Research Article

Analysis of Drug Promotional Literature Against WHO Ethical Criteria for Medicinal Drug Promotion

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Abstract

Aim: To analyse drug promotional literature available in a tertiary care teaching hospital using the WHO Ethical Criteria for Medicinal Drug Promotion.
Materials and Methods: A cross-sectional observational study was conducted in the Departments of Pharmacology and ENT at MMIMSR, MMDU, Mullana. A total of 300 drug promotional literature (DPL) brochures related to allopathic medicines were collected from various clinical departments and evaluated according to the WHO Ethical Criteria for Medicinal Drug Promotion. Promotional claims were categorized into efficacy, safety, cost-effectiveness, convenience, pharmacokinetic properties, pharmaceutical properties, and exaggerated claims. Data were analysed using SPSS version 22.0 and expressed as frequencies and percentages.
Results: Single-drug formulations constituted 59.67% of promotional materials, while fixed-dose combinations accounted for 40.33%. Cardiovascular (18.67%) and endocrine (18.3%) drugs were the most frequently promoted therapeutic categories. Efficacy-related claims were the most common (47.3%), followed by safety claims (19.0%), whereas 7.7% of advertisements contained exaggerated or unjustified claims. Brand name (100%), dosage form (100%), generic name (98.7%), and manufacturer details (99%) were reported in most brochures. However, essential safety information was incompletely presented, with contraindications mentioned in 62.7%, warnings in 55%, precautions in 50%, and drug interactions in 54% of the promotional materials. Scientific references were cited in only 45% of brochures. None of the promotional materials fulfilled all WHO ethical criteria.
Conclusion: Drug promotional literature demonstrated only partial compliance with WHO Ethical Criteria for Medicinal Drug Promotion. While basic product information was generally adequate, important safety information and scientific evidence were frequently omitted. Regular monitoring of pharmaceutical promotional materials and training healthcare professionals in the critical appraisal of DPL are essential to promote rational, evidence-based prescribing.

Keywords: Drug promotional literature; World Health Organization; Ethical criteria; Pharmaceutical promotion; Rational prescribing; Drug advertisements.

Introduction: The rapid expansion of the pharmaceutical industry has led to a substantial increase in the number of drugs entering the market, making access to accurate and reliable drug information essential for rational prescribing. Drug information is obtained from multiple sources, including textbooks, journals, formularies, websites, and drug promotional literature (DPL). Among these, DPL remains one of the most readily available sources of information for busy clinicians because of its accessibility and attractive presentation.[1,2]

The World Health Organization (WHO) defines drug promotion as all informational and persuasive activities by manufacturers and distributors intended to influence the prescription, supply, purchase, or use of medicinal drugs.[2] Pharmaceutical companies invest heavily in promotional activities through brochures, pamphlets, package inserts, reminder advertisements, and interactions with medical representatives to increase product utilization.[3,4] Although DPL can provide useful information regarding indications, dosage, contraindications, and adverse effects, its primary objective is marketing rather than education. Consequently, promotional materials may present incomplete, biased, or misleading information, potentially influencing prescribing practices and compromising rational drug use.[5,6]

To promote ethical pharmaceutical marketing, the WHO established the Ethical Criteria for Medicinal Drug Promotion (1988), which recommend that promotional materials should be accurate, balanced, evidence-based, up-to-date, and capable of substantiation.[2,7] Similar principles have been adopted by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the Organization of Pharmaceutical Producers of India (OPPI).[8,9] Despite these guidelines, several studies have reported inadequate compliance

with WHO criteria and demonstrated that pharmaceutical promotion significantly influences physicians' prescribing behaviour.[10–12]

Given the continued reliance on DPL by healthcare professionals, periodic evaluation of promotional materials is essential to assess their completeness, accuracy, and ethical compliance. Therefore, the present study was undertaken to critically analyse drug promotional literature available in the Indian market using the WHO Ethical Criteria for Medicinal Drug Promotion.

Material and Methods: The present cross-sectional study was conducted with the Department of ENT & Department of Pharmacology MMIMSR, MMDU Mullana. Permission to carry out the study was obtained by Institutional Ethics Committee of MMIMSR, MMDU Mullana.

