ORIGINAL RESEARCH

Assessment of Package Inserts

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ABSTRACT

Background: For marketed products to be used safely and effectively, accurate and trustworthy drug information is crucial. Package Inserts (PIs) are the main source of drug information.The present study was conducted to assess Package Inserts. **Materials & Methods:** 110 Package Inserts (PIs) was studied. A total score of 25 was assigned to each, based on 25 criteria. Presence of information was scored as '1' and absence was scored '0'. Total score was expressed in percentages. If a package insert met more than 20 criteria, it was graded as 'A'; 10-20 criteria as 'B', and less than 10 as 'C'. **Results:** Out of 110 Package Inserts (PIs), 72% were from Indian companies and 28% from multinational companies. The difference was significant (P< 0.05). There were 55 anti-diabeticsPIs, 38 anti-hypertensives and 17 Hypolipedemic PIs. Under anti-diabeticsPIs, 40 were oral and 15 injectable. Under anti-hypertensivesPIs, 32 were oral and 6 were injectables. Under Hypolipedemic PIs, 16 were oral and 1 was injectable. The difference was significant (P< 0.05).24.6% had grade A and 74.4% had grade B. The difference was significant (P< 0.05). **Conclusion:** The examined package inserts lacked information pertinent to the safe and efficient use of medication. Therefore, it is advised that the current package inserts be updated in accordance with the standards outlined in Schedule D of the Drug and Cosmetic Act of 1945.

Keywords: anti-hypertensives, Hypolipedemic, Package Inserts

INTRODUCTION

For marketed products to be used safely and effectively, accurate and trustworthy drug information is crucial. Package Inserts (PIs) are the main source of drug information.[1] It is a printed pamphlet with information based on legal requirements for a medication's safe and efficient use. It is sometimes referred to as prescribing information or a prescription medicine label. The acceptable, necessary, and correct information on a drug is contained in a good PI. It is not written in a way that is deceptive, untrue, or promotional.[2] It is supported by evidence and is periodically updated in light of new preclinical and clinical information. With thorough examination of the information that is now accessible, this medication product information starts early in the pharmaceutical product's development phase.[3]

The "Drugs and Cosmetics Act (1940) and Rules (1945)" govern the idea of a package insert in India. The headers that should be used to give information in the PIs are listed in Schedule D (II) of the rules, section 6. "Section 6.2" stipulates that the PIs must be in "English" and gives details on the particular requirements.[4] Pharmaceutical information on the list of excipients is required under "Section 6.3." Several studies have demonstrated that the use of prescription medications is one of the most important aspects of managing medical disorders.[5] Unfortunately, approximately 50–60% of individuals with chronic diseases like diabetes, hypertension, and dyslipidemia take their medications as directed. In urban India, the prevalence of diabetes mellitus is currently 8.3%, making it a significant health care burden. By 2030, India is predicted to have the greatest number of diabetic sufferers. With a frequency of 19.04% in central India, hypertension is a highly frequent condition that affects people past middle age. It is a significant cardiovascular mortality and morbidity risk factor.[6,7]The present study was conducted to assess Package Inserts.

MATERIALS & METHODS

The study comprised of 110 Package Inserts (PIs).

PIs were gathered upon request from a variety of pharmacies. Examination of the pis's content: Section 6.2 of Schedule D of the Indian Drug and Cosmetic Rules, 1945, established the parameters that were used to grade PIs. A total score of 25 was assigned to each, based on 25 criteria. Presence of information was scored as '1' and absence was scored '0'. Total score was expressed in percentages. If a package insert met more than 20 criteria, it was graded as 'A'; 10-20

criteria as 'B', and less than 10 as 'C'.Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Grading of Package Inserts (PIs)

Companies	Percentage	P value
Indian	72%	0.01
Multinational	28%	

Table I shows that out of 110 Package Inserts (PIs), 72% were from Indian companies and 28% from multinational companies. The difference was significant (P< 0.05).

Table II Assessment of parameters

Parameters	Variables	Number	P value
anti-diabeticsPIs (55)	oral	40	0.02
	injectable	15	
anti-hypertensivesPIs (38)	oral	32	0.01
	injectable	6	
Hypolipedemic PIs (17)	oral	16	0.01
	injectable	1	

