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# ASSESSING ETHICAL COMPLIANCE OF ANTIMICROBIAL DRUG PROMOTIONAL MATERIALS IN INDIA: A WHO-GUIDED CROSS-SECTIONAL STUDY

Pharma

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## ABSTRACT

**Background:** Pharmaceutical promotional materials significantly influence prescribing behaviours, particularly in the case of antimicrobials, where inappropriate promotion contributes to antimicrobial resistance (AMR). Compliance with the ethical standards established by the World Health Organization (WHO) for drug promotion is still uncertain in India. **Methods:** An observational, cross-sectional study was performed in the Department of Pharmacology at Moti Lal Nehru Medical College, Prayagraj. Ethical criteria of WHO were implemented to evaluate a total of 160 printed drug promotional literatures (DPLs) obtained from private healthcare facilities. **Results:** All 160 drug promotional literatures (DPLs) mentioned both brand and generic names. The information about the active ingredient quantity and therapeutic indications were mentioned in 90% and 85% of cases, respectively. However, safety-related details were inconsistently reported: side effects (18%), warnings (15%), contraindications (16%), and drug interactions (11%). Only 31% included scientific references, and none of them addressed important issues like antimicrobial resistance or stewardship principles. **Conclusion:** There are significant gaps in the ethical quality of antimicrobial promotional materials. These findings underscore the need for regulatory vigilance and better education of healthcare professionals to support rational antibiotic use and AMR control.

## KEYWORDS

Antimicrobial agents, Drug promotion, WHO criteria, pharmaceutical ethics, antimicrobial resistance, India

## INTRODUCTION

### Background

Pharmaceutical drug promotional literature markedly shapes physicians' prescribing behaviours by influencing drug choices and clinical decisions [1]. While such materials aim to propagate information regarding newer drugs and formulations, several studies have shown that they often prioritize marketing over evidence-based education [2,3]. This is notably alarming when it comes to antibiotics, where inappropriate promotion can accelerate antimicrobial resistance (AMR), a worldwide health emergency.

### Antimicrobial Resistance: A Global and National Concern

In 2019, drug-resistant infections resulted in approximately 1.27million deaths, as per Global Research on Antimicrobial Resistance (GRAM) report. Low- & middle-income countries, particularly India, were subjected to greater impact [4]. The Indian Council of Medical Research (ICMR) reports that resistance to frequently utilized antibiotics, notably ciprofloxacin, ceftriaxone, and carbapenems, has risen profoundly in India over the past decade [5]. The irrational use of antibiotics— regularly influenced by misleading pharmaceutical promotion—has been identified as a major contributor to this trend [6].

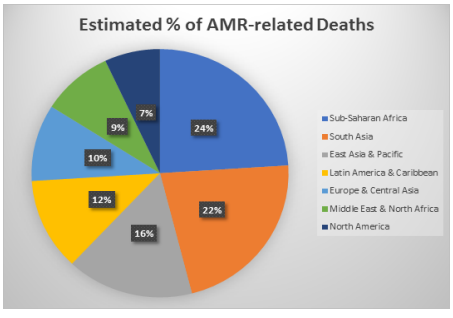


**Figure 1:** Global AMR-related Deaths by Region
(Source: GRAM Report, 2022 – Hypothetical Distribution)

### WHO Ethical Criteria For Medicinal Drug Promotion

For addressing the issue of biased drug promotion, WHO introduced ethical criteria for medicinal drug promotion in 1988 [7]. Such criteria are designed to ensure that promotional content is balanced, evidence-based, and not misleading. Essential elements are those as shown in **Table 1.** Failure to include these components may mislead prescribers, resulting in irrational drug use and contributing to AMR.

