

EVALUATION OF INFORMATION IN DRUG PROMOTIONAL LITERATURE AS PER WHO CRITERIA

Pharma

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ABSTRACT

Purpose: This study was conducted to evaluate the information of drug promotion brochures (DPBs) in Amritsar, Punjab. **Methods:** A cross sectional and observational document review was done. DPBs were evaluated for fulfilment of the World Health Organization's (WHO) criteria for ethical promotion of drugs. They were also evaluated for font size, type of formulation, pictures depicted, and source of references used. **Results:** A total of 72 DPBs were collected from the outpatient department of tertiary care hospital. Brochures promoting medicinal devices and equipments, orthopedic prosthesis, ayurvedic medicines, drug monographs and literature promoting more than two brands were excluded from the study. Antimicrobials were the most promoted drugs (28%). Brand names, generic names, indications were written in all of the DPBs. Side effects and contraindications were written in 17% and 11% of the DPBs. The percentage of drug promotional brochures showing pictures of drugs was 71% i.e. 51 out of 72 and percentage of drug promotional brochures showing graphical representation of pharmacological activity was 24% i.e. 17 out of 72. **Conclusion:** We conclude that the design and content of studied drug promotional brochures are most effective as sales materials rather than thorough informational vehicles. The WHO and Food, Medicine and Health Care Administration are rarely met.

KEYWORDS

WHO, drug promotion, ethical drug promotion, promotional information

INTRODUCTION

According to World Health Organization's (WHO), medicinal 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." [1] Pharmaceutical companies are interested in promoting the sale of new drugs. [2] The primary goal of pharmaceutical advertisements is to convince physicians to prescribe the manufacturer's product. [3] A major marketing technique used by pharmaceutical companies is direct-to-physician (DTP) marketing. [2,4] Different modes of drug promotion include visual aids, flip charts, leave-behinds, advertisements, gifts, and audio-visuals for promotion of drugs. [3] There are universally applicable baseline standards coded by International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) for marketing practice, and these standards apply to all promotional communications from the pharmaceutical industry to the medical profession.

The reality at present is that most health professionals get their information from commercial sources, usually through an extensive network of medical representatives. [5] The pharmaceutical companies claim that their new formulations are superior to existing, effective, and inexpensive products, to which prescribers and consumers are familiar. They target prescribers through weekly or monthly visits, distributing samples and attractive, eye-catching brochures. These materials are often misleading and confusing. [5,6] One of the well known promotional activities of pharmaceutical industries is to produce advertising brochures which at times are inaccurate and of poor educational value. These promotional activities create the potential for inappropriate prescribing practices by influencing physicians prescribing behaviour without necessarily benefiting the patients but contributes to increased health care cost.

However, the information contained in promotional material may be inadequate or altogether inaccurate and when these are accepted without any question, can contribute to irrational prescribing. In an attempt to support and encourage the improvement of health care through the rational use of drugs, WHO has published ethical criteria for medicinal drug promotion and has recommended their implementation to its member states. Since promotional activities influence the prescribing behavior of the health care providers, it is of utmost importance to critically analyze the promotional material of the drugs in step with the growing popularity of evidence-based medicine. [7]

The accuracy and usefulness of drug advertisements has been the subject of debate for many years. [7] Growing concern about this situation and its negative impact on rational drug use, the need exists to alert the medical professionals to the extent of the problem. Therefore, this study has been taken up with the aim of evaluating the scientific and ethical status of the drug promotional literatures available in Indian market using WHO criteria.

