



CRITICAL APPRAISAL OF DRUG PROMOTIONAL LITERATURE AS PER THE WHO CRITERIA

Pharmacology

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ABSTRACT

Background- Drug promotional literature (DPL) mainly comprises of pamphlets or brochures printed by pharmaceutical companies and the advertisements of drugs in the Medical Journals in order to promote the sale of their products. Websites of the Pharmaceutical Companies are also a source of drug promotion. DPLs represent a major marketing technique. **Methodology-** An Observational study was conducted by the Department of Pharmacology at Gandhi Medical College and Hamidia Hospital, Bhopal, India, for a period of 3 months from August 2023 to October 2023. These DPLs were critically analyzed as per the WHO Criteria and ultimately the rationality and effectiveness of these was judged based on their ability to fulfill the WHO criteria.

Results-

A total of 150 DPL's were collected from the various outpatient departments of Gandhi Medical College and Hamidia Hospital. These 150 DPL's were taken from 3 different sources-

- 1.) Medical Representatives-92(61.3%)
- 2.) Journals-44(29.3%)
- 3.) Websites-14(9.3%)

The information about the brand name, generic name, and active ingredients was present in 100% of the collected DPL's. Therapeutic uses of the promotional agents were mentioned in only 106(70.70%) DPL's; references were cited in only 34(22.7%). The adverse effects were listed in 24(16%) DPLs. The drug safety information like Precautions, Contraindications and Drug Interactions were mentioned in 22(14.7%), 23(15.3%) and 19(12.7%) of DPL's respectively. The name of the manufacturer was mentioned in 100% of the DPL's but the address of the manufacturer was only added in 106 (70.7%) of the DPL's. **Discussion-** Amongst the total 150 DPL's collected only 6 DPL's were found to fulfill all the 9 WHO criterias, whereas 10 DPL's fulfilled 8 out of the 9 WHO Criteria's. Only 63 (31.5%) DPL's consisted of relevant pictures of drugs being promoted and 59 (29.5%) DPL's showed a graphical representation of pharmacological properties of various drugs. Antibiotics [20(13.3%)] were the most promoted, followed by Multivitamins and Supplements [14(9.3%)] and Cardiovascular drugs [12(8%)]. Single drug was promoted in 90(59.7%) of DPL's whereas Fixed Drug Combination were present in 60(40.3%) of the DPL's. Drug cost was revealed only in 21(14%) DPL's. Most of the DPL's claimed for Efficacy [138(92%)] and Safety [46(30.7%)]. While only a few claimed for Pharmacokinetics [12(8%)], Pharmacological properties [6(4%)] and Convenience [38(25.3%)]. **Conclusions-** Majority of DPLs satisfied only half of the WHO criteria for rational drug promotion and only 6 of them fulfilled all the specified criteria. Incomplete or exaggerated information in DPL's can be misleading and result in irrational prescribing by the clinicians. Therefore, physicians should critically evaluate DPL's regarding updated scientific evidence required for quality patient care.

KEYWORDS

safety information, brand name, who criteria, drug promotional literature

INTRODUCTION-

According to the World Health Organization (WHO), medicinal drug promotion is defined as "all informational and persuasive activities by manufactures and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs."

Drug promotional literature (DPL) consists of pamphlets or brochures printed by pharmaceutical companies in order to promote the sale of their products. As such, DPLs represent a major marketing technique.¹ The World Health Organization (WHO) states that "all promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up to date, capable of substantiation and in good taste".²

Drug promotional literature (DPL) distributed by the medical representative is an essential source of seeking information for busy medical practitioners. As drug companies are promoting the literature for their brand products, there is a possibility of partiality. Various studies have denoted that printed DPLs disseminated by pharmaceutical companies are usually biased.³

The pharmaceutical industry's medication promotion activities are governed by the WHO criteria for "Ethical criteria for medicinal drug promotion, 1988"³