**Table 1: WHO Ethical Criteria For Drug Promotion**

| WHO Criteria No. | Element Evaluated | Description |
|---|---|---|
| 1 | Drug name | Brand name and generic name |
| 2 | Active ingredients | Quantity per dosage unit |
| 3 | Approved uses | Indications and therapeutic uses |
| 4 | Dosage | Dosage regimen and dosage form |
| 5 | Pharmacological mechanism (additional) | Mechanism of action (included for extended academic relevance) |
| 6 | Side effects | Adverse effects and serious risks |
| 7 | Contraindications | Medical conditions for which the drug is inadvisable |
| 8 | Precautions and warnings | Cautions before or during use |
| 9 | Drug interactions | Major clinically relevant interactions |
| 10 | Manufacturer's name | Name of manufacturer or distributor |
| 11 | Manufacturer's address | Address of the manufacturer or distributor (split for detailed analysis) |
| 12 | Scientific references | Supporting literature cited for promotional claims |
| 13 | AMR-related content | Mention of antimicrobial resistance or stewardship principles (extended) |

(Adapted from WHO Ethical Criteria for Medicinal Drug Promotion, 1988 with additional parameters for expanded analysis)

"Although the WHO ethical criteria for medicinal drug promotion (1988) outline 11 key parameters, our study included 13 elements for comprehensive analysis. We separately assessed the manufacturer's name and address to evaluate transparency, and we added 'pharmacological mechanism' as an extended criterion to reflect

scientific content integrity."

### Rationale For The Study

Multiple Indian studies have found that a significant proportion of drug promotional materials (DPLs) fail to meet WHO ethical criteria, often omitting safety details or citing poor-quality references [8–10]. However, antimicrobial-specific evaluations remain limited. Given the urgency of AMR control, it is essential to assess the quality and completeness of antibiotic promotional content distributed in Indian healthcare settings.

What sets this study apart is its exclusive focus on antimicrobial promotional materials in India, with an extended evaluation that includes criteria related to antimicrobial resistance, an area often overlooked in previous research.

### Objectives

**This Study Was Undertaken To:**

1. **Evaluate** antibiotic promotional materials based on WHO ethical standards.
2. **Determine** the proportion of DPLs lacking critical information.
3. **Assess** the implications of unethical promotion on antimicrobial resistance.

## MATERIALS AND METHODS

### Study Design And Setting

A cross-sectional, observational study performed in the Department of Pharmacology, Moti Lal Nehru Medical College, Prayagraj, over a period of 4 months (January to April 2025). It attempts to determine antibiotic drug promotional literature (DPL) complies with WHO Ethical Criteria for Medicinal Drug Promotion.

### Study Material

Private physicians and private clinics in Prayagraj, U.P., were randomly selected for collecting a total of 160 printed drug promotional materials associated with antimicrobial agents. Promotional literature was obtained either directly from medical representatives or indirectly via healthcare professionals who received it during their routine clinical practice.

### Inclusion Criteria

- Printed promotional materials for antimicrobial (antibacterial, antiviral, antifungal, antiparasitic) agents.
- Materials distributed in outpatient clinical settings by pharmaceutical representatives.
- Materials that mention drug indications or therapeutic claims.

### Exclusion Criteria

- Non-antimicrobial promotional literature.
- Promotional materials that were incomplete, illegible, or duplicated.
- Materials lacking therapeutic claims (e.g., only announcing product launches without indications).

### Evaluation Tool

The content of each DPL was determined employing WHO's ethical criteria for medicinal drug promotion (1988) [7].

### Data Analysis

The presence or absence of each WHO parameter was recorded in a structured proforma. Data were entered into Microsoft Excel and analysed employing R statistical package and Microsoft Excel. We employed descriptive statistics to summarise the data. Findings have been displayed as frequencies & percentages.

## RESULTS

A total of 160 antimicrobial drug promotional literatures (DPLs) were analysed for adherence to WHO ethical criteria. Findings are summarized in the table below:

**Table 2: Compliance of Drug Promotional Literature with WHO Ethical Criteria (n=160)**

| WHO Criteria | DPLs Meeting Criteria (%) |
|---|---|
| Brand & Generic Names | 100% |
| Active Ingredient Amount | 90% |
| Therapeutic Uses | 85% |
| Dosage Form | 89% |
| Pharmacological Mechanism | 35% |
| Side Effects | 18% |
| Precautions & Warnings | 15% |
| Contraindications | 16% |
| Drug Interactions | 11% |
| Manufacturer's Name | 70% |
| Manufacturer's Address | 25% |
| Scientific References | 31% |
| Mention of Antimicrobial Resistance (AMR) | 0% |

