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Research Article

ADHERENCE TO THE WHO CRITERIA ON DRUG PROMOTION LITERATURE: AN EVALUATION OF PHARMACEUTICAL ADVERTISING AT A TERTIARY HEALTHCARE FACILITY IN NORTH INDIA

MADHUMITA DIXIT*, KARTIKEY SHARMA, RAKESH CHANDRA CHAURASIA, DWIVIDENDRA KUMAR NIM

Department of Pharmacology, Moti Lal Nehru Medical College, Prayagraj, Uttar Pradesh, India
***Corresponding author: Madhumita Dixit; Email: dixitmadhumita600@gmail.com**

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ABSTRACT

Objective: This research seeks to evaluate how closely drug promotional materials at a tertiary care center in North India follow the WHO's ethical standards.

Methods: A cross-sectional analysis was carried out, involving the organized gathering of drug promotion literatures (DPLs) from the healthcare institution over a specific timeframe. A checklist, derived directly from the WHO's guidelines for ethical drug promotion, was used to evaluate the DPLs' content. The data were thoroughly examined to determine the degree of adherence to the WHO standards.

Results: In an analysis of 149 DPLs, all included both generic and brand names. Information on the amount of active ingredient and therapeutic applications was present in 91% and 86% of the DPLs, respectively, and dosage forms appeared in 91%, with the remainder depicted pictorially. Only 32% of DPLs described the pharmacological mechanism. Details about side effects and significant adverse drug reactions, as well as precautions and warnings, contraindications, and major drug interactions, were included in 19%, 16%, 18%, and 11% of DPLs, respectively. The manufacturer's name was mentioned in 72% of the documents, while the manufacturer's address appeared in 26%. References to scientific literature were included in just 29% of the DPLs.

Conclusion: This research highlights the need for improved oversight and regulation of drug promotion activities within the healthcare facility. Less than 20% of DPLs provide information on drug safety. Compliance with the WHO standards is crucial for ethical drug promotion, protecting patient care, and maintaining the integrity of healthcare services. Cooperative initiatives among healthcare facilities, pharmaceutical firms, and regulatory agencies are urgently required.

Keywords: Drug promotion, Drug safety information, Compliance, The WHO criteria.

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INTRODUCTION

Drug "promotion" refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs. The primary goal of ethical criteria for promoting medicinal drugs is to enhance healthcare by promoting the judicious use of these drugs [1]. Drug manufacturers and distributors focus on promoting new drugs, with advertisements aimed at persuading healthcare professionals to prescribe their specific products [2]. The responsibility of medical representatives is to make physicians aware of the new drugs and its beneficial as well as harmful effects [3]. drug promotion literatures (DPLs) are a crucial source of drug information for many healthcare providers; however, the lack of up-to-date and referenced scientific literature in these documents is alarming [4]. Given that promotional activities affect how healthcare providers prescribe medications, it is crucial to critically evaluate drug promotional materials in line with the increasing emphasis on evidence-based medicine [5].

Pharmaceutical companies spend roughly one-third of their sales income on marketing their products, which is twice the amount they allocate to research and development. A 2001 study at Boston University found that the advertising departments of these companies employed 81% more people than their research and development departments [6,7].

The WHO's ethical criteria for drug promotion, along with the International Federation of Pharmaceutical Manufacturers Association (IFPMA) and the Organization for Pharmaceutical Producers of India (OPPI-2019), serve as regulatory authorities. Their objective is to enhance healthcare by promoting the ethical advertising and rational use of medicines [8,9]. The WHO advises that DPLs should offer authentic, comprehensive, and dependable information that aligns with scientific research [10].

Various methods of drug promotion include visual aids, flip charts, continuous medical education (CME), electronic detailing, advertisements, gifts, and audiovisual materials. A significant strategy employed by drug companies is direct-to-physician (DTP) directed-to-prescriber, directed-to-consumer advertisements. Concerns exist regarding the impact of DTP marketing on doctors' prescribing habits, including potential ethical conflicts and healthcare costs. Research consistently demonstrates that pharmaceutical promotions influence physicians' actions [2,6,11].