MATERIAL AND METHODS

This was a cross-sectional and observational study carried out in a tertiary care hospital in Amritsar, Punjab. A total of 72 drug promotional brochures of different pharmaceutical companies were collected randomly from outpatient departments (OPDs). Brochures promoting medicinal devices and equipments, orthopedic prosthesis, ayurvedic medicines, drug monographs and literature promoting more than two brands were excluded from the study. All the brochures were evaluated based on the following parameters of WHO Ethical criteria of medicinal drug promotion:

- The name of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug
- The brand name
- Name of other ingredients known to cause problems
- Approved therapeutic uses
- Dosage form or regimen
- Side-effects and major adverse drug reactions
- Precautions, contra-indications and warnings
- Major interactions
- Name and address of manufacturer or distributor
- Reference to scientific literature as appropriate

All the parameters were individually studied and analyzed for every brochure. Mention of product price on the brochures, if any, was recorded as it forms important parameter to assess the cost benefit of the drug. The brochures were studied for classes of drugs and all classes of drugs were tabulated in numbers and percentages. Brochures were studied for references and their sources i.e. journal article, books, website and data on file. The brochures were also studied for type of formulation i.e. single drug and fixed drug combination (FDC). The percentage of pictures of drugs on brochures and graphical representation of pharmacological activity were also studied.

RESULTS

Table 1: Evaluation Of Drug Promotional Brochures As Per WHO Criteria (n=72)

S. no.	Parameter	Number Of Brochures Mentioning Parameters	Percentage Of Brochures Mentioning Parameters
1	Name of active ingredient/ generic name	72	100%
2	Brand name	72	100%
3	Amount of active ingredient/ dose	71	99%
4	Frequency of drug to be given (regimen)	26	35%
5	Indications	72	100%
6	Dosage form	71	99%
7	Mechanism of action	52	72%
8	Adverse drug reactions	12	17%

9	Drug interaction	9	13%
10	Contraindications	8	11%
11	Specialized population	13	18%
12	Precautions	9	13%
13	Approved therapeutic Uses	72	100%
14	Manufacturer name	71	99%
15	Address of manufacturer	22	31%
16	Cost	4	6%
17	References to scientific information	56	78%

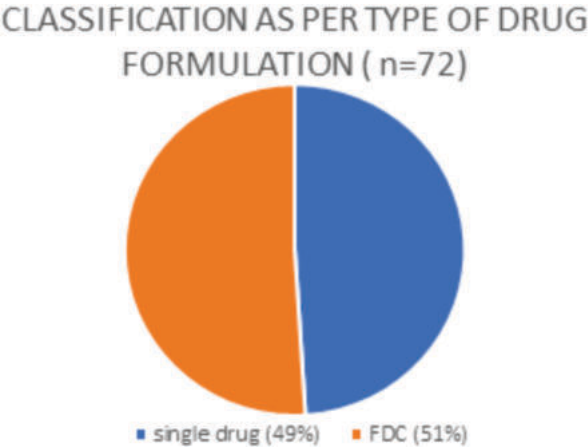


Figure 1: Classification as per type of drug formulation (n=72)

Table 2 : Classes Of Drugs Promoted In The Drug Promotional Brochures (n=72)

S. No.	Class of drugs	Number in drug promotional brochures	Percentage in drug promotional brochures
1	NSAIDs	3	4%
2	Antiseptics	2	3%
3	Antimicrobial drugs	20	28%
4	Multivitamins	13	18%
5	Hematinics	1	1%
6	Contraceptives	1	1%
7	Antiemetics	1	1%
8	Antiulcer drugs	2	3%
9	Antihypertensives	1	1%
10	Antidiabetic drugs	7	10%
11	Antihistaminic drugs	7	10%
12	Minerals	3	4%
13	Corticosteroids	2	3%
14	Anticoagulant drugs	3	4%
15	Antianginal drugs	1	1%
16	Antispasmodic drugs	2	3%
17	Immunomodulators	2	3%
18	Cough syrup	1	1%

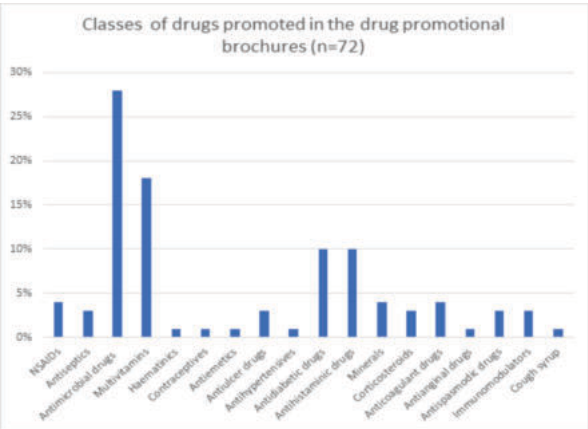


Figure 2 : Classes Of Drugs Promoted In The Drug Promotional Brochures (n=72)

