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Arpit Verma
Associate Professor, Department of Pharmacology, Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh, India

Jitendra Kumar Mehta
Assistant Professor, Department of Pharmacology, RSDKS Government Medical College, Ambikapur, Chhattisgarh, India

Akanksha Grace William
Assistant Professor, Department of Pharmacology, Late Shrimati Indira Gandhi Memorial Government Medical College, Kanker, Chhattisgarh, India

Nikita Toshi
Manager, Growth and Marketing at PharmEasy, Mumbai, Maharashtra, India

Corresponding Author:
Arpit Verma
Associate Professor, Department of Pharmacology, Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh, India

Evaluating the Rationality of Drug Promotional Literature Using WHO Criteria: A Study from a Tertiary Care Hospital

Arpit Verma, Jitendra Kumar Mehta, Akanksha Grace William and Nikita Toshi

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Abstract
Background: Pharmaceutical companies aggressively pursue drug promotional activities to gain a large market share. Printed brochures are among the most commonly used marketing media, but they often highlight advantages while minimizing safety information, thereby influencing prescribing patterns and impacting clinical decision-making.
Aim: To critically evaluate the rationality of drug promotional literature (DPL) using the World Health Organization (WHO) ethical criteria.
Methods: A total of 120 DPLs were collected from clinicians across multiple specialties in a tertiary care teaching hospital in central India. Each DPL was systematically assessed against the 11 ethical criteria recommended by WHO for drug promotion. Data were tabulated and analyzed using descriptive statistical methods.
Results: The most frequently promoted therapeutic groups were antibiotics (28%), antidiabetic drugs (24%), and cardiovascular medicines (18%). Approximately 60% of the brochures were for fixed-dose combinations (FDCs). While all brochures mentioned the manufacturer's name, only 48% carried a complete address. Information completeness was inadequate—contraindications were provided in 30%, adverse drug reactions in 26%, and precautions in 22%, and no brochure contained information regarding drug interactions. Only 3% of brochures complied fully with the WHO criteria. Of the 156 references cited, the majority (90%) were from journals, but fewer than half were recent.
Conclusion: The majority of DPLs failed to provide balanced and complete information, favoring promotional intent over scientific accuracy. Enhanced regulatory control and greater physician awareness are essential and urgently needed to promote rational prescribing.

Keywords: Drug promotion literature, DPL. WHO Criteria, rational prescribing, pharmaceutical marketing, drug brochure

Introduction
The pharmaceutical industry plays a pivotal role in drug discovery and development, but invests substantial resources in marketing and drug promotions as well. Drug promotional literature (DPL) including brochures, leaflets, and printed advertisements serves as a primary marketing tool for medical representatives. However, these materials frequently exaggerate therapeutic benefits and underreport risks, leading to biased prescribing practices.
To address this, the World Health Organization (WHO) introduced 11 ethical criteria in 1988 to ensure that drug promotion is actual, evidence-based, and unbiased. Despite these guidelines, evidence from both global and Indian studies suggests that much of the promotional content falls short of these standards, raising significant concerns about irrational prescribing. This study was conducted to evaluate the rationality of DPLs distributed to clinicians at a tertiary care hospital, using WHO ethical criteria as the standard reference.

Aim and Objectives
1. To assess drug promotional literature using WHO ethical criteria.
2. To analyse the completeness and reliability of information presented.
3. To identify the most frequently promoted drug categories.

Materials and Methods
Study Design: This was a cross-sectional, observational study conducted in the Department of Pharmacology at a tertiary care teaching hospital.

The study period extended over six months, during which drug promotional literature (DPL) in the form of printed brochures, leaflets, and pamphlets distributed by pharmaceutical representatives to healthcare professionals was collected and analysed.

Study Site: Conducted in the Department of Pharmacology at a tertiary care Government Medical College in Central India.

Sample Size: A total of 120 brochures were collected over 3 months from outpatient departments across various specialties.

Evaluation Tool
Each brochure was analyzed using 11 WHO ethical criteria, including-

- The active ingredient(s) using international nonproprietary name (INN).
- The brand name of the product.
- Quantitative composition of active ingredient(s) per dosage form.
- Approved therapeutic uses (indications).
- Dosage form and regimen.
- Side effects and adverse reactions.
- Precautions, contraindications, and warnings.
- Major drug interactions.
- Name and address of the manufacturer/distributor.
- Reference to scientific literature for claims made.
- Other relevant information consistent with approved product labelling

Data Analysis
Data were expressed as percentages and frequencies. Graphs and tables were prepared for better visualization.

