

**Original Article**

**ANALYSIS OF PACKAGE INSERTS OF ANTIMICROBIAL DRUGS UTILISED IN A TERTIARY CARE HOSPITAL OF NORTH KARNATAKA**

**ANAND M. INGALE\*, PRIYANKA S. PALABHAVI**

Department of Pharmacology, Shri B. M. Patil Medical College Hospital and Research, Centre, Vijayapura, India  
Email: dr.anandingale@gmail.com

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**ABSTRACT**

**Objective:** To evaluate the package inserts of antimicrobial drugs utilized in a tertiary care Hospital of North Karnataka

**Methods:** A cross-sectional, observational, prospective study was undertaken to analyze the package inserts of antimicrobial drugs utilized in a tertiary care hospital in North Karnataka for two months. 218 that belonged to antimicrobials were included in our study and analyzed based on criteria mentioned in Schedule D of the Drug and Cosmetic Act of 1945.

**Results:** None of the Package Inserts analyzed by us adhered to the standard guidelines. Legibility, Approved generic name of active ingredients, and Content of active ingredient per dosage was mentioned in all. In contrast, the least mentioned criteria included References (n=2) and Retail price of the drug (n=9).

**Conclusion:** Updating the existing ones and stricter adherence to the PI with the standard guidelines will achieve better quality and, in turn, improve health care in our society, especially by these antimicrobial agents, which can prevent the development of antimicrobial resistance.

**Keywords:** Package inserts, Antimicrobial drugs, Drug and cosmetic act, Drug-information

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**INTRODUCTION**

Drugs play a significant role in managing various clinical disorders [1]. Drugs undergo multiple procedures to assess their safety and efficacy before making them available in the market [2]. Despite this, these drugs are not found to be safe and effective when used in patients. Various modalities have been advocated to enhance the efficacy and safety of marketed drugs. These Packet Inserts (PIs) are one of them.

Package Insert (PI), also known as Prescription Drug Label or Prescribing Information, is a document provided with the drug by the drug manufacturers [3].

PIs are the primary source of drug information for the physician, the pharmacist, and the patient [4]. It is of utmost importance to physicians in cases of newly marketed drugs that have recently developed and whose information is not known.

PI is a regulated document [5] whose main motto is to provide complete information about the prescribed drug regarding its purpose, benefits, and risks. PI was first introduced in the 1960 and 1970s for isoproterenol inhalators, followed by oral contraceptives and other drugs [6].

A good PI should provide accurate, trustworthy, and correct information that should be regularly updated based on the relevant pre-clinical and clinical data [7]. A more complete and precise PI helps improve the prescribed drug's safety and accuracy [8]. PI must adhere to the standard guidelines that are in place. Various studies have shown the non-adherence of these PI to the standard guidelines [9].

Antimicrobial agents form the most common group of drugs used in clinical practice, especially in ICUs [10]. Proper usage of these antimicrobial agents is of utmost importance in clinical practice [11]. To achieve this purpose, PI does play a significant role. Accurate and timely usage of antimicrobial agents helps in the better management of patients with infections. Rationale usage of antimicrobials helps in preventing the development of drug resistance.

Because of the non-adherence of many PIs to the standard guidelines and not many studies are done with PIs of antimicrobial agents, especially in our part of the state, the present study is undertaken to

analyze the PI of antimicrobial drugs that are dispensed in a tertiary health care centre of North Karnataka. The results of our research will reveal the adherence status of these PIs to the standard guidelines reflecting their completeness and accuracy. Accurate and timely usage of antimicrobial agents helps in the better management of many life-saving serious infections. Also, they prevent the development of resistance to these antimicrobial agents, which is of profound clinical importance to the patients.

**MATERIALS AND METHODS**

**Study type**

Our present study was a cross-sectional, observational, prospective study.

**Ethical consideration**

Our study was conducted only after obtaining our institutional ethics committee's approval.

[BLDE (DU)/IEC/610/2022-23]

**Collection of PIs**

A total of 350 PIs were collected from the pharmacy and wards of Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapura, on request between 8<sup>th</sup> August and 15 October of 2022.

**Inclusion and exclusion criteria**

The PI belonging to the group of antimicrobial agents was included in our study.

The PIs of devices, non-antimicrobial agents, herbal products, and traditional medicines were excluded from our study.

