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A Study On the Evaluation of Drug Package Inserts: A Prospective Observational Study

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ABSTRACT

Background

A drug package insert is a regulatory document which is included in the package of a medication that provides information about that drug and its clinical application. An ideal Package Insert (PI) contains the approved, essential and accurate data regarding a drug and it contains information in a language that is not promotional, false or misleading. However, not all PIs satisfy the above standards. On that account, the present study was conducted to evaluate the completeness of presently available drug PIs.

Aim and Objective

The aim of this study is to evaluate the completeness of the Package inserts and grade them accordingly.

Methods and Materials

The present study is a Prospective, Observational study. 63 PIs were collected from various pharmacies in and around Ongole. Out of them, 03 of the PIs were found to be duplicated and were rejected. Remaining 60 PIs were evaluated hinged on criteria laid down by the Drugs and Cosmetics Rules 1945 under section 6.2 and 6.3 of schedule D containing a total of 25 criteria. Each criterion will be given a score of '1' for presence of an information and absence will be scored '0'. And based on this scoring, PIs were categorized accordingly.

Results

Among the PIs, 49 (82%) were of Indian Companies

and 11 (18%) were of Multinational Companies. Furthermore, 18 (30%) were parenteral preparations, 36 (60%) were oral formulations, and 06 (10%) were topical preparations. PIs were inadequate to information with respect to retail price of the drug (0%), effect on ability to drive and use machines (25%), references (30%) and provision of full information on request (32%). 20% of Package inserts were A category, 80% were B category and none of them under C Category.

Conclusion

This study implies that still there are some paucities among the drug PIs and is necessary for revising and improving the concept of PIs to make it more effective in serving its purpose.

Keywords

Drug Package Insert, Drug Information, Patient Information Leaflet

INTRODUCTION

For an effective and safe utilization of marketed pharmaceutical products, accurate and reliable drug information is needed. This can be achieved using Package Insert (PI). It is a printed leaflet which is included along with the drug and it contains information based on certain regulatory guidelines for the safe and effective use of that particular drug[1]. A Package Insert (PI) is considered satisfactory when it contains the essential and accurate data regarding a drug, in a language that is not promotional, false or misleading[2]. It is revised time to time based on relevant clinical and pre-clinical information.

The patient package inserts, together with the label, provides the patient with primary information concerning the proper use of the product, potential adverse reactions and interactions, storage conditions and the expiry date[3]. From the patients point of view, it is to instruct them on how and when to use a medicine and to promote an understanding of the purpose, benefits and risks of the medication prescribed[4].

In India, healthcare professionals rely on a variety of sources like textbooks, journal articles and compilations for information and updates on drugs[5]. Prescribers also mostly depend on product information provided by the pharmaceutical companies. However, the information provided by the pharmaceutical companies in India has found to be insufficient and not adhering with the WHO standards. Therefore, PIs are useful sources of information both for patients and healthcare providers[6,7]. Incomplete and incorrect product information may have serious consequences including disability or death[8].

Package Inserts in India are governed by the Drugs and Cosmetics Act (1940) and Rules (1945). The PIs are to be provided with information as listed in section 6 of Schedule D (II). The Section 6.2 directs that the PIs must be in 'English' and provides details regarding the specific requirements and under 6.3 pharmaceutical information on list of excipients is mandated[9].

From the previous studies, it is evident that many of the available PIs in Indian Market fail to adhere to guidelines, yet the data published in the recent years shows that the PIs are getting better. However, the information is still not found to be complete and adhering as per guidelines. They contain inadequate information regarding storage, shelf life and pricing of the drug[7,8]. With this background, this study was conducted to assess the integrality of the presently

available package inserts based on the standards mentioned in Schedule D of Drug and Cosmetic act 1945.

MATERIALS AND METHODS

Study Design: Prospective, cross sectional and observational study.

Study setting & Methodology

The study was conducted in Government Medical College, Ongole. Package inserts were collected from various pharmacies in and around Ongole for a period of 1 month. Duplicated PIs were subjected to rejection. Finalised PIs were evaluated hinged on the criteria laid down by the Drugs and Cosmetics Rules 1945, containing a total of 25 criteria (Table 1). Each criterion will be given a score of '1' for presence of an information and absence will be scored '0'. Total score is expressed in percentages. Total score of >20 is graded as 'A', 10-20 as 'B' and <10 as 'C'. Data were extracted twice to minimize the chance of missing any information.

