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ORIGINAL ARTICLE

Analysis of Package Inserts Available in the Indian Market

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ABSTRACT

Medicine has advanced, necessitating access to accurate drug information. Package inserts (PIs) are crucial sources, approved by authorities, providing essential and updated drug details. Package inserts significantly impact patient compliance and drug effectiveness in chronic therapy. This study examines Indian market PIs, evaluating information quality and accessibility to improve medication safety. A prospective observational cross-sectional study was carried out. A total of 300 package inserts were collected from various pharmacies situated across different sites in Ahmedabad. Package inserts were scored out of 21 based on assessment criteria, expressed as percentages, and analysed descriptively. A total of 300 package inserts were analysed, among them 130 were tablets, 81 were injections, 17 were capsules, 15 were eye drops and the rest includes syrup, ear drops, nasal drops, suppositories, powder, ointment, gel, cream, lotion and suspension. 209 PIs were single drug preparations while 91 were fixed dose combinations. More than 90% of the score was achieved by 37 PIs. 96 PIs had scored between range 81% to 90%, while 86 PIs had scored between 71% to 80%. Only 6 PIs had scored below 50%. Most commonly missing information was the average duration of treatment (83% of PIs), excipients (93% of PIs), and shelf life (81% of PIs). The finding of this study revealed that, although only 2% of PIs had scored below 50%, some crucial information was lacking from a major number of PIs. Regular review and collaboration among stakeholders ensure updated, reliable and comprehensive information, benefiting patient care and healthcare delivery.

Keywords: Drug information; Package insert; Indian market

INTRODUCTION

The field of medicine has made remarkable progress over the past few decades, with countless new drugs and therapies being developed and made available to the public. To ensure the safe and effective use of these medications, patients and healthcare providers must have access to accurate and up-to-date information about the drugs. The primary source of drug information is a Package Insert (PI)[1]. A package insert, also known as a prescribing information or patient information leaflet, is an informational document provided by pharmaceutical manufacturers and approved by regulatory authorities[2]. A good PI should contain the approved, essential, and accurate information about a drug. It is written in a language that is not promotional, false, or misleading. It is evidence-based and is updated from time to time as relevant pre-clinical and clinical data becomes available[3].

Regulatory standards for drug package inserts differ globally. The United States Food and Drug Administration (US-FDA) and the Directorate-General for Health and Food Safety of the European Commission periodically update their guidelines on the content and format of drug product labelling[4,5]. Package inserts (PIs) have garnered substantial attention in developed nations, but their comprehensive consideration is yet to be realized in developing countries such as India. Significant room for enhancement exists in refining these PIs[6].

Various studies have shown that one of the major components of health management is the use of package inserts. Unfortunately, neither the doctor nor the patient gives the utmost importance to package inserts[7]. As package

inserts are easily available, it can produce major impact on patient compliance to the chronic therapy as well as on the effectiveness of drug use[8]. They act as a link between the healthcare provider and the patient[9,10], enhancing both medication utilization and patient adherence[11]. Despite continuous efforts to raise awareness among authorities about the insufficiency of information in the current package inserts, both nationally and internationally, there remain notable shortcomings in the existing regulations for developing package inserts. This is particularly evident in a developing country such as India[12–15].

This study aims to examine the package inserts available in the Indian market and evaluate the quality and accessibility of the information provided.This study will contribute to our understanding of the quality of information provided to patients and healthcare providers in India and will provide important insights into the ways in which the regulatory system can be improved in order to ensure the safe and effective use of medications in this country.

MATERIAL AND METHODS

- **Gathering of Package Inserts**: 300 package inserts were collected from various pharmacies situated across different parts of Ahmedabad, over 6 months period.
- **Evaluation of Package Insert Contents**: The package inserts were evaluated based on the criteria outlined by the "Guidelines for the Regulatory Assessment of Medicinal Products, World Health Organization Geneva 2000"[16].
- **Criteria of Package Inserts**: The package inserts were assessed using the following criteria:

1) Generic (INN) name. 2) Dosage form. 3) Strength of dosage form. 4) Dosing interval. 5) Average dose range for adults/children. 6) Average duration of treatment. 7) Indications. 8) Contraindication. 9) Warning & precaution. 10) Adverse effects. 11) Drug interaction. 12) Overdosage. 13) Pregnancy & lactation warning. 14) Special condition which requires increase/decrease dose. 15) Pharmacokinetics. 16) Mechanism of action. 17) Pack size. 18) Excipients. 19) Storage condition. 20) Shelf life. 21) Name & address of manufacturer.