Table 3: Classification Of References As Per Its Source (n=85)

S. No.	Types of references	Number in drug promotional brochures	Percentage in drug promotional brochures
1	Journal article	45	53%
2	Books	31	36%
3	Website	5	6%
4	Data on file	4	5%

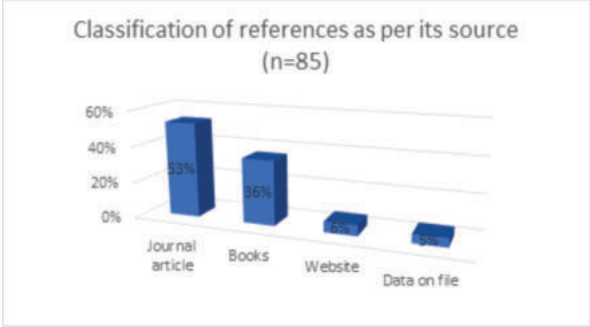


Figure 3: Classification Of References As Per Its Source (n=85)

The percentage of drug promotional brochures showing pictures of drugs was 71% ie 51 out of 72 and percentage of drug promotional brochures showing graphical representation of pharmacological activity was 24% ie 17 out of 72.

DISCUSSION

This study was done to evaluate the information of drug promotional literatures as per WHO criteria for ethical drug promotion. Study has indicated that prescribing decisions of physicians are influenced by medical representatives. This same study has also pointed out that DPMs were the most widely used mode of promotion next to face to face talking.[8] Thus, DPBs must present the most accurate possible data and needs to be regulated. According to this study, none of the DPBs analyzed has fulfilled the WHO criteria. This was similar to studies from other parts of the world.[9] The result of this study shows that antimicrobials are the most commonly promoted drugs (28%). This might be due to two reasons. The first reason is that antibiotics are prescription only drugs. The second justification goes to the culture of inappropriate use of antibiotics which has been reported in different parts of the country including the largest tertiary teaching hospital of the country.[10] Inappropriate use of drugs could prevent or delay patients from getting desired therapeutic outcomes.[11] In particular with antibiotics, their misuse and overuse are associated with the emergence of resistance and increased health costs.[12] In this study, the brand name and generic name were written in all of the DPMs. All of them also displayed information about the indications (100%) of the promoted drugs which are similar to a study from India.

However, the safety information like side effects, precautions, and drug interactions were found to be overlooked despite the fact that side effects and drug interactions have been described as drug-related problems in different parts of the country.[13] Such neglects have also been reported in other studies.[14] Fonts used to write the safety information were small in size and usually at the bottom of the page. This makes the information to be unnoticed and at worst cases, it might create the perception that those information are not crucial.

This combined with the type of claims made by the pharmaceutical companies might say a lot about their motives. The DPMs has displayed a total of 51 pictures. Almost half of the pictures were the cover of the product being promoted. However, this space could have been used to inscribe the much-needed safety information of the drugs. Majority of the references used were journal articles. By limiting or de-emphasizing content related to safety, adverse drug effects and other concerns, these materials seem to be primarily advertisements.

The WHO recommendations are rarely met. We believe the potential risk to patient health by reliance on these incomplete materials is a significant public health concern. Physicians and pharmacists should be provided with additional training and information about drug selection and use. Audit of promotional materials for both essential and non essential drugs should be considered.

CONCLUSION

We conclude that the drug information provided in the DPAs can be biased, incomplete, unauthentic, and unreliable with references exhibiting questionable credibility. These might not help the physician to arrive at evidence based good prescribing decisions. Physicians need to be aware of the ambiguity in the information provided by DPAs and should be cautious not to rely solely on these. Awareness campaigns could be carried out for prescribers regarding deceptive information disseminated through DPBs.

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