Original Research

CRITICAL REVIEW OF DRUG PROMOTIONAL LITERATURE USING THE WORLD HEALTH ORGANISATION GUIDELINES

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ABSTRACT

Objective: Drug promotional literature (DPLs) is used to promote new drugs entering the market to doctors. The objective of the present study is to evaluate the accuracy of DPLs by using the World Health Organisation (WHO) criteria.

Methods: An observational study was conducted from August 2024 to January 2025 at B.S. Kushwaha Institute of Medical Sciences, Kanpur. The DPLs were collected from various hospital outpatient departments. The literature was evaluated according to the criteria set by the WHO.

Result: Three hundred DPLs were evaluated. Cardiovascular drugs (51 [17%]) were most frequently promoted, followed by antidiabetic drugs (46 [15.3%]) and antimicrobial agents (44 [14.7%]). A single drug was promoted in 201 (67%) and a fixed-dose combination in 99 (33%) brochures. Manufacturer's name was mentioned in 291 (97%), but their address was mentioned in 165 (55%) claims only. Drug cost was revealed only in 30 (10%) DPLs. Each ingredient's generic name, brand name, and dosage form were mentioned in 294 (98%) brochures. Indication for use was stated in 290 (96.7%) claims. Contraindications, adverse effects, precautions, and drug interactions were listed in 103 (34.3%), 98 (32.7%), 98 (32.7%), and 88 (29.3%) advertisements, respectively. References were cited in 200 (66.7%) brochures. Only 95 (31.7%) literatures had relevant pictures of drugs being promoted and 89 (29.7%) had a graphical representation of pharmacological properties. A total of 207 (69%) DPLs followed more than 50% of the WHO criteria.

Conclusion: Majority of DPLs satisfied only half of the WHO criteria for rational drug promotion, and none of them fulfilled all the specified criteria. Incomplete or exaggerated information in DPLs may mislead and result in irrational prescriptions.

Keywords: Drug Brochures, Drug Promotion, Drug Promotional Literature.

INTRODUCTION

A large number of new drugs are introduced into the market every day.[1] Pharmaceutical companies utilise drug promotional literature (DPLs) as a primary marketing tool to promote their new medications.[2] DPLs are claimed to provide vital drug information and are being utilized to convince health professionals to prescribe the new drug.[3-5] Many times, it is the only source on which treating physicians depend for updating their knowledge about existing and novel drugs.

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[6] In 2024, the global pharmaceutical industry spent over US$35 billion on marketing and promotion to educate healthcare professionals about their products.

[7] Such marketing influences clinicians' prescribing behaviour with or without benefiting the patient. According to the World Health Organisation (WHO), medicinal drug promotion is defined as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs."[8,9] Therefore, for the rational use of drugs, the WHO has laid down ethical criteria for medicinal drug promotion and has recommended that pharmaceutical industries implement these guidelines.[3] The Organisation of Pharmaceutical Producers of India, a self-regulatory code of pharmaceutical marketing practices,

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effective from December 2012, stated seven criteria which DPLs should follow.[10] Few studies have observed that the information provided in DPLs varies according to the code of ethics.[11,12] This can affect the drug prescription, utilization, and sometimes be irrational. Hence, this study was conducted to critically evaluate the accuracy of promotional drug literature in accordance with the WHO guidelines.

MATERIALS AND METHODS

An observational study was conducted by the Department of Pharmacology at B.S. Kushwah Institute of Medical Sciences, Kanpur for a period of 6 months from August 2024 to January 2025, after getting approval from the Institutional Ethics Committee. DPLs in the form of flyers, leaflets, and brochures were collected from various outpatient departments, which were available in the hospital through medical representatives. Collected DPLs were assessed as per the WHO guidelines. Literature promoting medicinal devices and equipment (insulin pump, blood glucometer, and orthopaedic prosthesis), ayurvedic medications, drug monographs, reminder advertisements, drug' name lists, and literature promoting more than one drug or more than one fixed-dose combination were excluded.