Results
Drug Class in DPLs

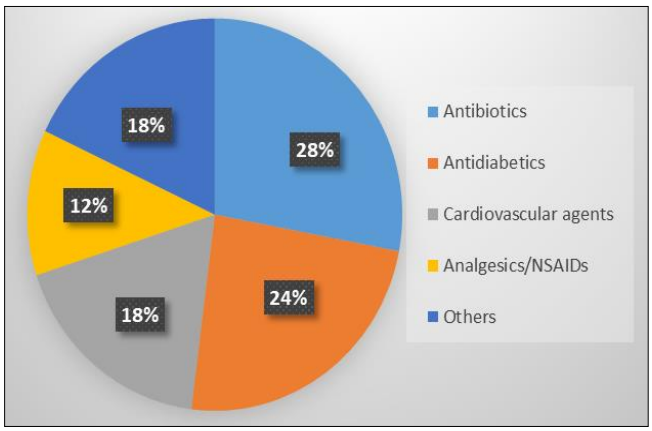

Fig 1: Drug Class in DPLs-

Formulation Type

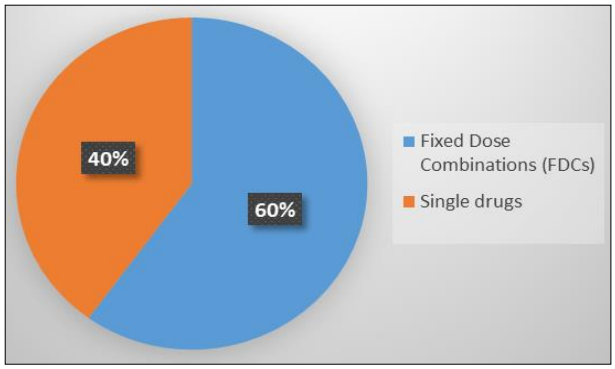

Fig 2: Formulation Type-

Manufacturer Information
Manufacturer's name: 100%
Manufacturer's Address: 48%

Information Completeness
Reference Analysis

Total cited: 156
From journals: 90%
Company sources/textbooks: 10%
Up-to-date (<5 years): 45%

Therapeutic Groups Promoted

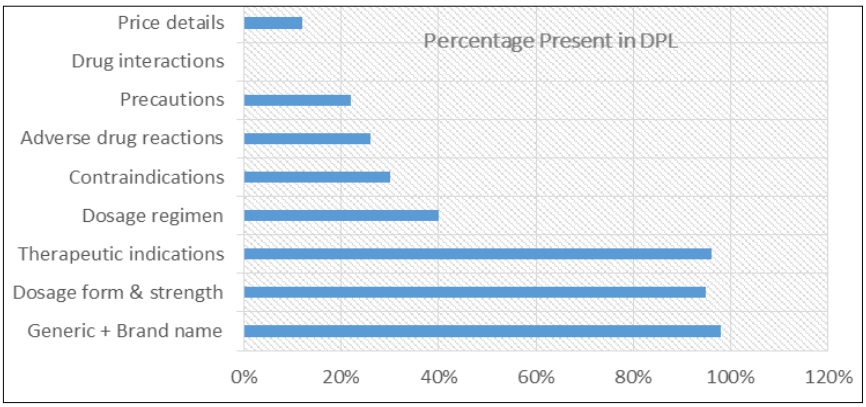

Fig 3: Therapeutic Groups Promoted

Overall WHO Compliance

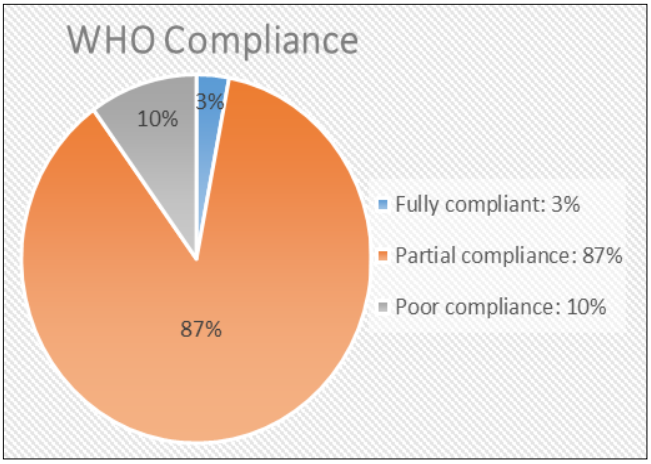

Fig 4: Overall WHO Compliance

Discussion

The findings of this study indicate that drug promotional literature (DPL) distributed within a tertiary care hospital was largely incomplete and lacked rational, evidence-based content. Consistent with previous Indian studies, antibiotics and anti-diabetic agents emerged as the most frequently promoted therapeutic categories, reflecting both their extensive clinical use and high market demand.

A striking observation was the predominance of fixed-dose combinations (FDCs), which constituted approximately 60% of all promotional materials. Many of these combinations may not be supported by adequate scientific justification or robust clinical evidence. Furthermore, critical safety-related information, including contraindications, adverse drug reactions, and necessary precautions, was missing from a substantial proportion of brochures. The complete absence of data on drug interactions poses a significant concern, as it may predispose patients to harmful or irrational combinations.

Despite the World Health Organization's (WHO) 11 ethical criteria established to ensure accurate and balanced medicinal drug promotion, only 3% of the analysed brochures were fully compliant. This observation reinforces the perception that commercial interests often take precedence over scientific transparency and patient safety in pharmaceutical marketing practices.

To address these concerns, physicians should be encouraged to critically appraise promotional materials rather than accepting them at face value. Incorporating training on the evaluation of drug advertisements into undergraduate and postgraduate curricula may help foster rational prescribing habits early in medical education. Additionally, strict regulatory oversight and periodic monitoring by competent authorities are essential to ensure that promotional content adheres to ethical standards. Strengthening collaboration between medical institutions, professional bodies, and regulatory agencies can further promote responsible dissemination of drug information and safeguard patient welfare.

Conclusion

The present study highlights that a significant number of drug promotional literature (DPL) often exhibit substantial bias and lack adequate scientific integrity. Most promotional materials tend to emphasize therapeutic advantages while downplaying potential risks, thereby contributing to misleading information and irrational prescribing practices.

To promote ethical and evidence-based use of medicines, the following measures are essential:

- **Enhanced regulatory vigilance:** Strengthening monitoring mechanisms to ensure that promotional content adheres to WHO ethical standards.
- **Educational reinforcement:** Integrating training programs that enable healthcare professionals to critically evaluate promotional materials before incorporating them into clinical decision-making.
- **Institutional ethical policies:** Establishing clear guidelines within healthcare institutions to regulate interactions between the medical community and the pharmaceutical industry.

Collectively, these strategies can help foster transparency, ensure rational prescribing, and ultimately safeguard patient safety.

Conflict of Interest
Not available

Financial Support
Not available

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