EVALUATION OF RATIONALITY IN DRUG PROMOTIONAL LITERATURE USING WORLD HEALTH ORGANIZATION GUIDELINES

Abstract:

Introduction: Drug Promotional Literatures (DPLs) are commonly used by pharmaceutical companies to market their products to healthcare professionals. While these materials are meant to provide useful drug-related information, concerns exist regarding the accuracy, balance, and completeness of the data presented.

Objective: To evaluate the rationality of drug promotional literature based on the ethical criteria for medicinal drug promotion outlined by the World Health Organization (WHO).

Materials and Methods: An observational study was conducted over six months, from January to June 2024. A total of 120 drug promotional brochures were randomly collected from physicians across different departments at Government general hospital, Kurnool. These brochures, provided by medical representatives, were assessed using the WHO ethical criteria.

Results: Only 3% of the brochures met all WHO guidelines. High compliance (≥70%) was noted for brand and generic names (100%), active ingredients (95.83%), indications (84.16%), dosage form (91.66%), and manufacturer information (74.16%). Moderate compliance (40–69%) was seen for other ingredients (44.16%). However, poor compliance (≤39%) was observed in critical safety information: side effects (25.83%), precautions and contraindications (24.16%), drug interactions (15.83%), and references (20%).

Conclusion: Although most brochures provide basic product details, important safety information is often lacking or minimized. This can mislead healthcare providers and affect rational prescribing. Therefore, strict regulation and monitoring of promotional practices are essential to ensure ethical standards and prioritize patient safety.

Keywords: Drug promotional literature, Drug brochures, WHO guidelines

INTRODUCTION:

Pharmaceutical promotion includes various informational and persuasive efforts by drug manufacturers and distributors intended to encourage the prescribing, distribution, purchase, or use of medications. Among these promotional tools, brochures and other drug-related literature supplied by pharmaceutical companies are considered a major source of information for healthcare professionals[1]. Drug promotional literature (DPL) is widely used by pharmaceutical companies as a key marketing strategy to promote newly launched medications[2]. These materials are presented as important sources of drug information and are primarily aimed at influencing healthcare professionals to adopt and prescribe these new products[3,4]. Often, drug promotional literature serves as the sole source of information that physicians rely on to stay updated about existing and newly introduced medications[5]. In 2005, pharmaceutical companies in the United States spent over 30 billion dollars on marketing and promotional activities aimed at informing clinicians about their products. These marketing efforts have been shown to influence prescribing patterns, regardless of whether they ultimately benefit the patient[6]. Several studies have reported inconsistencies between the content of Drug Promotional Literature (DPL) and ethical standards. Such inconsistencies may impact prescribing behaviours, influence drug use patterns, and potentially lead to inappropriate or irrational prescribing. To promote the rational use of medicines, the World Health Organization (WHO) has established ethical guidelines for drug promotion and has encouraged pharmaceutical companies to adopt and adhere to these standards[3].In light of this, the present study aims to systematically analyse the accuracy of promotional drug materials by applying the evaluation criteria set forth by the World Health Organization (WHO)[7,8].

METHODS:

A cross-sectional, observational, and descriptive study was carried out at Government general Hospital, Kurnool. The study was conducted over a six-month period, from January 2024 to June 2024, and included a total of 120 samples. DPLs, including flyers, leaflets, and brochures, were obtained from various outpatient departments within the hospital, where they were made available by medical representatives. Promotional materials related to medical devices, equipment, orthopaedic prostheses, and other non-drug products were excluded from the study. These collected materials were then evaluated based on the criteria outlined in the WHO guidelines & OPPI (Organization of Pharmaceutical Producers of India) criteria for medicinal drug promotion and graded based on the percentage compliance: Grade A- >70%, Grade B- 35- 70% and Grade C- < 35%.

WHO has outlined specific criteria for pharmaceutical companies to ensure completeness in DPL[9],

1. The names of the active ingredients using either international nonproprietary names or the approved generic names of the drug
2. The 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 reaction
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 included materials were also evaluated according to the OPPI Code of Ethical Practice[10].