The following are the WHO criteria to be followed by pharmaceutical industries for the completeness of DPL:[13]

1. The names of the active ingredients using either international nonproprietary names or the approved generic name of the drug
2. Brand name
3. Content of active ingredient per dosage form or regimen
4. Name of other ingredients known to cause problems, i.e., adjuvant
5. Approved therapeutic uses
6. Dosage form or regimen
7. Side-effects and major adverse drug reactions
8. Precautions, contraindications, and warnings
9. Major interactions
10. Name and address of the manufacturer or distributor
11. Reference to scientific literature as appropriate.

The DPLs were also analyzed for additional information, such as various pictures printed, the cost mentioned, the source and year of references used to defend the DPL claims. Descriptive statistics were used to analyse the data. The data were expressed as a percentage.

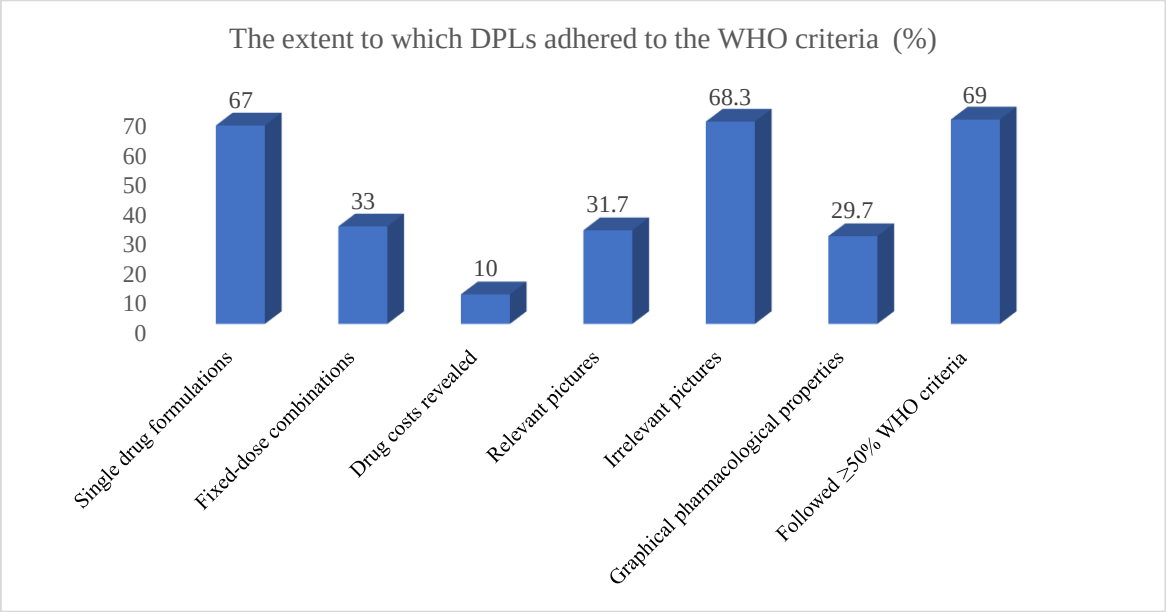
RESULTS

A total of 300 DPLs were collected and analysed, which revealed that 201 (67%) were single-drug formulations and 99 (33%) were fixed-dose combinations.

Table 1: The extent to which DPLs adhered to the WHO criteria

Parameter	Count (n)	Percentage (%)
Single drug formulations	201	67.0
Fixed-dose combinations	99	33.0
Drug costs revealed	30	10.0
Relevant pictures	95	31.7
Irrelevant pictures	205	68.3
Graphical pharmacological properties	89	29.7
Followed ≥50% WHO criteria	207	69.0

Table 1 Represents the Drug costs, which were revealed in only 30 (10%) brochures. Pictures occupied a considerable amount of space on all brochures. DPLs depicted photographs of drug formulation, disease or organ, healthy/depressed men and women, and others. Only 95 (31.7%) DPLs had relevant pictures of drugs being promoted, and 205 (68.3%) had irrelevant representations in the form of a car, a tree, a fruit, etc. Graphical representation of pharmacological properties was observed in 89 (29.7%) DPLs. A total of 207 (69%) DPLs followed more than 50% of the WHO criteria.