S. No	Criteria
1	Legibility
2	Approved generic name of active ingredients
3	Content of active ingredient per dosage form
4	Generic names of other ingredients
5	Therapeutic indications
6	Posology and method of administration
7	Contraindications
8	Special warnings and precautions
9	Drug interactions
10	Pregnancy and lactation
11	Pediatric and geriatric indications
12	Special conditions and contraindications
13	Effect on ability to drive and use machines
14	Undesirable effects
15	Drug dose
16	Over dosage
17	Pharmacokinetic information
18	Storage information
19	Instructions for use and handling
20	Shelf life
21	Date on which information was last updated
22	Name and address of the manufacturer /distributor
23	Provision of full information on request should be highlighted
24	Retail price of the drug
25	References

Table 1: Criteria for Package Inserts hinged on the criteria mentioned by the Drugs and Cosmetics Rules 1945

RESULTS

A total of 96 drugs were checked for package inserts and among them only 63 (66%) drug boxes contained PIs. Other 33 (34%) drug boxes were without PIs. Out of 63 PIs, 3 were repeated and were not considered for the study. A total of 60 PIs were evaluated. The results are evaluated and shown in Table 2. None of the appraised package inserts contained all the sections as per the standards mentioned by the Drugs and Cosmetics Rules, 1945. In a total of 25 criteria's which were evaluated under Section 6.2 and 6.3, the highest score of a package insert for presence of headings and pertaining information was 22.

S. No	Criteria	Mentioned (%)	Not mentioned (%)
1	Legibility	54(90%)	6(10%)
2	Approved generic name of active ingredients	60(100)	0(0)
3	Content of active ingredient per dosage form	60(100)	0(0)
4	Generic names of other ingredients	36(60)	24(40)
5	Therapeutic indications	60(100)	0(0)
6	Posology and method of administration	60(100)	0(0)
7	Contraindications	60(100)	0(0)
8	Special warnings and precautions	60(100)	0(0)
9	Drug interactions	51(85)	9(15)
10	Pregnancy and lactation	49(82)	11(18)
11	Pediatric and geriatric indications	44(73)	16(27)
12	Special conditions and contraindications	52(87)	8(13)
13	Effect on ability to drive and use machines	15(25)	45(75)
14	Undesirable effects	57(95)	3(5)
15	Drug dose	60(100)	0(0)
16	Over dosage	42(70)	18(30)
17	Pharmacokinetic information	53(88)	7(12)
18	Storage information	36(60)	24(40)
19	Instructions for use and handling	34(57)	26(43)
20	Shelf life	33(55)	27(45)
21	Date on which information was last updated	19(32)	41(68)
22	Name and address of the manufacturer /distributor	48(80)	12(20)
23	Provision of full information on request should be highlighted	10(17)	50(83)
24	Retail price of the drug	0(0)	60(100)
25	References	18(30)	42(70)

Table 2: Evaluation results of PIs based on the criteria laid down by the Drugs and Cosmetics Rules 1945

Out of 60 PIs, 49 (82%) were from Indian Companies and 11 (18%) from Multinational Companies (Figure 1). Also, the number of PIs of oral, injectable and topical were 35 (58%), 19 (32%) and 6 (10%) respectively. In accordance with scoring, 12 (20%) PIs fall under 'A' category, 48 (80%) PIs under 'B' category and none came under 'C' category (Figure 2).

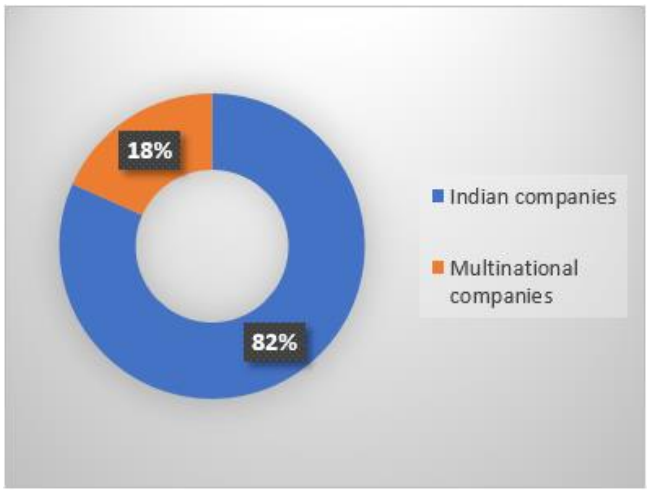

Figure 1: Pie diagram representing the Percentage of package inserts by Indian and Multinational Companies.