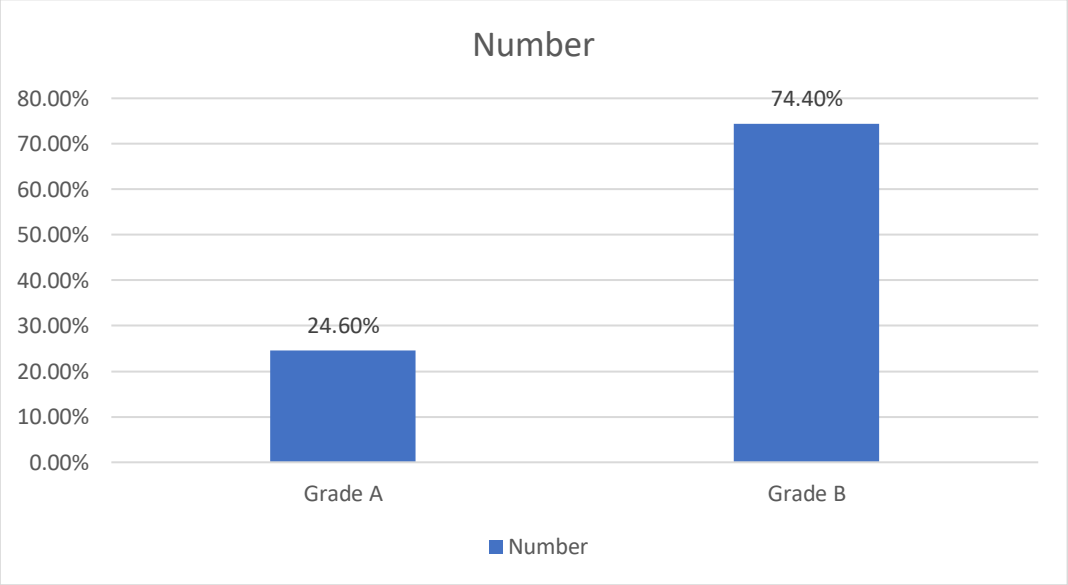
Table II shows that there were 55 anti-diabeticsPIs, 38 anti-hypertensivesand 17 Hypolipedemic PIs. Under anti-diabeticsPIs, 40 were oral and 15 injectable. Under anti-hypertensivesPIs, 32 were oral and 6 were injectables. Under Hypolipedemic PIs, 16 were oral and 1 was injectable. The difference was significant (P< 0.05).

Table III Grading of PIs

Grading	Number	P value
Grade A	24.6%	0.01
Grade B	74.4%	

Table III, graph I shows that 24.6% had grade A and 74.4% had grade B. The difference was significant (P< 0.05).

Graph I Grading of PIs



DISCUSSION

With a frequency of 19.04% in central India, hypertension is a highly frequent condition that affects people past middle age. It is a significant cardiovascular mortality and morbidity risk factor.[8,9] With a prevalence of 30.3% in urban India, hyperlipedimia is a significant risk factor for coronary artery disease, hypertension, and diabetes mellitus.[10,11]The present study was conducted to assess Package Inserts.

We found that out of 110 Package Inserts (PIs), 72% were from Indian companies and 28% from multinational companies. Ramdas et al[12]assessed the presentation and completeness of clinical information provided in the currently available package inserts for anti-diabetic, antihypertensive and hypolipedemic

drugs. Around 130 package inserts were collected from pharmacies located at different areas of Bangalore. Out of 134 package inserts, 64 were anti-diabetics, 40 anti-hypertensives, and 30 hypolipedemics. Out of them, 31 (23.14%) belonged to Grade 'A' (including all injectable preparations) and remaining 76.86% to Grade 'B'. None of the PIs belonged to Grade 'C'. The inserts were inadequate in many aspects; for example, they had unclear instructions about generic name of other ingredients used, about handling, undesirable effects, pediatric and geriatric use, and guidelines for use of the drugs.

We found that there were 55 anti-diabeticsPIs, 38 anti-hypertensives and 17 Hypolipedemic PIs. Under anti-diabeticsPIs, 40 were oral and 15 injectable. Under anti-hypertensivesPIs, 32 were oral and 6 were injectables. Under Hypolipedemic PIs, 16 were oral and 1 was injectable. 24.6% had grade A and 74.4% had grade B. Tayyem et al[13]evaluated the inserts of 48 medications used in routine neuroanesthesia practice in the department against a set of three safety criteria Drug interactions information, Hypersensitivity and general precautions. Inserts were variable in several safety categories for neurosurgical patients, Drug interaction was mentioned in 76%, Hypersensitivity in 76% and general precaution in variable health conditions were in 82% if the drug inserts. The quality of information was poor in drugs coming from developing countries versus those drugs coming from North America and Europe. 90% of inserts were directed to medical staff, which is going to use it. Only 10% had information directed to patient directly or indirectly through physician warning.The pharmaceutical industry should address this as well as implement the patient safety of dangerous drugs, depending on available animal or human studies.

Al-aqeel SA[14]examined if package inserts (PIs) supplied with prescribed and over-the-counter medications in Saudi Arabia contain information relevant for the safe and appropriate use of these medications.Sixty PIs for prescription-only medications (n = 37) and over-the-counter medications (n = 23) were evaluated against a set of safety criteria compiled from the literature.Analyzed PIs were defective in many aspects. Particularly of concern were unclear dosage instructions, lack of measures to be taken when an administrative error was made, inappropriate presentation of side effects, and lack of measures to be taken if serious side effects occurred.This study indicated that information relevant to the safe and appropriate use of medications was not uniformly mentioned in the PIs analyzed. To avoid medication errors due to deficits in the current PIs, we recommend improvement in the existing PIs based on best practice for information content and design.

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that the examined package inserts lacked information pertinent to the safe and efficient use of medication. Therefore, it is advised that the current package inserts be updated in accordance with the standards outlined in Schedule D of the Drug and Cosmetic Act of 1945.

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