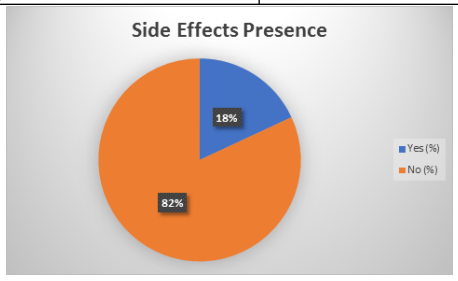


**Figure 2:** Distribution of DPLs mentioning side effects. Only 18% included this information.

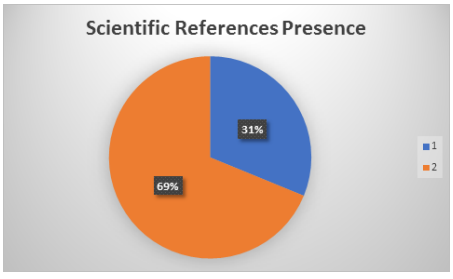


**Figure 3:** Proportion of DPLs citing scientific references. Only 31% included supporting literature.

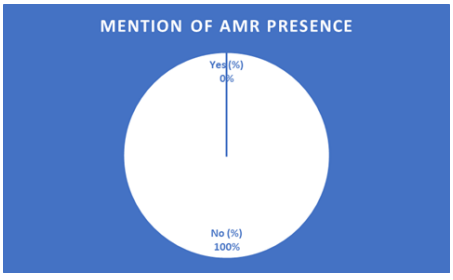


**Figure 4:** AMR mention in DPLs. None of the materials included antimicrobial resistance content.

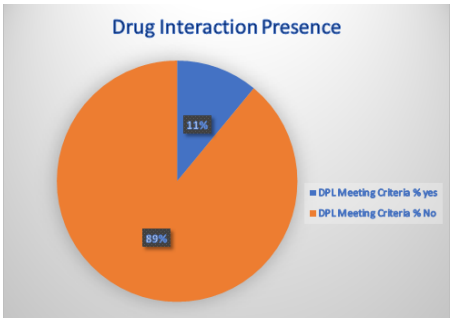


**Figure 5:** Proportion of DPLs mentioning drug interactions. Only 11% provided relevant interaction information.

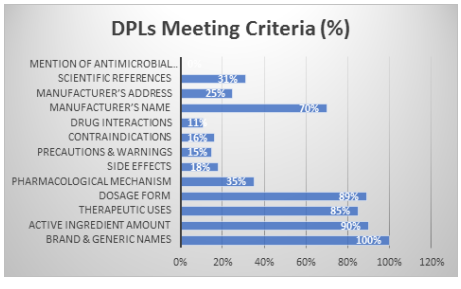

**Figure 6:** Depicting compliance percentage of each WHO criterion by DPLs.

**Key Observations**

- While all DPLs included brand and generic names, safety information was grossly underrepresented.
- Less than one-third cited scientific references.
- Not a single promotional item addressed antimicrobial resistance or stewardship principles.
- Pharmacological mechanism was visually depicted in only a minority of DPLs (35%).

These results indicate a strong promotional bias in Favor of marketing claims over balanced scientific communication, particularly for critical drug safety and AMR-related information.

## DISCUSSION

This study assessed the ethical quality of antimicrobial drug promotional literature (DPL) utilizing WHO's ethical criteria in tertiary care centre in India. The results underscore striking imbalance: while basic identifiers like brand and generic names were universally present, critical safety and scientific components were frequently omitted. These findings have profound implications for antimicrobial stewardship and rational prescribing.

All 160 DPLs assessed (100%) included the generic and brand names, which is consistent with prior studies evaluating general drug promotional material in India and abroad [11,12]. However, content related to pharmacovigilance was severely lacking—only 18% mentioned adverse effects, 11% included drug interactions, and 15% provided warnings. This is particularly troubling for antimicrobials, where incomplete information can lead to inappropriate use, treatment failure, or resistance development [13,14].