Roughly one in every 1,000 potential drug molecules advances to clinical trials following preclinical testing, and about 90% of those tested in clinical trials do not make it to the market. This trend is nearly universal according to data from regulatory agencies in most countries, leading to intense competition among pharmaceutical companies to profit from the few drugs that do receive approval [12].

This research article delves into the important realm of DPL and evaluates its adherence to the comprehensive criteria outlined by the WHO. Focusing on a tertiary healthcare facility in North India, this study seeks to shed light on the alignment between promotional materials and the internationally recognized standards set forth by the WHO. Such an investigation is paramount, not only for healthcare providers

but also for pharmaceutical companies, regulatory authorities, and ultimately, the welfare of patients.

METHODS

A prospective, cross-sectional analysis was carried out systematically, gathering DPLs from a healthcare facility over a 2-month period (July 2024–August 2024). Using a checklist derived from the WHO's guidelines for ethical drug promotion, the content of 149 DPLs from various outpatient departments of a tertiary care center in North India was evaluated. The data were thoroughly examined to assess compliance with the WHO standards. DPLs pertaining to medical devices, equipment, or non-allopathic medicines were not included in the study.

Sample selection

The study sample consisted of promotional materials distributed within the healthcare facility, such as pamphlets and any other promotional literature related to pharmaceutical products. These materials were acquired through the following sources:

1. Pharmaceutical Representatives: Promotional materials provided by pharmaceutical company representatives during visits to the healthcare facility were collected.
2. Healthcare Professionals: Materials made available to healthcare professionals within the facility, including physicians, nurses, and pharmacists, were collected from common areas such as medical offices, break rooms, and distribution points.

The data collection process involved the systematic collection of promotional materials. Collected materials were cataloged, organized, and reviewed by the research team. Each piece of promotional literature was checked against the drug promotional criteria of the WHO.

Evaluation criteria

Here are the WHO standards that pharmaceutical companies must adhere to for ensuring the completeness of drug promotional literature:

1. International Non-proprietary Name (INN) or the approved generic name of each active substance.
2. Brand name.
3. Content of active ingredient(s) per dosage form or regimen.
4. Approved therapeutic uses.
5. Pharmacological action/mechanism.
6. Dosage form.
7. Side-effects and major adverse drug reactions.
8. Precautions and warnings.
9. Contraindications.
10. Major interactions.
11. Name and address of manufacturer or distributor.
12. Reference to scientific literature.

RESULTS

Out of 149 DPLs evaluated, none met all of the WHO eligibility criteria. Various drugs were promoted by pharmaceutical companies (Fig. 1).

The percentage distribution of DPLs across various therapeutic categories was Antimicrobials: 11.34%, Autacoids: 11.34%, cardiovascular system: 10.31%, Diuretics: 1.03%, gastrointestinal tract: 7.22%, Hematinics: 5.15%, Hormones: 16.49%, Nervous system: 22.68%, Respiratory system: 6.19%, Skin: 1.03%, Supplements: 7.22%.

DPL analysis according to the WHO criteria is shown in (Table 1).

Information on the generic name and brand name appeared in all DPLs (100%). The amount of active ingredient and approved therapeutic uses were mentioned in 91% and 86% of DPLs, respectively, and the dosage form was also noted in 91% of cases. Meanwhile, information on the pharmacological mechanism was only provided in 32% of DPLs. Details on side effects and major adverse drug reactions, precautions and warnings, contraindications, and major drug interactions were included in 19%, 16%, 18%, and 11% of DPLs, respectively (Fig. 2).

The name and address of the manufacturer were disclosed in 72% and 26% of DPLs, respectively, while references to scientific literature were made in 29% of the cases. References used in various DPLs as sources of information are as shown in (Table 2). References were cited in 43 DPLs, making up 28.86%. Majority were from journals (10.74), followed by books (6.04%) and online (3.36%).