**Analysis of the content of PIs**

218 PIs belonging to the antimicrobials group were included in our study.

The obtained Package inserts were scored based on criteria laid down by the Indian Drug and Cosmetic Rules, 1945, under section

6.2 of Schedule D [3]. Data were extracted twice to minimize the chances of missing any information

They were surveyed for the following 25 criteria as laid down by Indian Drug and Cosmetic Rules, 1945. 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 the ability to drive and use machines. 14. Undesirable effects. 15. Drug dose. 16. Overdosage. 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 manufacturer/distributor. 23. Provision of full information on request should be highlighted. 24. Retail price of the drug. 25. References.

**Scoring of PIs**

For each of the criteria, a score of 1 and 0 was respectively assigned for the presence and absence of the criteria. The scores of individual criteria were summed, representing the score of that PI. The total score for each PI was 25.

**Grading of PIs**

Each PI was graded based on their scores as follows:

Individual score	Grade
>20	A
10-20	B
<10	C

**Statistical analysis**

Descriptive statistics were used to analyze the data.

The total scores were expressed as absolute numbers and percentages.

**Observation and results**

**Sample size**

Out of the 350 PIs collected during the study period, 218 PIs were of antimicrobial agents, included in our study, and thoroughly analyzed.

**Legibility and language**

All (n=218) PI were legible and were in English.

**Score of PIs**

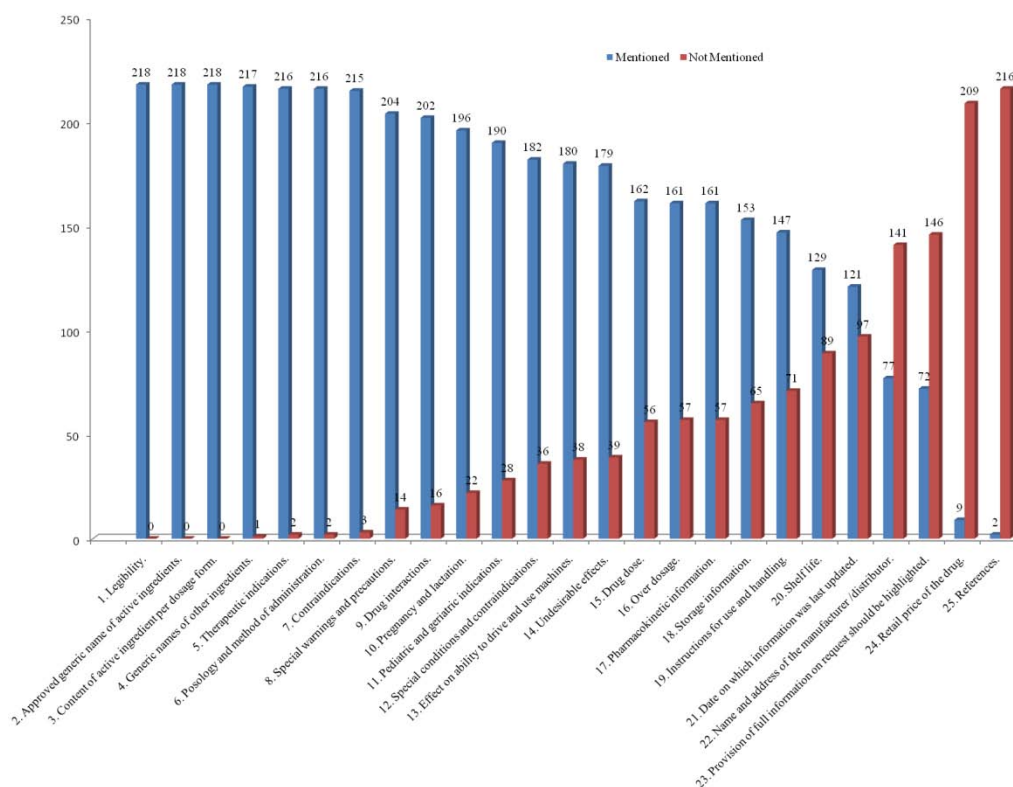
After analyzing and scoring the obtained Package inserts based on criteria laid down by Indian Drug and Cosmetic Rules, 1945, under section 6.2 of schedule D, the results obtained were as depicted in fig. 1.

**Grades of PI**

Grading of the PI showed that 207 belonged to Grade A, whereas 11 belonged to Grade B, as depicted in fig. 2.

**Most common mentioned criteria**

The five most commonly mentioned criteria in our study were as depicted in table 2.