Organization of Pharmaceutical Producers of India, a self-regulatory code of pharmaceutical marketing practices, effective from December 2012, stated seven criteria which DPLs should follow. Few studies

have observed that information provided in DPLs are varying with the code of ethics. This can affect the drug prescription, utilization, and sometimes can be irrational. Hence, this study was conducted to critically assess the accuracy of the promotional drug literature using the WHO guidelines.⁴

METHODS-

An Observational study was conducted by the Department of Pharmacology at Gandhi Medical College and Hamidia Hospital, Bhopal, India, for a period of 3 months from August 2023 to October 2023 after the protocol was approved by the Institutional Ethics Committee.

- DPLs in the form of flyers, leaflets, and brochures were collected from various outpatient departments which were available in the hospital through Medical representatives.
- The DPLs available in the Journals of various subjects were collected from the Central Library of Gandhi Medical College.
- Other DPLs were collected from the different Websites of various Pharmaceutical Companies

Collected DPLs were assessed as per the WHO guidelines.

Literature promoting medicinal devices and equipment (insulin pump, blood glucometer, and orthopedic prosthesis), drug monographs, reminder advertisements, drugs' name list, were excluded.

The following are the WHO criteria to be followed by pharmaceutical industries for the completeness of DPL validity:⁵

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 (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 DPLs were also analyzed for additional information such as various pictures printed, cost mentioned, and source and year of references used to defend the DPL claims. Descriptive statistics were used to analyze the data. The data was expressed as percentage.

RESULTS-

A total of 150 DPL's were collected from the various outpatient departments of Gandhi Medical College and Hamidia Hospital. These 150 DPL's were taken from 3 different sources-

- 1.) Medical Representatives-92(61.3%)
- 2.) Journals-44(29.4%)
- 3.) Websites-14(9.3%)

The information about the brand name and generic name was present in 100% of the collected DPL's. Active ingredients and adjuvants were mentioned in 146(97.3%) and 10(6.7%) DPL's. Therapeutic uses of the promotional agents were addressed in only 106(70.70%) DPL's; references were cited in only 34(22.7%). The dosage form and schedule were present in 139(92.7%) and 53(35.3%) DPL's. The adverse effects were listed in 24(16%) DPLs. The drug safety information like Precautions, Contraindications and Drug Interactions were mentioned in 22(14.7%), 23(15.3%) and 19(12.7%) of DPL's respectively. The name of the manufacturer was mentioned in 100% of the DPL's but the address of the manufacturer was only added in 106 (70.7%) of the DPL's.

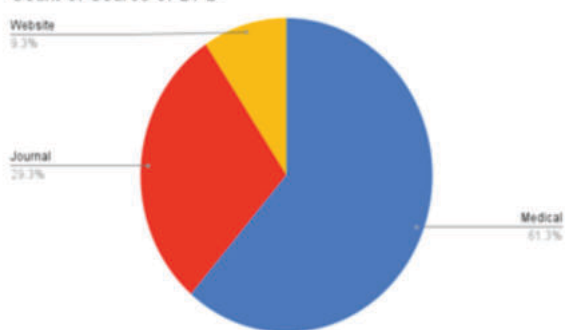
The highest number of DPL's were promoting Antibiotics (20-13.3%), followed by Multivitamins and Supplements (14-9.3%) and the Cardiovascular drugs (12-8%). Both NSAID's and Gastrointestinal drugs were promoted equally [11(7.3%)] followed by the Respiratory drugs (10-6.7%).

Out of the 150 DPL's- 90(59.7%) were Single drugs while 60(40.3%) were Fixed Dose Combinations.

FDCs are highly popular in the Indian pharmaceutical market and have been particularly flourishing in the last few years. The rationality of FDCs should be based on certain aspects such as-

- The drugs in the combination should act by different mechanisms.
- The pharmacokinetics must not be widely different.
- The combination should not have supra-additive toxicity of the ingredients.