DISCUSSION

The findings of our study align closely with the studies conducted previously. In research conducted by Jadav *et al.* (2014), 200 DPLs were examined, and while 100% included generic names and brand names, essential information, such as side effects and adverse drug

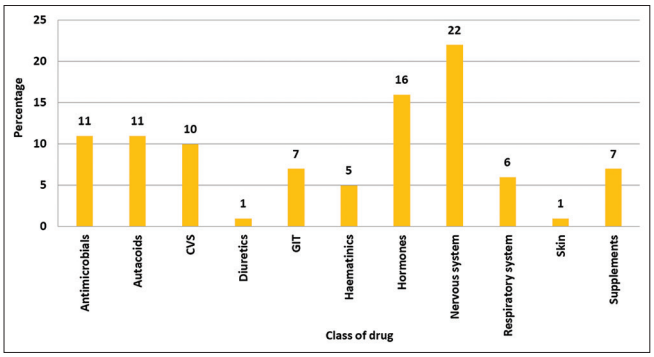

Fig. 1: System wise distribution of DPLs.

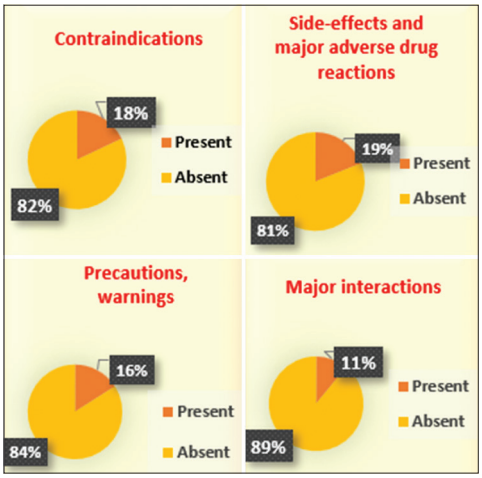

Fig. 2: Drug safety information.

Table 1: Analysis of DPL using the WHO criteria

The WHO criteria	No. of DPLs and percentage (n=149) (%)
The name of the active ingredient/INN/Generic name	147 (99)
Brand name	149 (100)
Content of active ingredient (s) per dosage form or regimen	136 (91)
Approved therapeutic uses	128 (86)
Pharmacological action/mechanism	48 (32)
Dosage form	136 (91)
Side-effects and major adverse drug reactions	29 (19)
Precautions, warnings	24 (16)
Contraindications	27 (18)
Major interactions	17 (11)
Name and address of manufacturer or distributor	108 (72)
Reference to scientific literature	43 (29)

Table 2: References used in various DPLs as source of information

References	No of DPLs (n=149)	Percentage
Cited reference	43	28.86
Book	9	6.04
Journal	16	10.74
Before 2020	5	3.36
After 2020	11	7.38
Online	7	3.36
Others	0	0

reactions were significantly underreported, with only 1.5% providing complete safety details. Furthermore, only 35% of the DPLs included references, with 88% of those references being journal articles, aligning with your observation that only 29% of DPLs had scientific references. This practice of not mentioning the references not only questions the reliability of the information provided but also reflects a broader trend in the pharmaceutical industry where promotional content often overshadows the educational imperative [13,14].

Our research revealed that none of the DPLs completely adhered to the WHO guidelines, which is indicative of a broader issue within the pharmaceutical industry's promotional practices. Similarly, Kaushal *et al*. (2015) reported that none of the DPLs in their sample fulfilled all the WHO criteria, with only 22% providing brief prescribing information (BPI). They further emphasized the issue of biased or incomplete safety information, noting that only 42% of DPLs mentioned the drug's safety profile, and vague or exaggerated claims were made in 80% of the advertisements. This supports our observation that only 16% of the DPLs provided clear precautions and warnings leading to biased advertisement [4].