Only 31% of DPLs cited scientific literature, falling short of WHO's requirement for verifiability [11]. Rathnakar et al. found a similar trend in Indian promotional literature, with only 28% providing references, many of which were poorly sourced [10]. In contrast, investigation by Cooper et al. in South Africa reported over 50% citation inclusion, suggesting better regional compliance where stricter regulatory oversight exists [15].

The most alarming finding was the complete absence of AMR-related content in all DPLs reviewed. This is despite national and international emphasis on integrating AMR education into every level of healthcare delivery [16]. WHO's Global Action Plan on AMR and India's National Action Plan on AMR (NAP-AMR) call for responsible promotion practices and inclusion of stewardship principles in drug advertising [17,18]. The omission signals either negligence or deliberate minimization of risks by pharmaceutical companies, prioritizing sales over public health.

**Table 3: Missing WHO Criteria in DPLs And Associated Risks**

| Missing Information | Potential Risks |
|---|---|
| Adverse Effects | Prescribing without awareness of potential harm |
| Drug Interactions | Increased risk of contraindicated co-prescriptions |
| AMR Consideration | Unchecked antibiotic overuse and rising resistance |
| Scientific References | Lack of accountability and evidence-based credibility |

**Comparative Literature Insights**

Other Indian studies echo these concerns. Padhy and Gupta found that 47% of promotional materials lacked adverse effect information, and 52% lacked dosage details [8]. Patel et al. assessed 200 promotional materials and found that only 13.5% were fully compliant with WHO guidelines, and fewer than 5% mentioned any form of resistance or long-term treatment risk [19].

Internationally, a review by Othman et al. encompassing over 30 studies across 20 countries concluded that most drug advertisements do not meet WHO ethical criteria, particularly in LMICs [20]. Villanueva et al. assessed journal advertisements in Spain and reported that only 11% of promotional claims were backed by strong evidence [3].

These global parallels serve to substantiate the notion that pharmaceutical industry's pursuit of self-regulation has largely failed and that stronger legislative frameworks are essential.

**Implications For Policy And Practice**

1. **Regulatory Response**: India's CDSCO must mandate pre-approval of DPLs and integrate AMR clauses in advertising regulations. Publishing houses and hospitals should also vet promotional content distributed within their premises [21].
2. **Educational Countermeasures**: Medical institutions must sensitize undergraduates and postgraduates to identify biased promotion, via **academic detailing**, **critical appraisal training**, and **drug information centres** [22].
3. **Healthcare Professional Responsibility**: Clinicians must adopt a skeptical, evidence-based approach to DPLs, relying on independent drug bulletins or formulary guides for rational prescribing.

**Limitations**

This study was limited to one hospital and printed DPLs; digital or mobile-based promotional platforms were not included. Additionally, it did not measure the behavioural impact of the materials on prescribing patterns, which could be addressed in future longitudinal research.

## CONCLUSION

This study provides critical insight into the current state of antimicrobial DPL in a tertiary care setting in Northern India. Although basic identifiers, such as brand and generic names, were universally present, overall compliance with WHO ethical criteria was found to be inadequate. Most concerning was the near-total omission of safety-related information and the complete lack of reference to AMR, a pressing public health threat both globally and nationally.

Findings underscore a systemic promotional bias that prioritizes drug sales over patient safety and evidence-based practice. In the context of AMR, where rational antibiotic use is essential, such gaps in information can have serious clinical and epidemiological consequences. Healthcare professionals, regulators, and pharmaceutical industry should collaborate to establish drug promotion practices that are transparent, ethical, and informative.

**To Address These Issues, It Is Imperative That:**

- Regulatory bodies like the CDSCO enforce strict guidelines for promotional content, including mandatory mention of AMR implications in antimicrobial advertisements.
- Medical educators promote critical appraisal skills and pharmacovigilance awareness through structured training modules.
- Clinicians are encouraged to critically evaluate promotional materials and seek information from unbiased sources, such as peer-reviewed journals, national formularies, and institutional drug bulletins.

Future investigations ought to examine the impact of promotional content on actual prescribing behaviour and extend evaluations to digital formats, which are increasingly used in the pharmaceutical marketing landscape. Strengthening ethical promotion is not just a regulatory goal but a public health requirement in fight against AMR.