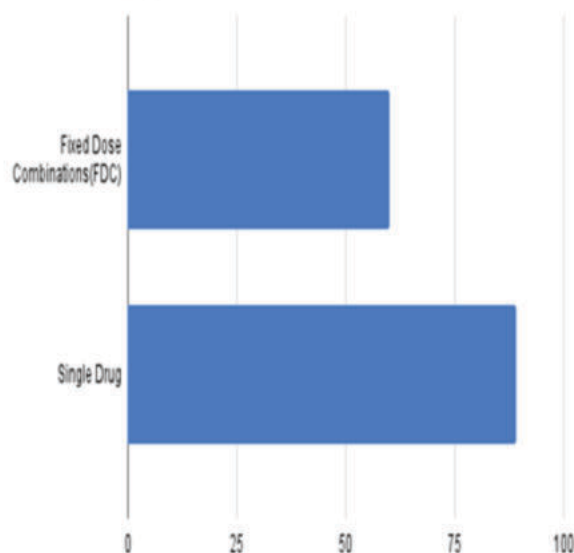
Count of Source of DPL-



Fulfillment of WHO Criteria by DPL	Number of DPL's	(%)
1.Generic name	150	100
2.Brand name	150	100
3.Active ingredients	146	97.3
4.Adjuvants	10	6.7
5.Therapeutic Use	106	70.7

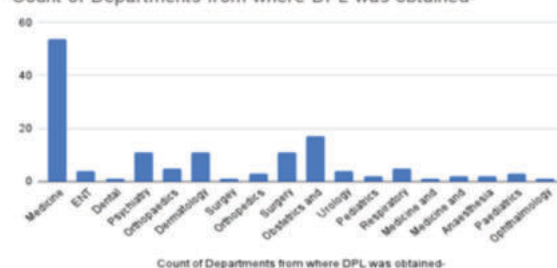
7.Dosage Schedule	53	35.3
8.Adverse Drug Reaction	24	16
9.Precautions and Warnings	22	14.7
10.Contraindications	23	15.3
11.Drug Interactions	19	12.7
12.Name of Manufacturer	150	100
13.Address of Manufacturer	106	70.7
14.Reference to scientific literature	34	22.7

Count of Drug type-

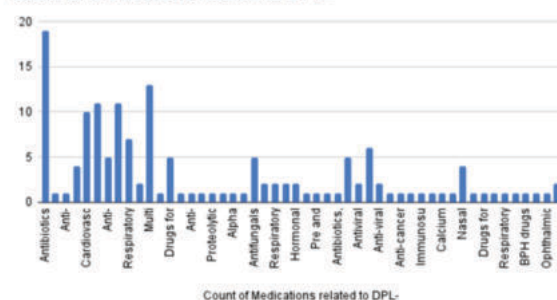


Count of Drug type-

Count of Departments from where DPL was obtained-



Count of Medications related to DPL-



DISCUSSION-

DPLs are used as a marketing strategy to publicize the introduction of new medications. Drug manufacturing companies usually claim that their new products are much better as compared to current efficient and affordable goods, with which both physicians and consumers are familiar. Unfortunately, these materials are often misleading and confusing. Therefore, physician-targeted promotion through medical representatives is one of the most common tactics for drug promotion.

Antibiotics (13.3%), followed by Multivitamins and Supplements(9.3%), Cardiovascular drugs(8%), NSAIDS(7.3%),GIT Drugs (7.3%)and Respiratory drugs(6.7%), were the most commonly promoted drugs showing that pharmaceutical industries target prevalent conditions in the population. Vitamins are the largest selling segment of the dietary supplement market. They are often purchased over the counter, without any specific indication. Vitamins should be prescribed for specific indications, and their indiscriminate use for preventing chronic diseases or general health promotion must be discouraged.