Inclusion Criteria: Drug promotional literature (DPL) related to allopathic medicines, collected from different departments and representing promotional content from various pharmaceutical brands.

Exclusion Criteria:

- **a.** Brochures that promotes medical devices or equipment, orthopedic prostheses, Ayurvedic medicines.
- **b.** Brochures that have more than two brands.

Criteria for evaluation:

1- Active ingredient names (INN or approved generic name)
2- Brand name
3- Amount of active ingredient per dose
4- Adjuvant
5- Approved therapeutic use
6- a - Dosage form, b. Dosage schedule
7- a - Side effects and major adverse drug reactions
   b- Precautions and warnings
   c- Contraindication
   d- Major drug interactions
8- a - Name of the manufacturer, b -Address of the manufacturer
9- Reference to scientific literature

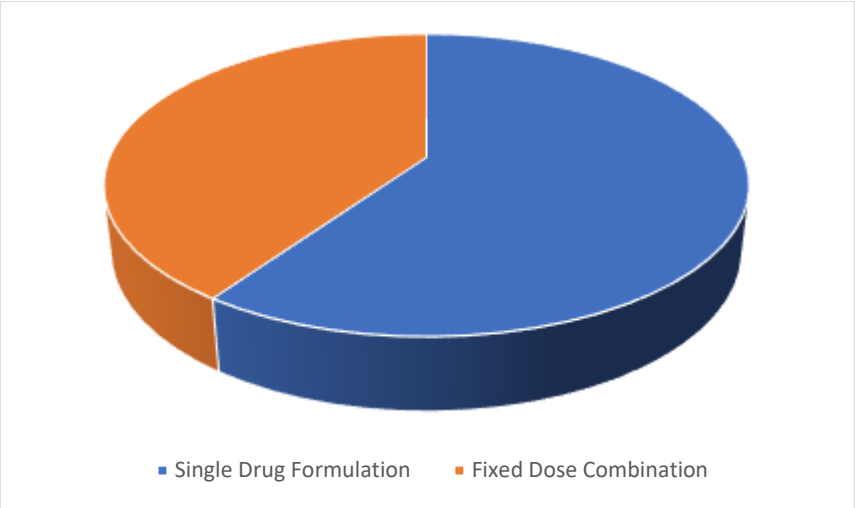
Data collection - Drug promotional literatures (DPLs) of different pharmaceutical companies was collected from various clinical departments.

Analysis - All DPL were analysed based on the WHO Ethical criteria of medicinal drug promotion. In addition to this information, DPLs were evaluated for various claims about the medicinal product. Claims were classified into seven categories as efficacy, safety, cost, convenience, pharmacokinetic property, pharmaceutical property and exaggerated emotional claims.

1. Efficacy: Statements about improved effectiveness of promoted drug as a disease outcome or a patient outcome solely or in comparison with other group of drugs for similar outcome (e.g., antihypertensive action of calcium channel blocker and β-blocker) or another brand of the same drug.
2. Safety: Use of the word “safe” in the promotional text or the mention of reduction in adverse drug reaction and/or drug interaction and/or contraindication.
3. Cost: Pointing out low price of promoted drug in absolute or relative terms or any description related to its better cost effectiveness.
4. Convenience: Statements stating the comfort of patient, e.g., improved dose, low frequency of dosage, ease of administration, etc. with or without reasons to support the same.
5. Pharmacokinetic property: Properties of the drug related to its absorption, metabolism, half-life, etc
6. Pharmaceutical property: New dosage formulations, different manufacturing procedures, excipients (e.g., cyclodextrin, sodium bicarbonate, etc.), storage facilities, etc.
7. Extravagant emotional claims: Apart from all these claims, some PDLs also had some tall/unjust claims which gave exaggerated information which was not supported by any references. For e.g. some PDLs stated that the advertised drug had 95% efficacy without quoting any proof to support it.
8. Numerous pictures have been used by the pharmaceutical companies to make the DPLs more attractive and to influence doctors for prescribing the drug promoted in it. Pictorial content of the promotional brochures was evaluated for the type of pictures (men, women, elderly, children, doctors, medicinal products, or other treatment unrelated pictures) and number of scientific Figures.