1. The name of the product (Brand name)
2. The active ingredients
3. The name and address of the pharmaceutical company or its marketing agent

4. The date of production of the advertisement
5. Approved indications
6. Dosage
7. Method of use
8. Succinct statement of contraindications, precautions and side effects

Data was analysed as proportions & percentages and the results are represented in the form of bar diagrams & pie chart.

RESULTS:

Out of 120 DPLs collected and analysed in this study, only 3% (4 DPLs) fulfilled all the WHO ethical criteria and none fulfilled OPPI Code of Ethical practice, 65% (78 DPLs) are FDC (fixed drug combination) form, 35% (42 DPLs) are Single drug form. Compliance of DPLs with WHO criteria was presented in Table 1. High compliance (≥70%) was noted for brand and generic names (100%), active ingredients (95.83%), indications (84.16%), dosage form (91.66%), and manufacturer information (74.16%). Moderate compliance (40–69%) was seen for other ingredients (44.16%). However, poor compliance (≤39%) was observed in critical safety information: side effects (25.83%), precautions and contraindications (24.16%), drug interactions (15.83%), and references (20%). Table 2 represented evaluation of DPL according to OPPI criteria. Figure 1 represented the Comparison between drug promotional literature collected from OPD according to the WHO and OPPI criteria. Antihistamines (20%) were the most promoted group of drugs (figure 2).

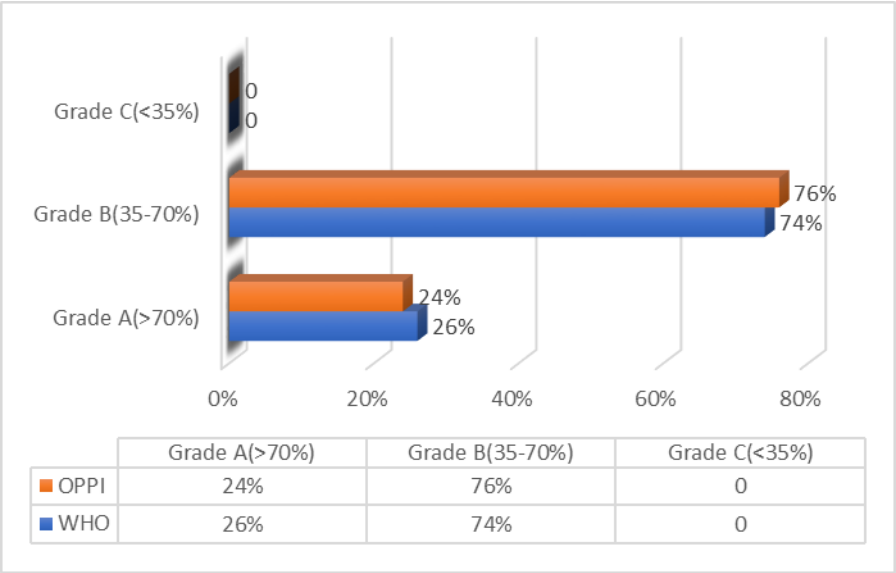
Table 1: Evaluation of DPL according to WHO ethical criteria

S. NO	WHO CRITERIA	DPLs from OPDs	
		Number (n=120)	Percentage (%)
1	Brand name	120	100%
2	Generic name	120	100%
3	Name of active ingredient	115	95.83%
4	Other ingredient	53	44.16%
5	Uses	101	84.16%
6	Dosage forms	110	91.66%
7	Side effects	31	25.83%
8	Drug precaution	29	24.16%
9	Drug interaction	19	15.83%
10	Manufacturer details	89	74.16%
11	Reference literature	24	20%

