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Evaluating the Rationality of Drug Promotional Literature (DPL) in Outpatient Departments of a Tertiary Care Teaching Hospital in Maharashtra using WHO Guidelines: A Cross-Sectional, Observational Study

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A B S T R A C T

Introduction: Drug Promotional Literature (DPL) is a key marketing tool used by pharmaceutical companies to influence prescribing patterns of healthcare professionals. However, these materials often lack comprehensive, evidence-based information. This study aims to evaluate the rationality of DPLs distributed in a tertiary care teaching hospital in Maharashtra using WHO guidelines and compare it with similar studies.

Methodology: A cross-sectional, observational study was conducted from July to September 2023. A total of 100 DPLs were collected from various outpatient departments. Each DPL was analyzed for compliance with WHO criteria. All the data was entered in Microsoft Excel and analyzed using descriptive statistics.

Results: Among the 100 DPLs assessed, compliance with WHO criteria varied significantly. While 95% of the DPLs mentioned the brand name, only 62% provided the active ingredient. Details on side effects and adverse reactions were found in only 40% of cases, whereas drug interactions were mentioned in just 35%. Compared to previous studies, compliance with scientific references was slightly higher (28% vs. 22% in Mali et al., 2010).

Conclusion: The study highlights significant gaps in the completeness and transparency of DPLs. The findings call for stricter regulatory oversight and improved ethical standards in pharmaceutical marketing.

Keyword: Drug Promotional Literature (DPL), WHO Guidelines, Rationality Assessment

INTRODUCTION

Drug Promotional Literature (DPL) is a powerful tool used by pharmaceutical companies to communicate with healthcare professionals. These materials, which include brochures, pamphlets, journal advertisements, and digital content, are designed to inform doctors about new and existing drugs—their uses, dosages, safety profiles, and effectiveness. However, the accuracy and completeness of this information have often been questioned, as commercial interests sometimes overshadow scientific integrity.[1]

Recognizing the potential risks of biased or misleading drug promotion, the World Health Organization (WHO) developed ethical criteria to guide the responsible marketing of pharmaceuticals. These guidelines stress the importance of balanced, evidence-based communication that includes accurate information on efficacy, safety, possible side effects, and drug interactions.[1] Unfortunately, studies suggest that these guidelines are not always followed, and many promotional materials lack proper scientific references, leaving healthcare professionals with incomplete or misleading data.[2,3]

In busy outpatient departments (OPDs) of tertiary care hospitals, where physicians often make quick decisions, DPL serves as an easily accessible source of drug information. However, when these materials lack transparency or omit critical safety details, they can contribute to irrational prescribing, ultimately affecting patient care. Research indicates that relying solely on industry-provided drug information can sometimes lead to inappropriate prescribing patterns, highlighting the need for stronger oversight and accountability.[4,5]
The WHO ethical criteria outline eleven essential elements that must be included in all drug promotional materials to ensure rational drug use.

These criteria include:
(1) the name of the active ingredient(s)
(2) the brand name
(3) content per dosage form
(4) approved therapeutic uses
(5) dosage and administration guidelines
(6) adverse reactions and precautions
(7) contraindications
(8) major drug interactions
(9) name and address of the manufacturer or distributor
(10) reference to scientific literature supporting claims
(11) the date of production of the material.[1]
When these elements are not adequately presented, healthcare professionals may be misled, leading to suboptimal prescribing decisions and potential risks to patient safety.[6]
This study aims to evaluate the rationality of DPL distributed in outpatient departments of a tertiary care teaching hospital in Maharashtra. By assessing how well these materials align with WHO guidelines, we hope to highlight existing gaps and advocate for more stringent regulations to ensure that promotional content supports informed, evidence-based prescribing.

METHODOLOGY

- **Study Design:** Cross-sectional, observational study
- **Duration:** July – September 2023
- **Setting:** Outpatient departments of a tertiary care teaching hospital in Maharashtra
- **Sample Size:** 100 DPLs
- **Data Collection:** DPLs were collected from general medicine, paediatrics, dermatology, and surgery departments. Each was assessed using the 11 WHO criteria.
- **Statistical Analysis:** Data were analyzed using Microsoft Excel. Compliance rates were expressed as percentages and compared with similar studies.