- **Data analysis**: For our observational cross-sectional study, each package insert was assigned a total score of 21, based on 21 different criteria. If information was present, it was given a score of 1, and if it was absent, it was given a score of 0, maximum score being 21 and minimum score being 0. The total score was then expressed as a percentage and descriptive data analytical methods were applied. The study was approved by the Institutional Ethics Committee.

RESULTS & DISCUSSION

A total of 300 package inserts were analysed. We had included package inserts of drugs having various dosage forms; among them, 130 (43%) were of tablet, 81 (27%) were of injection, 17 (6%) were of capsules, 15 (5%) were of eye drops, while the rest includes syrup, ear drops, nasal drops, nasal sprays, suppository, powder, ointment, gel, cream, lotion, and suspension, as shown in below Figure 1.

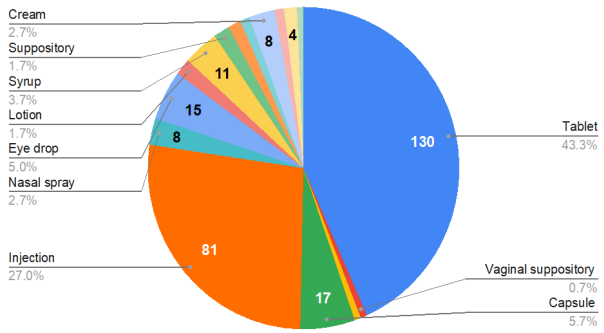

Fig. 1: Dosage form of drugs among package inserts

Among the included package inserts, they were found to be from various therapeutic drug groups. 85 (28%) were anti-microbial, 34 (11%) were anti-diabetic, 15 (5%) anti-inflammatory, 13 (4%) anti-hypertensive, 12 (4%) anti-platelets and others which are mentioned in below Figure 2.

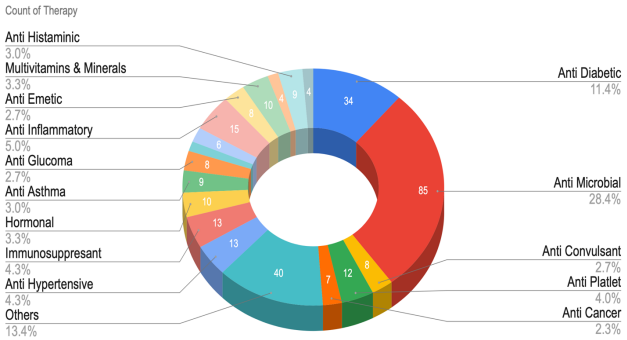

Fig. 2: Therapeutic drug groups of package inserts

Out of 300 package inserts, 209 were single drug preparations, while 91 were fixed dose combinations. 249 package inserts were from Indian pharmaceutical manufacturers, and the rest 51 were from Foreign pharmaceutical manufacturers. Package inserts were scored according to assessment criteria. Maximum number of PIs (63) had scored 16 points, which includes 50 Indian and 13 foreign pharmaceutical manufacturers. The rest of the scoring by package inserts are mentioned in the below Figure 3. The mean and median scores for all PIs were 15.91 and 16 respectively.

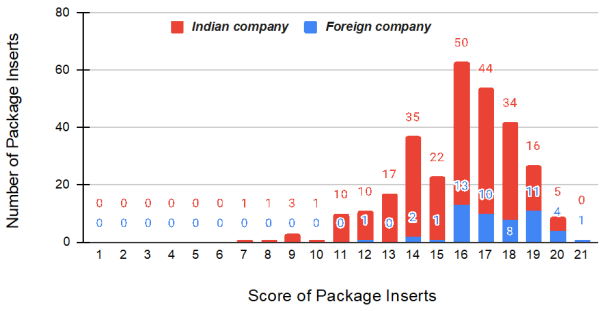

Fig. 3: Scoring of package inserts

In our study, more than 90% of the score was achieved by 37 PIs. 96 PIs had scored between range 81% to 90%, while 86 PIs had scored between 71% to 80%. Only 6 PIs had scored below 50% as shown below in Figure 4.