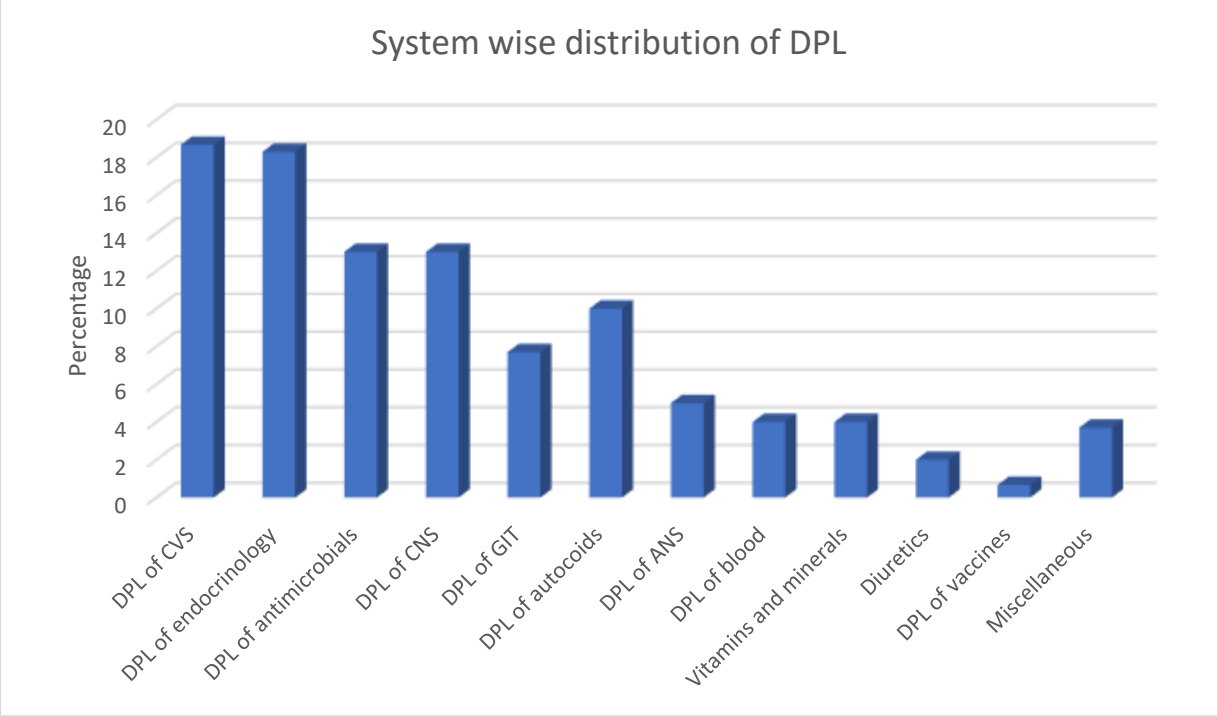
Statistical analysis: Data so collected was tabulated in an excel sheet, under the guidance of statistician and SPSS 22.00 for windows; SPSS inc, Chicago, USA was used for statistical analysis. All the results were expressed in numbers and percentages.

Results: Single drug formulations were the most common, accounting for 179 advertisements (59.67%) as shown in graph 1.



Graph 1: Drug formulation promotional literature advertise

Out of the 300 promotional materials analyzed, the majority belonged to the cardiovascular system (CVS) with 56 (18.67%), followed closely by endocrinology with 55 (18.3%). Promotional literature related to antimicrobials and the central nervous system (CNS) each accounted for 39 (13.0%). Autocoids constituted 30 (10.0%), while gastrointestinal tract (GIT) drugs accounted for 23 (7.7%). Smaller proportions were observed for autonomic nervous system (ANS) drugs 15 (5.0%), blood-related drugs 12 (4.0%), and vitamins and minerals 12 (4.0%) as shown in graph 2.



Graph 2: The system wise number and percentage of drug promotional literature assessed

Among the 300 claims assessed, efficacy-related claims were the most common, accounting for 142 (47.3%) of the total. This indicates that promotional materials primarily emphasized the effectiveness of the drugs. The next most frequent claims were related to safety, which constituted 57 (19.0%). Claims highlighting

pharmaceutical properties accounted for 45 (15.0%), while cost-effectiveness was mentioned in 27 (9.0%) of the promotional materials. Claims regarding pharmacokinetic properties and convenience were reported equally, each with 22 (7.3%). Additionally, tall or unjustified claims were identified in 23 (7.7%) of the promotional literature (table 1).