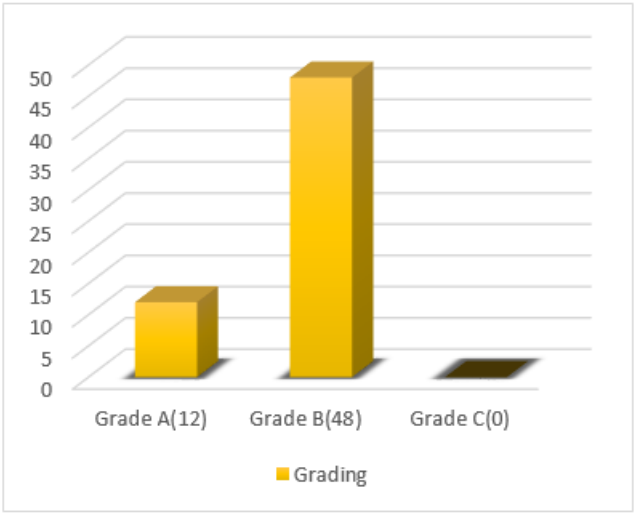

Figure 2: Grading of package inserts

Among the 60 Package inserts evaluated, 14 (23%) were of antibiotics, 8 (13%) of anti-diabetic drugs, 3 (5%) of Vitamins and Minerals, 10 (17%) of Cardiac drugs, 6 (10%) of Respiratory drugs, 5 (8%) of CNS Drugs, 6 (10%) of GIT, 4 (7%) of Antifungals and 4 (7%) of steroids (Figure 3).

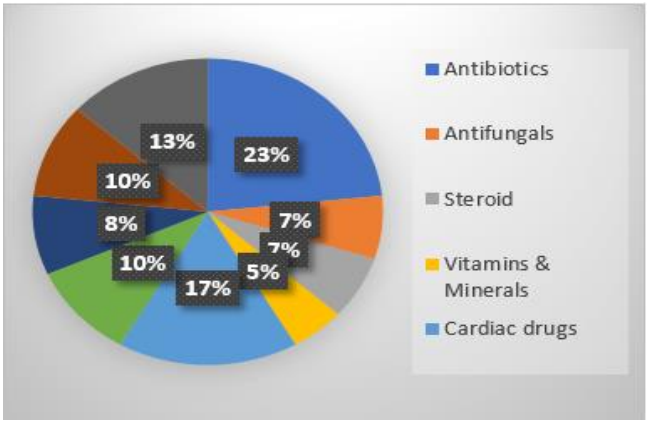

Figure 3: Percentage of various drug classes of package inserts

DISCUSSION

In this study, PIs of various drugs were evaluated to see if they contained information in accordance with Indian Regulatory Guidelines. It was observed that PIs were deficient in many aspects. The size of the package inserts was not uniform and it was difficult to retrieve information due to lack of common format. The presentation, font size and colour were appropriate in 90% of PIs, while the remaining 10% were undecipherable. Small font size was a foremost issue. Similar results are observed in previous studies conducted by Bansal et al and Joubert et al. If PIs are unread, they have potential educational and legal implications[10,11].

Out of 60 PIs, only 12 PIs belonged to "A" category, 48 PIs belonged to "B" category and none of them belonged "C" Category. This study is a contrary to the previous study conducted by Neha et al[12] in which 4 PIs belonged to the "C" category. Although this result favours the fact that the standard of the Package inserts are marching towards betterment, yet the number of PIs falling under "A" Category is a blemish.

Among the 11 Multinational PIs, 6 of them were graded as 'A' category (Figure 4). This results shows that the quality of information in Multinational PIs were superior than that of the Indian Drug PIs, which is similar to a previous study conducted by Gupta et al[13].

Figure 4: Comparison between PIs of Indian and multinational companies

In our study, under Section 6.2, indication, posology, generic name, active ingredient, contraindication, drug dosage, special warnings were present in all 60 (100%) package inserts. Study conducted by Solanki et al[14] conflicts this result by showing percentages between 70% - 85% but somewhat similar to the study conducted by Kalaam et al[15].

Information about use in pregnancy and lactation, pediatric and geriatric indications and undesirable effects were present in 82%, 73% and 95% PIs respectively. Again, storage information was mentioned in only 60%, instructions for use and handling in 57% and date on which information was last updated in 32% of PIs. Information about shelf life was present in 55% and references were present in 18%. However, retail price of the drug was not present in any of the PI, which is similar to the observations made in previous studies conducted by Sudhamadhuri et al[16].

Information on effect on ability to drive and over-dosage was present in 25% and 70% respectively, which is similar to the study reported by Agharia et al[17]. Many of the drugs which have sedative action or which interfere with the CNS function ,were not mentioned anything about driving or using machines after their consumption which can lead to impaired judgement, reaction time, motor skills deficiency and altered memory. Such data deficits act as a snag between consumers and the pharmaceutical companies.