**Declarations-**

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The authors declare that no funding was received for this study.

**Conflict Of Interest**

Nil.

**Ethical Approval**

Nil.

**Author Contributions**

Dr. Abhinandan Kumar (data collection, analysis, and manuscript drafting)

Dr. Ramesh Kumar Kannojiya (manuscript editing, proofreading, formatting)

Dr. Madhumita Dixit (manuscript review and research inputs)

Dr. Rakesh Chandra Chaurasia (study concept and design, critical review)

## REFERENCES


1. Lexchin J. What information do physicians receive from pharmaceutical representatives? CMAJ. 1997;157(4):513–9.
2. Mali SN, Dudhgaonkar S, Bachewar NP. Evaluation of rationality of promotional drug literature using WHO guidelines. Indian J Pharmacol. 2010;42(5):267–72.
3. Villanueva P, Peiro S, Librero J, Pereiró I. Accuracy of pharmaceutical advertisements in medical journals. Lancet. 2003;361(9351):27–32.
4. Murray CJL, Ikuta KS, Sharara F, Swetschinski L, Robles Aguilar G, Gray A, et al. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022;399(10325):629–55.
5. Indian Council of Medical Research (ICMR). Annual Report AMR Surveillance Network 2021. New Delhi: ICMR; 2022.
6. Huttner B, Goossens H, Verheij T, Harbarth S. Characteristics and outcomes of public campaigns aimed at improving the use of antibiotics in outpatients in high-income countries. Lancet Infect Dis. 2010;10(1):17–31.
7. WHO. Ethical criteria for medicinal drug promotion. Geneva: World Health Organization; 1988.
8. Padhy BM, Gupta YK. Promotion of medicines: ethical or unethical. Indian J Pharmacol. 2011;43(6):611–2.
9. Khakhkhar T, Mehta M, Shah R, Desai M. Evaluation of drug promotional literature using World Health Organization guidelines. J Pharmacol Pharmacother. 2013;4(1):4–8.
10. Rathnakar UP, Mane PP, Shenoy AK, Keshava B. A study on rationality of promotional drug literature given to medical practitioners in India. J Clin Diagn Res. 2012;6(6):945–7.
11. Giri BR, Phalke DB. Assessment of promotional drug literature provided to doctors in a tertiary care hospital. J Clin Diagn Res. 2014;8(6):FC14–6.
12. Roy D, Das P, Mondal K, Roy T. Evaluation of drug promotional literature using WHO guidelines. J Indian Med Assoc. 2018;116(1):35–8.
13. D'Arcy PF. Drug advertising—truth or dare? Pharm J. 1992;248:716–8.
14. Shankar PR, Subish P, Mishra P, Bhandari RB. Ambiguous drug promotion: what doctors should know. Kathmandu Univ Med J. 2006;4(3):238–41.
15. Cooper R, Oyelola F, Odeyemi K. Evaluation of drug promotional materials in South Africa. Pharm World Sci. 2007;29(3):193–6.
16. Laxminarayan R, Sridhar D, Blaser M, Wang M, Woolhouse M. Achieving global targets for antimicrobial resistance. Science. 2016;353(6302):874–5.
17. World Health Organization. Global action plan on antimicrobial resistance. Geneva: WHO; 2015.
18. Ministry of Health and Family Welfare. National Action Plan on Antimicrobial Resistance 2017–2021. Government of India.
19. Patel K, Bansal A, Gupta R. Ethical compliance of drug promotional brochures available at tertiary care hospitals in Gujarat. Int J Basic Clin Pharmacol. 2018;7(2):207–12.
20. Othman N, Vitry A, Roughead EE. Quality of pharmaceutical advertisements in medical journals: a systematic review. PLoS One. 2009;4(7):e6350.
21. Sood R, Sood A. Misleading drug advertisements in India: a regulatory review. Indian J Med Ethics. 2007;4(4):174–6.
22. Norris P, Herxheimer A, Lexchin J, Mansfield P. Drug Promotion: What We Know, What We Have Yet to Learn. Geneva: WHO/Health Action International; 2005.