of excipients, incompatibilities, shelf life as packaged, after dilution or reconstitution, or after first opening the container, special precautions for storage, nature and specification of container, and instruction for use/handling.[6]

Product information provided by pharmaceutical companies in India has been determined to be far from adequate and not conforming with the WHO recommendations and requirement of Indian regulatory.[3,7,8] Hence, it was decided to conduct a study to assess the presentation and completeness of clinically important information provided in the available package inserts in India.

METHODS

This study was approved by scientific review committee. The package inserts were provided by five pharmacies on request. The pharmacies were located nearby tertiary care hospital in Surendranagar, Gujarat, India. The package inserts were collected over a 12 weeks' period in January-March 2013. The duplicates package insets (same drug, formulation, and company) were also identified and excluded. The remaining package inserts were included in the study and analyzed for the presentation and completeness of clinical information. The clinical information included in the package inserts were analyzed according to the headings mentioned in "Section 6.2 and 6.3" of Schedule D of Drugs and Cosmetics Rules, 1945 (Table 1).[6] Then they were analyzed for presentation and completeness of clinical information. If the information was present under relevant heading, it was scored as one. Otherwise as score of zero was assigned. Total score for each heading was calculated by adding the score from the individual package inserts. The total scores were expressed as absolute numbers and percentages.

Table 1: Schedule D of Drugs and Cosmetics Act (1940) and Rules (1945).

Section 6.2	Section 6.3
Therapeutic information	Pharmaceutical information
Posology and method of administration	List of excipients
Contraindication	Incompatibilities
Special warning and precaution	Shelf life
Interaction	Shelf life after dilution or reconstitution
Pregnancy and lactation	Shelf life after opening the container
Effects on ability to drive, if contraindicated	Special precaution for storage
Undesirable effects	Nature and specification of container
Antidote for overdosing	Instruction for use/handling

RESULTS

The five pharmacies provided 75 package inserts during study period. Of these, 5 duplicate inserts were excluded and remaining 70 inserts were used for further analysis. The classification of drug package inserts according to indication and dosage form is given in the Tables 2 and 3 (Figure 1), respectively. Analysis of data presented as per Section 6.2 and 6.3 is given in Table 4. None of the reviewed inserts contained all the sections as required by the Drugs and Cosmetics Act. Totally 15 headings were evaluated under both Section 6.2 and 6.3, highest value for the presence of

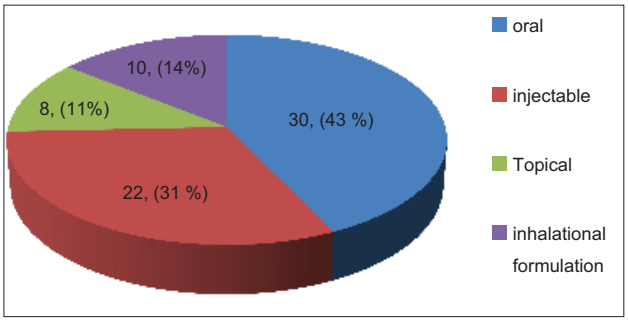

Figure 1: Classification of drug package inserts according to the type of formulation (total number = 70) (n, [%]).

Table 2: Classification of drug package inserts according to indication (total number=70).

Class	N (%)
Antibiotic drug	6 (9)
Antidiabetic drugs	10 (14)
Antiasthmatic drugs	10 (14)
NSAIDs and analgesics drugs	8 (11)
Antimalarial drugs	4 (6)
Antiplatelet drugs	6 (9)
Antiemetic drugs	2 (3)
Antitussive drugs	3 (4)
Anti-hypertensive drugs	5 (7)
Drugs for hyperlipidemia	4 (6)
Antifungal drugs	6 (9)
Hormone	6 (9)

NSAIDs: Non-steroidal anti-inflammatory drugs

Table 3: Classification of drug package inserts according to type of formulation (total number=70).

Type of formulation	N (%)
Oral	30 (43)
Injectable	22 (31)
Topical	8 (11)
Inhalational formulation	10 (14)

Table 4: Results of analysis of drug package inserts.

	N (%)
Section 6.2	
Indication	70 (100)
Posology and method of administration	58 (83)
Contraindication	56 (80)
Special precaution and warning	60 (85)
Interaction	51 (73)
Pregnancy and lactation, if contraindicated	56 (80)
Effects on ability to drive and use machine if contraindicated	5 (7)
Undesirable effects/side effects	60 (85)
Antidote for overdosing	4 (6)
Section 6.3	
List of excipient	60 (85)
Incompatibilities	23 (33)
Shelf life	17 (24)
Special preacaution for storage	62 (89)
Nature and specification of container	56 (80)
Instruction for use and handling	58 (83)

heading were 12 out of 15 heading evaluated. That shows the best value of compliance was 80%.

In therapeutic information, indications for use were present in all the inserts (100%). Information on posology, side effects, special warnings, drug interactions, and contraindications were mentioned in at least 80% of the package inserts studied. The information on antidote in case of overdose and effects on ability to drive and use machines were present only in 6% of package inserts.

In pharmaceutical information, the list of excipients, special precaution for storage, nature and specifications of container and instruction of handling and use were represented in at least 85% of the inserts. The self-life and incompatibilities were present only in 24% and 33% of inserts. The layout of inserts is varied from one company to other pharmaceutical company. All the inserts were easily readable.

DISCUSSION

Package insert is one 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 of medication errors.[2] In our study, under the section of 6.2, posology and method of administration, contraindication, special precaution and warning, interaction and undesirable effects are present in 83%, 80%, 85%, 73%, 85% of inserts studied, respectively, which are lower than study reported by Shivkar[3] and study conducted by Kalam et al.[9] At least 95% of compliance were reported to above-mentioned headings by Shivakar; Kalam et al. The effect on ability to drive and antidote for overdosing are present in only 5% of inserts studied which is comparable with study conducted by Kalam et al.[9]

In present study, under section 6.3 which includes list of excipient, pracaution for storage, specification of container, instruction of use, and handlings are present in at least 85% of inserts and shelf life is present in only 24% of inserts studied. The result shows higher percentage of availabilities of heading under pharmaceutical information compared to the study conducted by Kalam et al.[9]

CONCLUSION

The present study showed that the pharmaceutical company did not follow the Drug and Cosmetics Act and rules in making the drug package inserts. Accurate drug product information is important for the safe and effective use of medicines. Hence, pharmaceutical companies and regulators should ensure that accurate and up to date product information is provided in the package inserts.

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