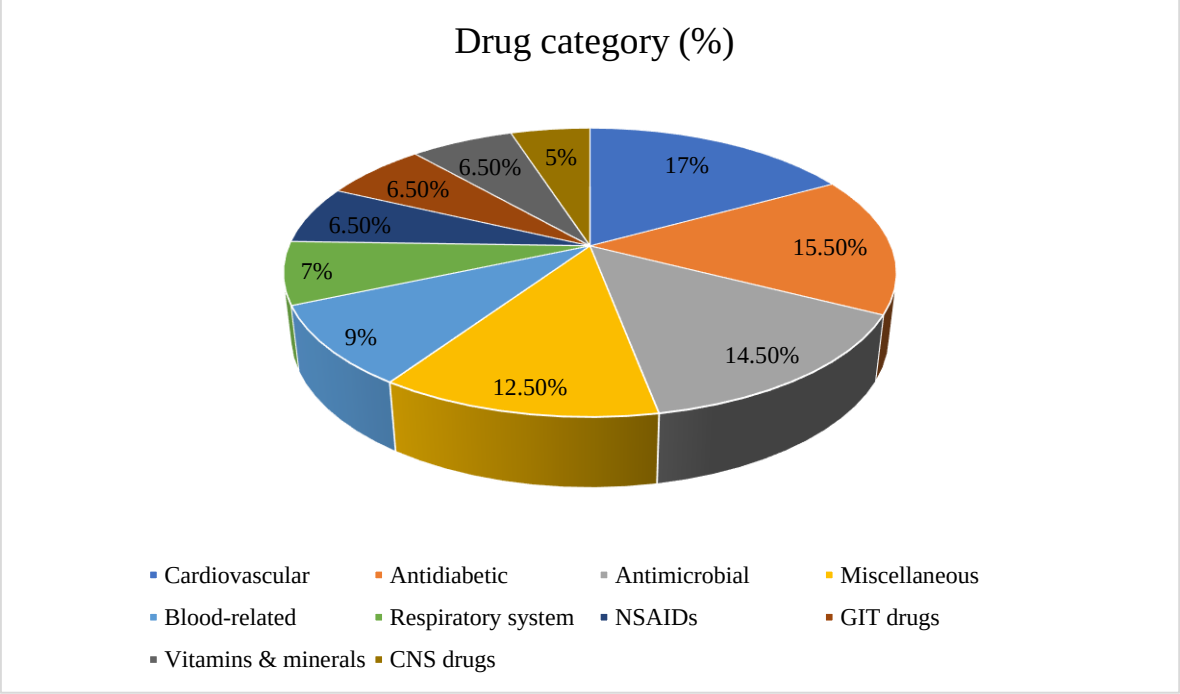


Figure 1. Represents the promoted drug categories/system-wise

Figure 1 shows that drug promotional literature (DPLs) were focused on cardiovascular (17%), antidiabetic (15.5%), and antimicrobial (14.5%) drugs, indicating these areas are the main targets of pharmaceutical marketing. Miscellaneous drugs formed 12.5%, while blood-related (9%) and respiratory system drugs (7%) had moderate representation. Categories such as NSAIDs, GIT drugs, and vitamins & minerals each contributed 6.5%, and CNS drugs had the lowest share at 5%. Overall, the distribution suggests a higher promotional emphasis on metabolic, cardiovascular, and infection-related therapies.