Table 2: Evaluation of DPL according to OPPI ethical criteria

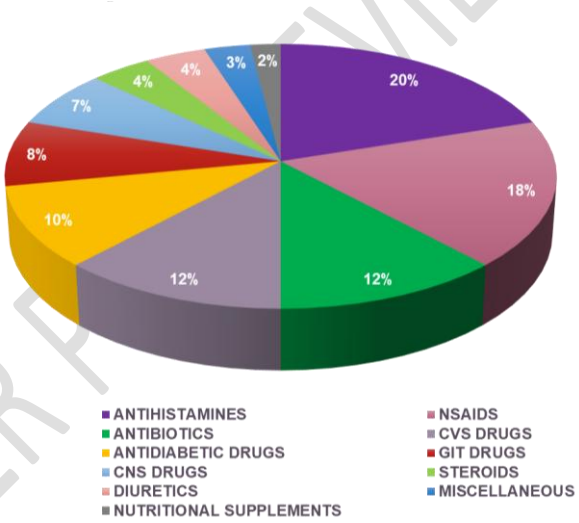
S. NO	OPPI CRITERIA	DPLs from OPDs	
		Number (n=120)	Percentage (%)
1	The name of the product (Brand name)	120	100%
2	The active ingredients	115	95.83%
3	Manufacturer details	89	74.16%
4	The date of production of the advertisement	0	0
5	Approved indications	101	84.16%
6	Dosage	110	91.66%
7	Uses	31	25.83%
8	Succinct statement of contraindications, precautions and side effects	31	25.83%

Figure 1: Comparison between drug promotional literature collected from OPD according to the WHO and OPPI criteria.



	Grade A(>70%)	Grade B(35-70%)	Grade C(<35%)
OPPI	24%	76%	0
WHO	26%	74%	0

Figure 2: Most commonly promoted drug categories



DISCUSSION:

In 1930, under the leadership of Sri Ram Nath Chopra, a Drug Inquiry Committee was established in India. This committee closely examined drug advertisements and marketing materials, revealing that many of the medicinal products being sold were promoted with exaggerated and false claims. Remarkably, this early effort to regulate drug information in India took place long before the WHO began formally addressing the issue of counterfeit and substandard medicines in 1988[11].The findings of this study indicate that pharmaceutical companies largely failed to adhere to WHO guidelines in their drug promotional practices, prioritizing commercial interests over ethical and educational responsibilities. The promotional materials provided limited therapeutic information, offering little support for physicians to make rational prescribing decisions. Emphasis was placed more on promoting fixed-dose combinations—many of which are not recommended by WHO—rather than introducing genuinely innovative medicines. Furthermore, the brochures frequently contained

unverified claims about drug safety and efficacy, often lacking therapeutic relevance. Crucial information such as adverse drug reactions, contraindications, and potential drug interactions was commonly omitted. In present study, out of 120 DPL only 3% fulfilled all the WHO ethical criteria and none fulfilled OPPI Code of Ethical Practice. Similar findings were also reported by Mali et al[2]. This suggests that drug promotional companies are more involved in establishing a commercial relationship with the practitioners whereas ethical educational aspect is compromised. Majority of DPL analyzed in this study were focused on FDC (65%) rather than single drug but rationale for combination was justified only for few FDCs. Similar findings are also seen in study done by Saibhavana et al[12]. so physicians were advised to consider the rationality of drug combination before prescribing as this will not only increase the cost of treatment but also lead to unnecessary adverse drug reactions and interactions. Most DPLs belong to Grade B compliance of WHO & OPPI with 74% & 76% respectively. Similar finding was seen in Vivek, et al.,[13] in the DPLs collected from the journals and evaluated as the key information missing from most of these DPLs in Grade B were the details of other ingredients known to cause problems, adverse effects, precautions, contraindications, warnings, drug interactions, and reference to scientific literature which are necessary for the safe and adequate use of new drugs coming into the market, but such information appears to be missing from most published DPLs.

CONCLUSION:

The majority of DPLs adhered to only a portion of the WHO guidelines for rational drug promotion, with most failing to meet all the recommended criteria. Given that the reliability of DPLs is often questionable due to incomplete or misleading information, such promotional content can significantly influence prescribing behaviours, potentially leading to irrational prescribing practices. Therefore, it is essential for physicians to become increasingly aware of these guidelines and to critically evaluate DPLs to ensure rational prescribing and improve the overall quality of patient care.

Conflict of interest: None declared

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