**Fig. 1: Package inserts that followed criteria laid down by drug and cosmetic rules, 1945**

**Table 2: Most commonly mentioned criteria in our study**

S. No.	Criteria	%
1.	Legibility.	100
2.	Approved generic name of active ingredients.	100
3.	Content of active ingredient per dosage form.	100
4.	Therapeutic indications.	99.54
5.	Contraindications, Drug dose.	99.08

Table 3: Least commonly represented Criteria in our study

S. No.	Criteria	%
1.	Retail price of the drug.	0.91
2.	References.	4.12
3.	Date on which information was last updated.	33.02
4.	Effect on ability to drive and use machines.	35.32
5.	Instructions for use and handling.	55.50

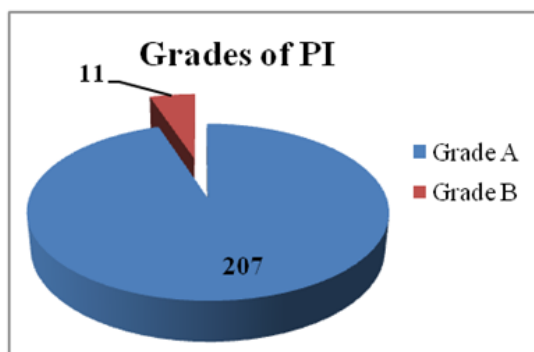


Fig. 2: Package inserts graded based on their scores (Grade A and B)

#### Least common mentioned criteria

The five least commonly mentioned criteria in our study were as depicted in table 3.

#### Common group of antimicrobial agents

The most commonly analyzed antimicrobial drug groups in our study were

Beta-lactam antibiotics (25.22%), Anti-Fungal agents (16.97%), Fluoroquinolones (13.76%),

Carbapenems (11.92%) and Lincomycins (8.71%)

#### DISCUSSION

A PI is a crucial regulated document that the drug manufacturers provide along with the respective drug serving as a reliable and accurate source of drug information for the prescribers and the patients. As it is readily available, a complete and precise PI forms a vital tool to enhance the safety and efficacy of the patient.

We found out that only some drugs were provided with their respective PI though it is mandatory. Similar findings were observed by Shruti *et al.* [16].

None of the PI completely adhered to their existing standard guidelines. Similar observations are seen with most of the drugs that are dispensed [17]. A complete and accurate PI aids in achieving the purpose of improving the safety and efficacy of the patient. Stricter guidelines on the implementation of compulsorily providing PI will serve the purpose.

All the PI were in English, as per Section 6.2 of Indian Drug and Cosmetic Rules, 1945, which mandates English to be the language [9]. As all the PI were in printed versions, they were legible.

The most commonly represented criteria in our study were similar to the study done by Prasad *et al.*, [13]. These criteria form the most important criteria that have to be mentioned. Complete adherence to the guidelines is mandated.

The least commonly represented criteria in our study were similar to the study done by Neha *et al.* [3] and Prasad *et al.* [13]. These criteria provide very valuable information regarding the drug dispensed and also add to the validity of the drug. Stricter adherence to the standard guidelines is mandated for the better quality of the dispensed medication, which improves the patients' safety.

Most PI (94.95%, n =207) were of Grade A, while others belonged to Grade B. We didn't encounter any PI with Grade C in our study. Our results are similar to the study done by Neha *et al.* [3]

The most common group of antimicrobials included in our study were Beta-lactam antibiotics.

The limitation of our study was that our study was done only in one tertiary health centre in the town. Analysis of PIs from other health centres and also analyzing a larger sample will overcome our limitation.

#### CONCLUSION

This study indicated that none of the PI completely adhered to their standard guidelines. They are deficient in many aspects that can be rectified and updated by correctly and accurately following the rules and regulations that are already in place. This will improve the quality of the dispensed drugs and aid in better health care in our society. This is of paramount importance with the antimicrobial agents associated with the rampant development of antimicrobial resistance.

#### ETHICAL APPROVAL

Taken prior to the study

#### AUTHORS FUNDING

Nil

#### AUTHORS CONTRIBUTIONS

Dr. ANAND M. INGALE:-Contributed to the collection and analysis of data, design and preparation of the manuscript

Ms. PRIYANKA S. PALABHAVI:-Contributed in the collection of data

#### CONFLICT OF INTERESTS

Declared none

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