Table 1: Types of claims made in the drug promotional literature

Type of claims	**N=300**	**%**
Efficacy	142	47.3
Safety	57	19.0
Cost effectiveness	27	9.0
Pharmacokinetic property	22	7.3
Convenience	22	7.3
Pharmaceutical property	45	15.0
Tall/Unjust	23	7.7

Images of medicines were the most frequently used, appearing in 106 (35.3%) of the advertisements. Images depicting women were the next most common, accounting for 54 (18.0%), followed by children with 45 (15.0%). Doctors were featured in 36 (12.0%) of the promotional materials, while men appeared in 28 (9.3%) as shown in table 2.

Table 2: Types of pictures depicted in promotional literature

Type of Pictures	**N=300**	**%**
Men	28	9.3
Women	54	18.0
Elderly	8	2.7
Children	45	15.0
Medicine	106	35.3
Doctor	36	12.0
Others	23	7.7

All the promotional materials (100%) mentioned the brand name and dosage forms of the drugs. The generic name was provided in 296 (98.7%) of the advertisements, while the name of the manufacturer and distributor appeared in 297 (99%) of the promotional materials. However, the address of the manufacturer and distributor was mentioned in only 150 (50%) of the cases. Information regarding therapeutic uses was present in 234 (78%) of the promotional materials, while dosage regimen was mentioned in 210 (70%). Details about side effects were provided in 225 (75%) of the advertisements. Important safety-related information was less consistently reported. Contraindications were mentioned in 188 (62.7%), warnings in 165 (55%), drug interactions in 162 (54%), and precautions in 150 (50%) of the promotional literature. Additionally, reference to scientific literature was cited in 135 (45%) of the materials (table 3).

Table 3: Analysis of drug promotional literature using WHO criteria

WHO criteria	**Number of DPL in compliance**	**%**
Brand name	300	100
Generic name	296	98.7
Amount of active ingredient per dose	226	75.33
Adjuvant	6	2
Dosage forms	300	100
Dosage schedule	210	70
Therapeutic uses	234	78
Side-effects	225	75
Contraindications	188	62.7
Precautions and Warnings	165	55
Drug interactions	162	54
Name of manufacturer and distributor	297	99

Address of manufacturer and distributor	150	50
Reference to scientific literature	135	45

Discussion: Drug promotional literature (DPL) remains one of the most frequently accessed sources of drug information by clinicians because of its convenience and easy availability. However, its primary objective is promotion rather than education, raising concerns regarding the completeness, balance, and scientific validity of the information presented. The present study evaluated 300 drug promotional materials using the WHO Ethical Criteria for Medicinal Drug Promotion and demonstrated that although basic product information was generally well reported, important safety information, scientific evidence, and overall compliance with WHO recommendations remained inadequate.

Single-drug formulations constituted the majority (59.67%) of promotional materials, whereas fixed-dose combinations (FDCs) accounted for 40.33%. Similar findings have been reported by Ganashree et al. [13], Rani et al. [14], Mali et al. [15], and Khakhkhar et al. [11], who also observed greater promotion of single-drug formulations. Nevertheless, the substantial proportion of FDC advertisements remains noteworthy because irrational combinations may increase treatment costs, adverse drug reactions, and inappropriate prescribing. Naikwadi et al. [16] and Jadav et al. [2] have similarly highlighted concerns regarding the promotion of FDCs lacking adequate scientific justification. WHO recommends that FDCs should be promoted only when their efficacy, safety, and therapeutic advantage are well established.

Cardiovascular (18.67%) and endocrine (18.3%) drugs were the most frequently promoted therapeutic categories, followed by antimicrobials and central nervous system drugs. Comparable trends have been reported by Ganashree et al. [13], Jindal et al. [3], Mali et al. [15], and Hoovinahole et al. [17]. This distribution likely reflects the increasing burden of chronic non-communicable diseases and the large commercial market for long-term therapies. However, WHO advocates that promotional activities should primarily support rational prescribing and public health priorities rather than commercial interests alone.