Ganashree *et al*. (2016) also reported that none of the 200 DPLs they analyzed adhered to all the WHO guidelines. They found that generic names and dosage forms were commonly mentioned, but only 32.5% of DPLs discussed precautions, contraindications, and adverse drug reactions similar to our study where significant adverse reactions were only reported in 19% of DPLs, and contraindications were mentioned in just 18% [15].

Furthermore, some studies also noted that while 100% of the DPLs included the name of the active ingredient, information about side effects, contraindications, and interactions was frequently absent, appearing in less than a third of the DPLs, further confirming the underreporting of critical safety information in promotional literature. This reflects the broader trend of pharmaceutical companies prioritizing marketing over comprehensive safety disclosures [10,12,16]. Major side effects go unrecognized due to biased marketing, usual side effects are discussed but printed in such small figures that they often go unrecognized and medical representatives often show only positive results. Therefore, references are not usually coated. DPLs are usually made attractive rather than informative, they are just for marketing strategies but not for academic benefits.

Worldwide the problem remains the same; Al-Aqeel *et al*. (2013) analyzed pharmaceutical advertisements in Saudi Arabia and found that 90.8% of DPLs included the generic name, while therapeutic uses were present in 98.7% of the cases, aligning closely with our result of 86% for therapeutic uses. Like our study, they found that side effects were mentioned in only 28.5% of the advertisements, and references to scientific literature were provided in only 64% of the DPLs, higher than ours at 29% [17].

In Russia, Vlassov *et al*. (2001) reported similar trends. Only 39% of drug advertisements provided the generic name, and safety warnings and drug interactions were reported in 11% and 5% of cases, respectively. This is consistent with our findings of low reporting of major drug interactions (11%) and side effects (19%) [18].

In Fadare *et al*.'s 2022 Nigerian study, 95.3% of drug package leaflets listed generic names, and all included brand names, aligning with similar findings. However, only 32.5% mentioned adverse reactions, 19.7% drug interactions, and 31.2% contraindications. Just 25.2% cited scientific references, close to your 29% result [19].

A Nepalese study by Jha *et al*. (2020) concluded that although 100% of the drug advertisements analyzed included generic names, brand names, and approved therapeutic uses, only 4% provided information on adverse effects, and just 19% had references to scientific literature. This underlines the common trend of missing safety data in drug promotion materials [20].

Similarly, a study conducted in Ethiopia by Hailu *et al*. observed that critical safety information, such as side effects (27.2%) and contraindications (18.5%) was underreported, correlating well with our findings that 19% and 18% of DPLs provided this information [14].

The study is limited to a single tertiary healthcare facility in North India and may not be fully representative of promotional practices in the region or the entire country. This study does not investigate the impact of non-adherence to the WHO criteria on actual prescribing practices or patient outcomes.

CONCLUSION

This research emphasizes the urgent need for stricter control and supervision of drug promotional practices at the healthcare center. Only a small fraction of the DPLs include information about drug safety. Observing the WHO guidelines is essential for ethical drug promotion, ensuring patient safety, and preserving the integrity of healthcare services. There is a pressing need for collaborative action between healthcare providers, pharmaceutical entities, and regulatory authorities. It concluded that incomplete DPLs might lead to irrational prescribing behavior by healthcare professionals, reinforcing the gaps noted in our findings. Doctors not satisfied with DPLs are advised to authenticate it from textbooks, and also packaging inserts provided should be made precise and to the point but drawbacks are small font, and most health professions usually avoid it due to their busy schedule, and reference if asked should be provided by medical representatives and references cited should be confirmed before marketing.

AUTHOR CONTRIBUTIONS

The authors confirm their contribution to the paper as follows:

Dr. Madhumita Dixit: Study concept and design, Literature search, Analysis and interpretation of results. Dr. Kartikey Sharma: Data acquisition, Manuscript preparation. Dr. Rakesh Chandra Chaurasia: Study concept and design, Manuscript editing. Dr. Dwividendra Kumar Nim: Study concept and design, Manuscript review.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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