Table 2: Extent to which DPLs followed the WHO criteria (n=300)

WHO Criteria	Number (%) complying
Generic name of active ingredient	294 (98)
Brand name	294 (98)
Content of active ingredient per dose/regimen	294 (98)
Other ingredients known to cause problems	45 (15)

Approved therapeutic uses	290 (96.7)
Dosage form or regimen	285 (95)
Side-effects and major adverse drug reactions	98 (32.7)
Precautions, contraindications, and warnings	98 (32.7)
Major interactions	88 (29.3)
Name and address of manufacturer/distributor	165 (55)
References to scientific literature	200 (66.7)

DISCUSSION

The present study revealed that a majority of the drug promotional literature (DPLs) (207/300, 69%) (Table 1) fulfilled only more than half of the World Health Organisation (WHO) criteria for ethical and rational drug promotion, while none of the brochures complied with all 11 specified criteria. This finding is consistent with another study conducted in 2014 (131/200, 69%)[1] and with numerous subsequent studies across India and globally, where overall adherence to >50% WHO criteria has ranged from 55% to 78%.[2-8] The remarkable similarity in the proportion of DPLs meeting >50% criteria a decade apart (69% in 2014 vs 69% in 2025) suggests that, despite increased regulatory awareness, self-regulatory codes, and repeated publication of critical evaluations, the quality of pharmaceutical promotion in real-world hospital settings has shown little meaningful improvement. Basic identifying information, such as generic name, brand name, content of active ingredient, dosage form, and approved therapeutic indications, was provided in more than 95% of the brochures — a finding almost identical to earlier reports.[1,4,9] In contrast, critical safety-related parameters remained grossly under-reported: side-effects and major adverse drug reactions (32.7%), precautions/contraindications/warnings (32.7%), and major drug interactions (29.3%) (table 2). These figures are comparable to or even slightly worse than those reported in 2014 (32.5%, 32.5%, and 29%, respectively)[1] and align with recent Indian studies (18–38%).[3,5,7,10] The persistent omission of safety information is particularly concerning because prescribers in busy outpatient settings often rely on DPLs as a rapid reference, and the absence of warnings about serious adverse reactions, contraindications, or interactions can directly contribute to preventable adverse drug events and irrational prescribing.[11,12]

References to scientific literature were cited in 200 (66.7%) brochures, marginally higher than the 66.5% reported in 2014.[1] However, the quality and retrievability of these references were not assessed in the present study; previous investigators have shown that a significant proportion of cited references are either company data, non-retrievable, or do not support the claims made.[13,14] Cost information, an important consideration for rational and affordable prescribing in a resource-limited setting like India, was mentioned in only 10% of DPLs — identical to our 2025 finding and consistent with nationwide trends (0–15%).[4,6,15]

Fixed-dose combinations (FDCs) constituted 33% of the promoted products. Many of these FDCs lack robust evidence of added efficacy or safety over individual components, and several have been banned or restricted by the Central Drugs Standard Control Organisation (CDSCO) in recent years.[16] Aggressive promotion of such combinations without justification remains a recurring ethical concern.[10,17]

Visual elements continue to dominate DPL design, with 68.3% containing irrelevant or attractive images (such as luxury cars, nature, and smiling families) that occupy significant space while conveying no scientific information—a marketing strategy repeatedly criticised for creating emotional rather than evidence-based influence on prescribers.[18,19] Only 29.7% included graphs or diagrams of pharmacological properties, and even fewer (31.7%) used images directly relevant to the drug or disease.

The stagnation in adherence over the past decade, despite the introduction of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) in 2015 (made mandatory in 2024) and multiple awareness programs, points to inadequate enforcement mechanisms and weak penalties for non-compliance.[20,21] Physicians, on their part, continue to accept and use DPLs as a convenient source of drug information despite knowing their limitations, perpetuating a cycle of industry-driven rather than evidence-driven prescribing.[22]

CONCLUSION

The Majority of DPLs satisfied only half of the WHO criteria for rational drug promotion, and none of them fulfilled all the specified criteria. Incomplete or exaggerated information in DPLs may lead to misinformed and potentially irrational prescriptions. Therefore, physicians should critically evaluate DPLs in light of updated scientific evidence required for high-quality patient care.

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