In this study, it was found that many drugs are dispensed without a package insert. This is a major area of consideration in the healthcare system. In developing countries like India, there is an inadequate doctor patient ratio. Accessibility to trained prescribers is cumbersome and also it is not easy for the physicians to spend enough time with their patients. This may result in self-medication, medication errors and adverse drug reactions. All these issues indicate the PIs, should be more patient oriented and provide the correct, concise and adequate information to its users[18].

However, compared to previous studies, the result from this study favour the furtherance of Package Inserts and none of the PIs were graded as 'C' category. The main limitation of our study is the sample size with which a precise interpretation is arduous.

CONCLUSION

Package Insert plays a salient role in promulgating primary knowledge about the drug and drug products to the consumer. Although in recent years, there has been overall improvement in presentation and information in drug package inserts, still the information provided are incomplete as per regulatory guidelines. In order to avoid the medication errors and to eliminate the deficits in drug information in package inserts, hefty monitoring and scrutiny of package inserts by regulatory authorities is required. With the recent emergence of increased consumption of over-the-counter medication, it is important for the pharmaceutical companies to dispense drugs with patient-oriented package inserts adhering to regulatory guidelines which act as an only source of information for the betterment of the community.

REFERENCES

1. Ramdas D, Chakraborty A, Hs S, et al. A study of package inserts in southern India. J Clin Diagn Res 2013;7(11):2475-7.

2. Ved JK. Package Inserts in India: Need for a Revision. International Journal of Pharmaceutical Sciences and Research. 2010;1(11):454-56.
3. Annex 9. Guidelines on packaging for pharmaceutical products, WHO technical report series, 2002;902. http://www.who.int/ medicines/areas/ quality_safety/q uality_ assurance/ Guidelines PackagingPharmaceuticalP roductsTRS902Annex9.pdf
4. Sinaa A Al-aqeel. Evaluation of medication package inserts in Saudi Arabia. Drug, Healthcare and Patient Safety. 2012;4:33-8.
5. Rajan MS, Sreedhar, Khan SA, Thiyagu R, Rao PG. Information seeking behaviour of clinicians in a semi urban town in southern India. Journal of Clinical and Diagnostic Research. 2008;2:1069-73.
6. Dikshit RK, Dikshit ND. What information is available on request from drug advertisers. BMJ. 1996;313:855-6.
7. Lal A, Sethi A. Drug package inserts in India. Ann Pharmacother. 1996;30:1041.
8. Shivkar YM. Clinical information in drug package inserts in India. J Postgrad Med 2009;55(2):104-7.
9. The Drugs and Cosmetics Act and Rules. Ministry of Health and Family Welfare, Government of India. 2003. p. 312. Available from: http://cdsco.nic.in Accessed on March 15th, 2013.
10. Bansal V, Dhamija P, Medhi B, Pandhi P. Package inserts-do they have any role? JK-Practitioner. 2006;13(3):152-4.
11. Joubert P, Lasagna L. Patient package inserts: nature, notions and needs. Clin Pharmacol Ther. 1975;18:507-13.
12. Deep N, Jose R, Chakrabo A. Medication package inserts: how far do they adhere to the guidelines. Int J Basic Clin Pharmacol. 2016;6(1):133.
13. Gupta MC. Analysis of completeness of information in package inserts of Indian and foreign multinational pharmaceutical companies: an Indian perspective. Int J Basic Clin Pharmacol [Internet]. 2020 May 21 [cited 2023 Dec. 13];9(6):863-9. Available from: https://www.ijbcp.com/index.php/ijbcp/article/view/3939
14. Solanki SN, Chhaiya SB, Mehta DS, Trivedi M, Acharya T, Patel D. Analytical evaluation of drug package inserts in India. International Journal of Basic and Clinical Pharmacology. 2015;4:322-4.
15. Kalam A, Anwar S, Fatima A. Drug package inserts in India: current scenario. World Journal of Pharmacy & Pharmaceutical Sciences 2014;3(4):385-92.
16. Sudhamadhuri A, Kalasker V. Evaluation of Completeness of Package Inserts in South India. International Journal of Research Studies in Biosciences. 2015;3(7):102-10.
17. Agharia MA, Gawali UP, Kesari HV, Shah KU. A critical appraisal of package inserts in India. Journal of Evolution of Medical and Dental Sciences. 2016 Jun 6;6(5):2885.
18. Morris LA, Patients package inserts: A new tool for Patient education Public Health Reports. 1997;92(5):421-24.