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RESEARCH ARTICLE

Critical Evaluation of Drug Promotional Literatures using who Criteria: An Observational Study

Keerthi R. Krishnan*, Femi Retna, and Ezhil J. Ramya

Department of Pharmacology, Tirunelveli Medical College, Tirunelveli - 627011, Tamil Nadu, India;
drkeerthiradhakrishnantvm@gmail.com

Abstract

Background: Drug Promotional Literatures (DPLs) are a primary source of drug information for healthcare professionals, particularly in resource-limited settings. However, concerns exist regarding their reliability, as they often contain biased or incomplete information. This study aimed to critically analyze 100 DPLs using WHO criteria to assess their adherence to ethical promotional practices. **Methods:** A cross-sectional, observational study was conducted at Tirunelveli Medical College Hospital, India, over four weeks (February–March 2024). DPLs were collected and evaluated using WHO criteria, including transparency of drug information, safety data, and promotional claims. Data were analyzed using descriptive statistics. **Results:** While brand and generic names were universally present (100%), critical safety information was underrepresented: side effects (44%), contraindications (43%), and drug interactions (30%). Efficacy claims dominated (52%), whereas safety (24%) and cost-related claims (6%) were scarce. Only 54% of DPLs included visual aids, and 39% lacked scientific references. **Conclusion:** DPLs frequently deviate from WHO guidelines, emphasizing benefits over risks and omitting essential safety information. Regulatory reinforcement, prescriber education, and institutional review mechanisms are urgently needed to ensure DPLs support rational prescribing.

Keywords: Brochures, Drug Promotion Literature, Pharmaceutical Company, World Health Organization

1. Introduction

Pharmaceutical companies use various marketing strategies to promote their products, with Drug Promotional Literature (DPL) being one of the most widely used tools. DPLs, which include printed brochures, pamphlets, and other promotional materials, serve as a major source of information for healthcare professionals regarding both established and newly introduced medications. Many physicians, especially in resource-limited settings, rely on these materials for updates on drugs, making them a crucial influence on prescribing patterns[1,2].

The World Health Organization (WHO) defines drug promotion as "All informational and persuasive activities by manufacturers and distributors, the effect of which is to influence the prescription, supply, purchase, or use of medicinal drugs." While promotional claims are expected to be reliable, balanced, and evidence-based, studies have consistently shown that DPLs often contain biased, misleading, or incomplete information[2].

Pharmaceutical companies, to market their brand-name drugs, may selectively present favorable data while omitting important safety concerns, leading to irrational prescribing practices[2].

Given these concerns, the critical evaluation of DPLs using standardized guidelines is essential to assess their reliability and adherence to ethical promotional practices. The WHO has established specific criteria for ethical drug promotion, emphasizing accuracy, transparency, and scientific validity[2,3].

*Author for correspondence

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In this observational study, we aim to critically analyze 100 DPLs using WHO criteria. By identifying deviations from ethical standards, this study seeks to highlight the need for more stringent regulatory oversight and greater awareness among healthcare professionals regarding the quality of promotional materials.

1.1 Aim and Objectives

To critically evaluate Drug Promotional Literature (DPL) using the World Health Organization (WHO) ethical criteria to assess their credibility.

1.2 Review of Literature

The quality and ethical standards of Drug Promotional Literature (DPLs) have been a subject of scrutiny in multiple studies, with researchers evaluating their adherence to the World Health Organization (WHO) criteria for medicinal drug promotion.

Adherence to WHO Criteria – A study by Sarala et al. analyzed 200 DPLs and found that only 15% (30 DPLs) followed 10 out of 11 WHO criteria, while 69% (131 DPLs) met at least 50% of the criteria. Notably, none of the brochures fully complied with all WHO guidelines, indicating significant gaps in regulatory adherence[1]. Similarly, Vyas *et al.* assessed 371 DPLs and reported that while most included basic details like generic name (98.39%), brand name (100%), and dosage form (91.37%), critical safety information such as side effects (14.56%), drug interactions (14.02%), and contraindications (14.29%) were often neglected or presented in fine print, making them difficult to read[4].