Brand name and generic name were mentioned in 100% of the literature. While the active ingredient, adjuvants and therapeutic uses were mentioned in 97.3%, 6.7% and 70.7% of the literature only. We could make out that a lot of DPLs quoted Dosage forms (92.7%) and only a few of them quoted the Dosage schedules(35.3%) but essential details regarding adverse drug reactions, contraindications, or drug interactions were missing in most of the DPL's. The name of the manufacturer was present in 100% of the DPL's but the address was present only in 70.7% of the literature.

Information about adverse drug responses, medication interactions, precautions, and over dosage was the most overlooked part of drug marketing. This suggests that unethical drug promotion is widespread, which needs concern from all health authorities.

In this study, unsubstantiated claims about Efficacy (92%) and Safety (30.7%) were found in most of the brochures. Other claims included Cost (14%), Pharmacokinetics (8%), Pharmaceutical properties (4%) and Convenience (25.3%).Promotional brochures were full of such unsubstantiated claims regarding safety and efficacy, and those claims were also therapeutically irrelevant.

The most important aspect of promotional literature is to look for sources of references that provide comprehensive updates to the physician from leading medical, national, or international journals. In our study, the references stating scientific information were mentioned only in 22.7% of the brochures. In addition, up-to-date references (latest within the last five years) were stated only in a few DPLs. This is crucial for updating the clinicians so as to enhance their existing knowledge and practice of evidence-based medicine so this aspect should be looked after by the pharmaceutical companies.

During the review of this study, the impression is that a few pharmaceutical companies do adhere to the WHO guidelines vigilantly. In contrast, the new and small setup pharmaceutical companies highlight only the positive points in their promotional literature.

In this study, only 6 brochure contained complete information according to the WHO criteria. Only these 6 DPL's fulfilled all the 9 WHO Criteria whereas 10 DPL's fulfilled 8 out of the 9 WHO Criteria's.

In some other studies conducted, various results were seen. For example: In a study conducted by Rode SB et al. in 2022, the results obtained were as follows- Vitamins (24%), followed by cardiovascular drugs, antidiabetic drugs, and antimicrobials, were the most commonly promoted drugs. Similarly a study done by Ganashree P et al. shows that none of the DPLs fulfilled all the criteria laid down by the WHO guidelines and also the most commonly promoted drugs were the Cardiovascular agents, antidiabetic drugs, and antimicrobials, indicating that pharmaceutical companies are targeting diseases which are widely prevalent.

As misleading and wrong information is not uncommon in this literature, physicians should be made aware of the limitations of the current methods of medical industry promotions and the influence of marketing on prescribing behavior. The education of prescribers, the enforcement of current regulations, the creation of guidelines, and their application by pharmaceutical corporations for medication promotion are some corrective methods for this problem.

CONCLUSION-

Evaluation of 150 promotional literature was done according to WHO's drug promotional criteria, but only 6 DPL's fulfilled all the 9 WHO criteria's, whereas 10 DPL's completed 8 out of the 9 criteria's.

The most commonly promoted drugs were the Antibiotics (13.3%),

followed by the Multivitamins & Supplements (9.3%) and then the Cardiovascular Drugs (8%).

Most common departments from where the DPL's were obtained are as follows- Medicine Department (39.1%) followed by Obstetrics and Gynecology Department (12.3%).

While using drugs, especially new drugs on patients, a prescriber should analyze research findings attentively and draw conclusions, as misleading and incorrect information is now frequently found in promotional literature. This could lead to patients suffering unnecessary adverse effects and being prescribed more expensive products when cheaper alternatives are available. Therefore, the apex regulatory authorities controlling the drug industry in their respective countries should put effort into enforcing a law that will improve the quality of DPLs, so that there is overall betterment for the patients.

Informed Consent-

Informed consent was obtained from participants.

Declaration of Conflicting Interests-

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding-

The author received no financial support for the research, authorship and/or publication of this article

Limitations-

Convenient sampling was done

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