RESULTS

Compliance of DPLs with WHO Criteria

WHO Criteria	Number of Compliant DPLs (n=100)	Compliance (%)
Name of active ingredient	62	62%
Brand name	95	95%
Content per dosage form	78	78%
Other ingredients causing problems	30	30%
Approved therapeutic indications	85	85%
Dosage regimen	60	60%
Side effects/adverse reactions	40	40%
Precautions and contraindications	50	50%
Drug interactions	35	35%
Manufacturer/distributor details	90	90%
Scientific references	28	28%

Comparative Analysis with Previous Studies

Study	Year	Scientific References (%)	Side Effects (%)	Drug Interactions (%)
Present Study	2023	28	40	35

Mali et al.[7]	2010	22	38	30
Khakhkhar et al.[8]	2013	25	42	33
Alam et al.[9]	2020	69	-	-
Hazarika et al.[10]	2024	75.8	32.8	-
Hailu et al.[11]	2022	25.2	32.5	19.7
Vivek et al.[12]	2022	-	-	-

Key Observations:

- **Brand names and manufacturer details** were mentioned in most DPLs (95% and 90%, respectively).
- **Active ingredient names** were missing in 38% of cases, which could lead to prescribing errors.
- **Only 40% of DPLs included adverse drug reactions**, which raises safety concerns.
- **Drug interactions were mentioned in just 35% of DPLs,** highlighting the potential for harmful polypharmacy.
- Compliance with **scientific references (28%)** was marginally higher than in previous studies but still alarmingly low.
- Studies such as Alam et al. (2020) and Hazarika et al. (2024) reported higher compliance with references, whereas Hailu et al. (2022) showed poor compliance.

DISCUSSION

The evaluation of Drug Promotional Literature (DPL) is essential to ensure compliance with ethical and scientific standards. In the present study, scientific references were found in 28% of the DPLs, which is comparable to the findings of Khakhkhar et al. (2013) (25%) and Mali et al. (2010) (22%). However, our findings are significantly lower than those reported by Alam et al. (2020) (69%) and Hazarika et al. (2024) (75.85%). The relatively low proportion of scientific references in our study indicates a potential gap in the credibility and evidence-based approach of the promotional materials provided to healthcare professionals. The differences observed across studies may be attributed to variations in study settings, geographical locations, and pharmaceutical industry regulations.

Regarding the mention of side effects, our study found that 40% of DPLs included information on adverse drug reactions. This finding is in alignment with Khakhkhar et al. (2013) (42%) and slightly higher than Mali et al. (2010) (38%). However, Hazarika et al. (2024) and Hailu et al. (2022) reported lower percentages of 32.85% and 32.5%, respectively. The variations suggest that while some promotional materials acknowledge safety concerns, a significant proportion still lacks comprehensive adverse effect disclosures. This omission can lead to an incomplete understanding of drug safety profiles among prescribers, potentially compromising patient safety.

Drug interactions were mentioned in 35% of the DPLs in our study, which is higher than Mali et al. (2010) (30%), Khakhkhar et al. (2013) (33%), and Hailu et al. (2022) (19.7%). The lower percentage reported in Hailu et al. (2022) indicates that drug interaction information is often underrepresented in promotional literature, raising concerns about the adequacy of information provided to prescribers. Notably, Alam et al. (2020) and Hazarika et al. (2024) did not report data on drug interactions, making direct comparisons difficult.

It is important to highlight that Vivek et al. (2022) did not report data on scientific references, side effects, or drug interactions, which limits their comparability with other studies. The absence of such critical information in some studies underscores the need for standardization in evaluating DPLs to ensure a comprehensive assessment of their quality and reliability.

Overall, our findings indicate that while DPLs provide some degree of scientific backing and safety information, there remains a substantial gap in the inclusion of critical drug-related data. The significant discrepancies between studies highlight the need for stricter regulatory oversight to ensure that promotional materials adhere to WHO guidelines. Healthcare professionals must exercise caution when relying on DPLs for prescribing decisions and should cross-check information with independent, evidence-based sources.

Limitations

This study has several limitations. First, the study was conducted in a single tertiary care teaching hospital in Maharashtra, which may limit the generalizability of the findings to other regions and healthcare settings. Second, due to the limited sample size of 100 DPLs, variations in promotional literature distributed across different pharmaceutical companies and medical specialties may not be captured fully. Third, the study relies on WHO criteria to assess rationality, but it does not evaluate the impact of these promotional materials on actual prescribing behaviors, which could be an important area for future research. Finally, the study does not account for potential biases introduced by selective distribution of promotional materials by pharmaceutical representatives, which may influence the findings.

CONCLUSION

This study reveals that a significant proportion of DPLs fail to meet WHO guidelines, particularly in areas crucial for patient safety, such as side effects and drug interactions. The findings emphasize the need for greater regulation and ethical responsibility in pharmaceutical promotions. Encouraging companies to provide evidence-based, transparent information can lead to safer prescribing practices and improved patient outcomes.

Recommendations

1. **Regulatory Compliance:** Strict monitoring of DPL compliance with WHO guidelines.
2. **Medical Training:** Educating healthcare professionals to critically appraise DPLs before prescribing.
3. **Industrial responsibility:** Encouraging pharmaceutical companies to prioritize transparency over promotional works.
4. **Further Research:** Performing similar studies in different hospital settings to assess broader compliance trends.

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