In contrast, Chaithra *et al.* reported a higher compliance rate, with 75.5% of DPLs (out of 326) meeting more than 50% of WHO criteria. However, this study also highlighted deficiencies, with only 23.3% mentioning side effects, 16.6% listing precautions, and 17.2% disclosing drug interactions[2]. Scientific References and Validity – The use of scientific references in DPLs varied across studies. Sarala *et al.* found that 32.5% of references were published post-2010, suggesting reliance on outdated literature. Vyas *et al.* further examined 203 references and noted that 74.38% were journal articles, with 55.63% being research articles (of which 44.05% were randomized controlled trials). However, 10.35% references were "data on file", which lacks transparency[1,4].

Visual Representation and Misleading Content – Visual elements in DPLs were often irrelevant or exaggerated. Sarala et al. observed that 68.5% of DPLs (137/200) used unrelated imagery (cars, cartoons, models), while only 31.5% had relevant drug/disease depictions. Chaithra *et al.* reported 52.1% relevance in pictures, but 34.5% of DPLs made exaggerated claims, raising concerns about misleading promotion[1,2].

The most frequently promoted drugs included: Antidiabetics (15.6%), Vitamins and minerals (12.9%), antimicrobials (12.9%), and respiratory drugs (12.9%) – Chaithra *et al*[2]. followed by Cardiovascular drugs (with 53.13% providing safety data) – Shekhar *et al*[5].

Regarding formulations, Sarala *et al.* found 67% single-drug vs. 33% Fixed-Dose Combinations (FDCs), whereas Shekhar *et al.* reported 54.2% single-drug vs. 45.8% FDCs. Chaithra *et al.* noted 67.5% FDC promotions, indicating variability in promotional trends[1,5].

Disclosure of Drug Costs and Manufacturer Information – Transparency in drug pricing was poor across studies, only 6% (Sarala *et al.*) and 9.2% (Chaithra *et al.*) disclosed costs[1,2]. Vyas *et al.* found that while 91.91% of DPLs listed manufacturer details, only 28.74% provided contact information, limiting accessibility for further queries[4].

2. Material and Methods

2.1 Collection of Drug Promotion Literature

Drug Promotional Literatures (DPLs) in the form of flyers, leaflets, and brochures were collected over a period of four weeks during February and March 2024 from practicing physicians in Tirunelveli district, Tamil Nadu.

Approximately 150 DPLs were obtained using purposive sampling and from that duplicates were excluded, and a total of 100 DPLs were selected for the study.

2.2 DPL Analysis

DPLs were analyzed according to WHO Criteria

To reduce possibility of missing any information, data were extracted twice Criteria:

Analysis of DPLs were done using the following WHO criteria

1. INN (International Non-proprietary Name) or approved generic name of the drug
2. Brand name of the drug
3. Active ingredients
4. Amount of active ingredient per dose
5. Adjuvants
6. Catchy statements
7. Relevant pictures/illustrations/diagrams
8. Types of promotional claims made
9. Approved therapeutic use/indications
10. Dosage form
11. Dosing schedule
12. Side effects and major adverse drug reactions
13. Precautions and warnings
14. Contraindications
15. Major drug interactions
16. Name of the manufacturer
17. Address of the manufacturer
18. Reference to scientific literature.

2.2.1 Data Analysis

Descriptive statistics such as frequencies and percentages were used to analyze the data. Microsoft Excel was used for data analysis

3. Results (Including Observations)

An in-depth evaluation of 100 drug promotional literatures (DPLs) revealed distinct trends in content quality, promotional strategies, and adherence to WHO guidelines. Brand names and generic names were universally present (100%), ensuring the basic identification of drugs across all materials. Active Pharmaceutical Ingredients (APIs) were mentioned in 97% of the DPLs, reflecting a reasonably high level of transparency regarding drug composition. However, marketing-driven elements were also prominent, with 71% of the DPLs featuring catchy promotional slogans. Only 54% included relevant diagrams or visuals that could have enhanced understanding and communication of clinical information, indicating an underuse of visual aids.