Efficacy-related claims were the predominant promotional strategy (47.3%), followed by safety claims (19.0%). Claims regarding cost-effectiveness, pharmacokinetic advantages, and convenience were comparatively infrequent, while 7.7% of advertisements contained exaggerated or unjustified claims. Similar observations have been reported by Rani et al. [14], Babu et al. [18], Tayade et al. [19], Randhawa et al. [20], Villanueva et al. [21], and Lexchin [22], who demonstrated that promotional literature often emphasizes benefits while minimizing limitations and potential risks. According to WHO ethical criteria, promotional claims should be accurate, balanced, evidence-based, and capable of substantiation. The presence of unsupported claims in the present study indicates continued deviation from these recommendations.

Visual presentation constituted another prominent feature of promotional materials. Images of medicines, women, and children were frequently used, whereas elderly individuals were rarely represented. Similar findings have been documented by Shetty et al. [1], Ganashree et al. [13], and Babu et al. [18], suggesting that promotional materials commonly employ attractive imagery and graphics to capture attention rather than enhance scientific communication. WHO recommends that illustrations should be directly relevant to scientific content and should not create misleading impressions regarding drug efficacy or safety.

Evaluation of compliance with WHO criteria revealed that basic product information, including brand name, generic name, dosage form, and manufacturer details, was reported in most promotional materials. However, important information such as manufacturer address, therapeutic indications, and dosage regimen was incompletely reported. Similar observations have been described by Ganashree et al. [13], Jindal et al. [3], Naikwadi et al. [16], and Hoovinahole et al. [17], indicating that promotional literature generally provides information useful for marketing while omitting details necessary for rational prescribing.

Safety-related information showed only partial compliance with WHO recommendations. Although adverse effects were mentioned in 75% of promotional materials, contraindications, warnings, precautions, and drug interactions were reported considerably less frequently. Similar deficiencies have been consistently reported by Ganashree et al. [13], Rani et al. [14], Mali et al. [15], Khakhkhar et al. [11], Jain et al. [23] and Rohra et al. [24]. Omission of essential safety information may result in irrational prescribing and prevent clinicians from adequately assessing the benefit-risk profile of promoted medicines.

Only 45% of promotional materials cited scientific references, and very few mentioned problematic excipients. Previous investigators, including Ganashree et al. [13], Rani et al. [14], Babu et al. [18], Villanueva et al. [21], Randhawa et al. [20], and Rohra et al. [24], have similarly reported inadequate or poor-quality referencing, with several promotional claims supported by outdated, inaccessible, or non-peer-reviewed

sources. WHO recommends that all promotional claims should be supported by valid, current, and retrievable scientific evidence, preferably from peer-reviewed literature.

Importantly, none of the promotional materials evaluated in the present study fulfilled all WHO ethical criteria. Similar findings have been consistently reported by Ganashree et al. [13], Mali et al. [15], Khakhkhar et al. [11], Jindal et al. [3], Naikwadi et al. [16], Hoovinahole et al. [17], Farooq et al. [25], Shankar et al. [26], and Babu et al. [18], indicating that incomplete adherence to WHO standards remains a persistent global concern. These observations suggest that pharmaceutical promotional materials continue to prioritize marketing objectives over comprehensive scientific communication.

Given the widespread use of DPL by practicing clinicians, the ability to critically appraise promotional material is essential for rational prescribing. Recognizing this need, the National Medical Commission (NMC) incorporated critical appraisal of drug promotional literature into the Competency-Based Medical Education (CBME) undergraduate pharmacology curriculum from the 2019–2020 academic session onwards. Educational interventions, workshops, and structured training in evaluating promotional claims can strengthen evidence-based prescribing and reduce undue influence of pharmaceutical marketing. Physicians should therefore consider DPL as supplementary information and verify promotional claims using independent, evidence-based sources before incorporating them into clinical practice.

Conclusion: Our analysis revealed that most drug promotional literature failed to comply with established ethical guidelines and was deficient in terms of adequacy, quality, and authenticity of information. Consequently, it can be inferred that the majority of promotional materials provided to prescribers do not effectively foster awareness for rational prescribing practices. Introducing training programmes and sensitization initiatives during the early years of undergraduate medical education may help improve ethical standards in pharmaceutical promotion.

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