



Evaluation of Rationality of Drug Promotional Literature using WHO Guidelines in a Tertiary Care Hospital

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ABSTRACT

The study was aimed to evaluate the rationality of drug promotional literature using WHO guidelines. This observational, cross-sectional time bound study was conducted at a tertiary care hospital, Mangaluru. A total of 750 drug promotional literature collected over a period of 6 months was assessed for rationality using WHO guidelines. Most of the drug promotional literature collected were from CVS, GIT & Chemotherapy. Out of 750 drug promotional literature, 71 (9.5%) followed WHO guidelines. Most of them mentioned indication, dosage form and its strength and description of the product and package but safety information was missing in most of the drug promotional literature. In addition to WHO criteria, Brief Prescribing Information (BPI) was present in 19% of drug promotional literature. Most of the drug promotional literature did not follow WHO guidelines while promoting their products. Description of the product and the package was present in all the drug promotional literature which give a hint towards their commercial interest.

Keywords: Drug promotional literature, WHO guidelines, BPI (Brief prescribing information).

INTRODUCTION

Developing and selling new drugs is the main business of pharmaceutical companies. Promotion of approved drugs is extremely important to update doctors knowledge and to increase use of these drugs.¹ Pharmaceutical advertisement is a convincing correspondence. The significant showcasing method of pharmaceutical organizations is "direct to physician marketing." Physicians are typically reached by medical delegates, who are going to advertise their drug product by presenting them with sample drugs, gifts, reminder advertisements and sponsoring continued medical education (CME), advertisements in the journals, etc.²

One of the surely understood special exercises of pharmaceutical businesses is to deliver publicizing pamphlets which now and again are not exact and are of poor instructive worth.³⁻⁵

These limited time exercises definitely will make the potential for improper influencing so as to recommend practicing doctors to endorse a product without fundamentally profiting the patients whenever⁶⁻⁸ and in any case, adds to expanded medicinal services costs, which is a sad fact.⁹

Organization of Pharmaceutical Producers of India (OPPI), a self-regulatory code of pharmaceutical marketing practices, January (2007)^{10,11} and national legislation governs the promotional activities done by pharmaceutical companies.

Adherence to the code of conduct is a condition of membership which has to be followed by manufacturers association. But, many studies have illustrated that most

of the information disseminated through drug advertisements is inconsistent with the code of ethics, a bitter truth¹²⁻¹⁵.

"World Health Organization criteria for ethical medicinal drug promotion, 1988" is thought to be the foundation of self-administrative code of International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) as well as OPPI. The promotional activity of pharmaceutical industries is regulated by this WHO criteria. By making utilization of this "World Health Organization criteria for ethical medicinal drug promotion, 1988", we can check the rationality of drug promotional literature.

Brief prescribing information (BPI) has to include an approved indication or indications for use together with the dosage and method of use, and a statement of the contraindications, precautions, and adverse effects. In spite of the fact that promotional literature made available by the pharmaceutical companies is based on good evidence, this may not be the fact every time. The evidence supporting the drug promotional literature may be of variable quality which ushers the need for the physician or the prescribing doctor to assess the evidence and also ensure its validity judiciously.¹⁶

Safety, efficacy, tolerability and cost determine the value of a drug. The efficacy of a drug should ideally be measured in terms of clinical endpoints that are relevant to patients; if at all any surrogate end points are used they should be valid. Promotional literature of low scientific validity (such as uncontrolled before and after trials) should not be allowed to influence practice. By applying STEP criteria i.e. Safety, Tolerability, Efficacy and



Price the prescribing physicians can quickly judge the quality of the promotional literature.¹⁶

The evidence from the past studies shows that physician prescribing is influenced by pharmaceutical advertisements.¹⁶ Eleven per cent of the verbal statements about medications made by pharmaceutical representatives to physicians has been found to be inaccurate or misleading information. And the interesting fact was only 1 out of 4 physicians was aware that the information provided was inaccurate.¹⁷ In this study, we evaluated the rationality of drug promotional literature using WHO guidelines.

MATERIALS AND METHODS

Inclusion criteria

Drug promotional literature collected from the doctors of various departments in our tertiary care hospital.

Exclusion criteria

Drug promotional literature pertaining to medical devices (insulin pump and glucometers, orthopedic prosthesis), medicines of other alternative systems of medicine like Ayurveda were excluded. Other information related to drugs (drug monographs, reminder advertisements, the list of drugs) were also excluded.