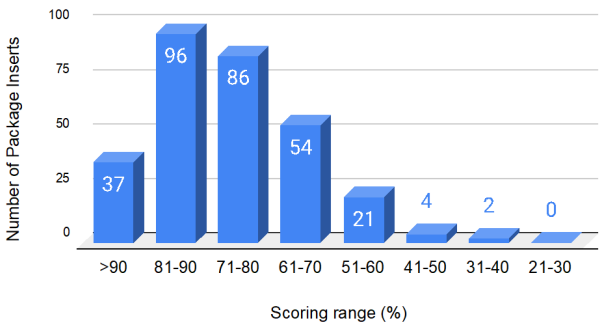

Fig. 4: Percentage scoring range of package inserts

Generic name, dosage form, indications, name, and address of manufacturer were given in all 300 PIs. The most commonly missing information were excipients (93% of PIs), the average duration of treatment (83% of PIs), and shelf life (81% of PIs). The percentage scores of PIs are shown in the below Table 1.

The safe and effective utilization of medications is a critical factor in ensuring the well-being of society. In order to achieve this, healthcare providers must have access to reliable and accurate information regarding the medications they prescribe. Package inserts serve as a valuable source of information in this regard, as they undergo approval by relevant authorities before being published. Maintaining updated package inserts with sufficient data is essential for promoting responsible prescribing practices and patient safety.

In our study, the analysis of package inserts revealed interesting findings. Remarkably, a noteworthy finding was that more than 90% of the maximum achievable score was attained by 37 package inserts, reflecting a commendable level of information inclusion and completeness. Out of the total sample size, 96 package inserts scored between

Table 1: Criteria fulfillment among package inserts in percentage

Criteria No.	Criteria	Total score of PIs in percentage (n= 300)
1	Generic name	100%
2	Dosage form (Composition)	100%
3	Strength of dosage form	98%
4	Dosing Interval	73%
5	Avg. dose range for adult/child	48%
6	Avg. duration of treatment	17%
7	Indications	100%
8	Contra Indications	96%
9	Warning & Precaution	96%
10	Adverse effects	96%
11	Drug interaction	85%
12	Over dosage	80%
13	Pregnancy & lactation warning	80%
14	Special condition which requires increase/decrease dose	67%
15	Pharmacokinetics	74%
16	Mechanism of action	77%
17	Pack size	84%
18	Excipients	07%
19	Storage condition	95%
20	Shelf Life	19%
21	Name & address of manufacturer	100%

the range of 81% to 90%, indicating a high level of compliance with the guidelines. Additionally, 86 package inserts scored between 71% to 80%, demonstrating a reasonably good adherence to the required standards. However, it is important to note that the study identified a small number of package inserts that did not perform well. Only 6 package inserts scored below 50%. Efforts should be made to improve the quality and accuracy of package inserts across the board, striving for consistently high scores to maximize patient safety and facilitate informed decision-making for healthcare providers and patients alike.

In comparison to the study done by Deepak Ramdas et al., improvement in information regarding adverse effects (96% vs 37%) and shelf life (19% vs 0%) had been seen[17]. The lower shelf-life percentage might be due to the mentioning of the same on the drug strip itself and not in the PIs. It was, however, noted that there has been an overall improvement in the percentage of inserts containing information as compared to previous studies[15,18].

In the Indian context, the limited doctor-to-patient ratio poses challenges in terms of accessibility to trained prescribers. Physicians often find themselves unable to dedicate

sufficient time to each patient, leading to potential consequences such as self-medication and medication errors. These issues emphasize the importance of patient-oriented package inserts (PIs)[19]. By providing comprehensive and easily understandable information about medications, PIs can empower patients to make informed decisions regarding their healthcare[20]. Patient-oriented PIs can help bridge the gap between healthcare providers and patients, enabling individuals to take an active role in managing their health and reducing the risks associated with inadequate supervision or improper medication use.

CONCLUSION

We examined 300 package inserts, covering various dosage forms and diverse therapeutic groups from both Indian and foreign pharmaceutical companies. Notably, only 2% of PIs had scored below 50% but some crucial information was lacking from a major number of PIs. The ongoing evolution and advancement of medical knowledge necessitate the regular review and revision of PIs to reflect the latest findings and guidelines. Collaboration among regulatory bodies, pharmaceutical companies, healthcare providers, and patients is essential in the ongoing refinement of PIs. By maintaining complete, reliable, and up-to-date PIs, we can enhance the ethical and effectual dissemination of healthcare services in our society.

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