When analyzing the nature of claims made in these DPLs, efficacy was the most emphasized aspect, appearing in 52%. In contrast, safety-related claims were comparatively scarce, found in only 24%. Information related to pharmacokinetic and pharmacodynamic profiles was noted in just 11%, while cost considerations—a key factor in prescribing decisions—were mentioned in a mere 6% of cases. Pharmaceutical properties such as formulation advantages were referenced in only 8%, highlighting a general lack of technical detail in many DPLs. (Table 1)

Table 1. Table assessment of drug promotional literatures using the WHO criteria

S.No	WHO Criteria	No. of DPLs (n)	Percentage (%)
1.	INN or approved generic name	100	100
2.	Brand name of the drug	100	100
3.	Active ingredients	97	97
4.	Adjuvants	25	25
5.	Catchy statements	71	71
6.	Relevant pictures/ illustrations/diagrams	54	54
7.	Promotional claims	93	93
8.	Types of promotional claims made - Pharmaceutical property	8	8
9.	Approved therapeutic use/indications	98	98
10.	Dosage form	97	97
11.	Dosing schedule	48	48
12.	Side effects and major adverse drug reactions	44	44
13.	Precautions and warnings	43	43
14.	Contraindications	43	43
15.	Major drug interactions	30	30
16.	Name of the manufacturer	100	100
17.	Address of the manufacturer	61	61
18.	Reference to scientific literature	70	70

The therapeutic and safety information in the DPLs showed considerable variation. While most materials clearly stated the approved indications (98%) and dosage forms (97%), fewer provided complete guidance on how to use the drugs. Only 48% included detailed dosage schedules. Key safety details were often lacking—side effects were mentioned in just 44% of the DPLs, and both precautions and contraindications were included in only 43%. Most concerning was the minimal focus on drug interactions, which were

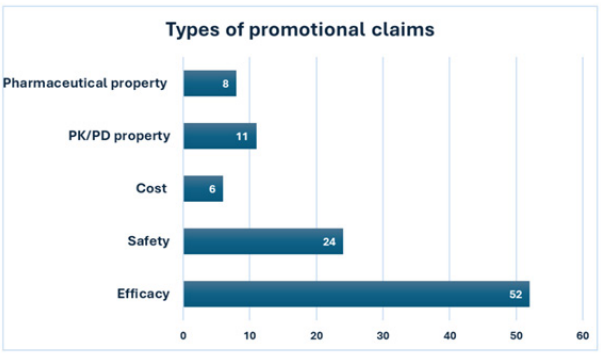

Figure 1. Table assessment of drug promotional literatures using the WHO criteria

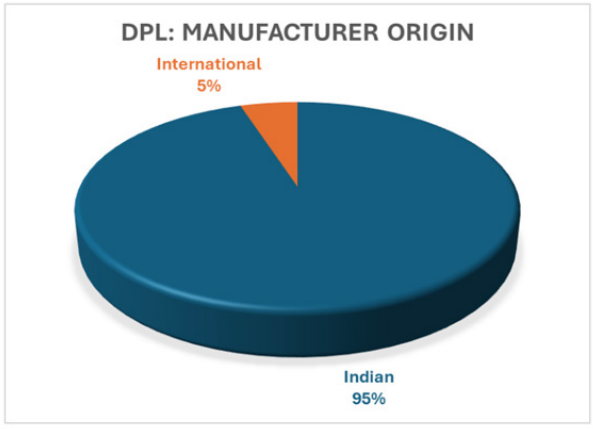

Figure 2. Chart drug promotional literature: Manufacturer origin (Indian vs International).

addressed in just 30% of the materials, despite being critical for ensuring patient safety.

From a manufacturing perspective, majority (95%) of the DPLs originated from Indian pharmaceutical companies, with only 5% being produced by international firms (Figure 2). Cardiovascular drugs were the most frequently promoted category, constituting 42% of the DPLs, Antidiabetic drugs were the next most common (22%). Dermatology-related products accounted for 10% and were mainly promoted by international brands. Other therapeutic areas such as gastroenterology (8%), central nervous system drugs, hematinic, obstetric-gynecological (OBG) drugs, and vitamins/minerals were sparsely represented, ranging between 1–4%. (Figure 3)

Critical omissions were also evident. Only 25% of DPLs disclosed information about adjuvants like preservatives or stabilizers. Furthermore, 39% of the materials lacked references to scientific evidence

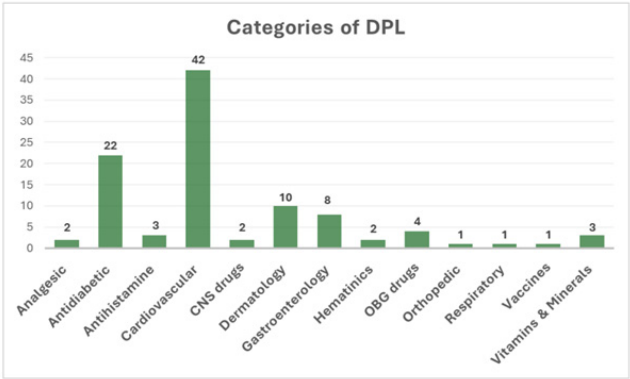

Figure 3. Chart categories of Drug Promotional Literatures (DPLs).

supporting the claims made, undermining the credibility of the promotional content. Manufacturer addresses were missing in 30% of the DPLs, raising concerns about transparency and traceability.

4. Discussion

The analysis of 100 Drug Promotional Literatures (DPLs) offers critical insights into the prevailing trends, strengths, and deficiencies in pharmaceutical promotional practices, particularly within the Indian context. While the inclusion of brand and generic names across all DPLs is encouraging and aligns with WHO guidelines for ethical medicinal drug promotion[6], the findings also underscore significant gaps in the completeness, transparency, and clinical utility of the information presented.

A notable finding was the strong emphasis on efficacy-related claims, which appeared in 52% of the DPLs, while much less attention was given to safety (24%), pharmacokinetics/pharmacodynamics (11%), and cost-related information (6%). This trend reflects what has been reported in earlier studies from India and other low- and middle-income countries, where DPLs tend to highlight the therapeutic benefits of drugs, often at the expense of crucial safety and affordability information[7]. The inadequate representation of safety data—including side effects (44%), contraindications (43%), precautions (43%), and drug interactions (30%)—is also concerning.

This imbalance can give a distorted view of a drug's overall profile, which may contribute to irrational prescribing—particularly when healthcare providers

depend on DPLs for quick drug information due to limited time or lack of access to unbiased, independent sources[8].

The WHO Ethical Criteria for Medicinal Drug Promotion emphasize that DPL should present both benefits and risks in a balanced manner[6]. Several studies, including those by Mali *et al*[9]. and Chisholm-Burns *et al*[10], highlight that omitting such critical information may lead to uninformed decision-making and compromise patient safety.

Furthermore, visual aids which are known to improve recall and understanding of drug-related information—were used in only 54% of the DPLs reviewed. Visuals can make complex pharmacological concepts easier to grasp. However, their inconsistent inclusion in DPLs reflect a missed opportunity to communicate more effectively with prescribers.

The low frequency of cost-related claims (6%) is another significant shortcoming. In resource-limited settings like India, where out-of-pocket expenditure is high, information on drug affordability and cost-benefit comparisons is crucial for rational prescribing.

The geographical distribution of manufacturers revealed that 95% of DPLs were produced by Indian pharmaceutical companies, which dominate the domestic market. International pharmaceutical companies were minimal (5%) and primarily focused on niche areas like dermatology.

A significant number of DPLs lacked scientific references (39%) or manufacturer addresses (30%), indicating poor compliance with WHO's transparency norms. References to clinical trials or peer- reviewed data lend credibility to promotional claims, and their absence undermines the scientific integrity of the content. Previous research has raised similar concerns, advocating for independent review of promotional material prior to dissemination[9,11].

Overall, the findings of this study highlight a clear deviation from WHO-recommended guidelines. There is a need for regulatory reinforcement and sensitization of prescribers to critically appraise promotional materials. Educational initiatives, stronger enforcement of ethical marketing guidelines, and systemic reviewing of DPLs before they are distributed could play a key role in making sure that DPLs support rational drug use.

5. Summary and Conclusion

The study highlights important gaps in DPLs, especially the lack of adequate safety information and an overemphasis towards promoting efficacy. Although basic identifiers like brand and generic names are usually included, crucial details—such as side effects, drug interactions, and cost—are often left out. To improve the reliability and ethical standards of these materials, stricter regulatory oversight, inclusion of mandatory safety data, training for healthcare professionals to critically assess claims, institutional review before distribution, and greater transparency about ingredients, manufacturers, and pricing are needed. This helps in making DPLs more dependable source of information that promotes rational prescribing and safeguards patient health.

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