Sample size

As this is a time-bound cross-sectional study, drug promotional literature was collected over a period of 6 months i.e. from 1st March 2015 to 31st August 2015.

Sampling method

Convenient non-random sampling

Evaluation of drug promotional literature

All the literature were evaluated by WHO criteria for fulfillment of each of the following parameters:¹⁸

- 1) International Non-proprietary Name (INN) of each active substance.
- 2) Pharmacological data: a brief description of pharmacological effects and mechanism of action.
- 3) Clinical Information:
 - a) Indications: whenever appropriate, simple diagnostic criteria should be provided.
 - b) Dosage regimen and relevant pharmacokinetic data:
 - Average dose and range for adults and children;
 - Dosing interval;
 - Average duration of treatment;
 - Special situations, e.g., renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage.
 - c) Contra-indications.

d) Precautions and warnings (reference to pregnancy, lactation, etc.).

e) Adverse effects (quantify by category, if possible).

f) Drug interactions (include only if clinically relevant; drugs used for self-medication should be included).

g) Overdosage:

- Brief clinical description of symptoms;
- Non-drug treatment and supportive therapy;
- Specific antidotes.

4) Pharmaceutical information:

- a) Dosage forms.
 - b) Strength of dosage form.
 - c) Excipients.
 - d) Storage conditions and shelf-life (expiry date).
 - e) Pack sizes.
 - f) Description of the product and package.
 - g) Legal category (narcotic or other controlled drug, prescription or non-prescription).
 - h) Name and address of manufacturer(s) and importer(s).
- 5) References

Statistical Analysis

The analysis was done by using SPSS (Statistical Package for the Social Sciences) software program, version 16. Categorical variables were summarized using frequency and percentage.

RESULTS

Type of drug

A total of 750 drug promotional literature (DPL) was analyzed. Out of these DPL, the majority of DPL were about CVS (23.2%) medications followed by GIT (20.7%), antidiabetic medications (12.67 %), chemotherapeutic agents (12.27%), RS (8%) and skin (1.3%) and others (21.2%). (Figure 1)

Fulfillment of WHO criteria

Out of these 750 drug promotional literature, criteria like INN, brand name, indication, description of the product and the package were present in all the cases (100%). Dosage form & its strength (98.7%), manufacturer address (97.3%), legal category (82.6%) were mentioned in most of the literatures. Information related to safety such as precautions (32.6%), contraindications (33.3%), adverse effects (34.6%), Overdosage (1.2%) were mentioned in some literatures. Pharmacological data i.e. mechanism of action and the effects of the drug were mentioned in 49.3%. Excipients (0.72%) were mentioned in very few literatures (Table 1, Figure 2).



Only 71 out of 750 drug promotional literatures met all the requirements mentioned in the WHO criteria (9.5%). (Figure 3).

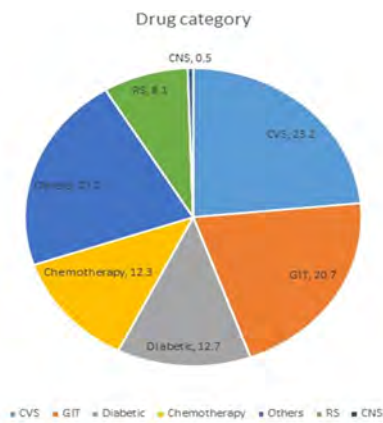


Figure 1: Classification as per type of drug promoted in the literature

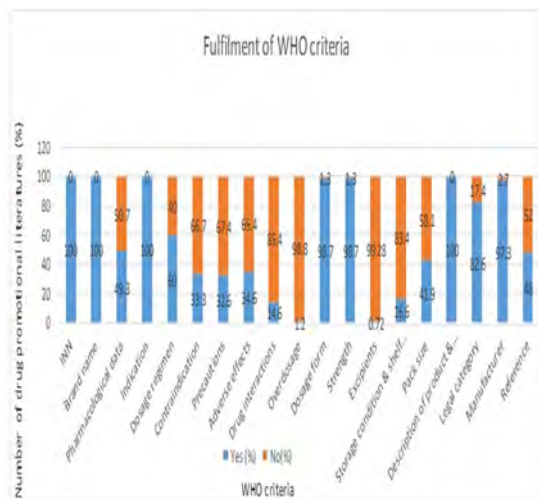


Figure 2: Evaluation of drug promotional literature as per WHO criteria

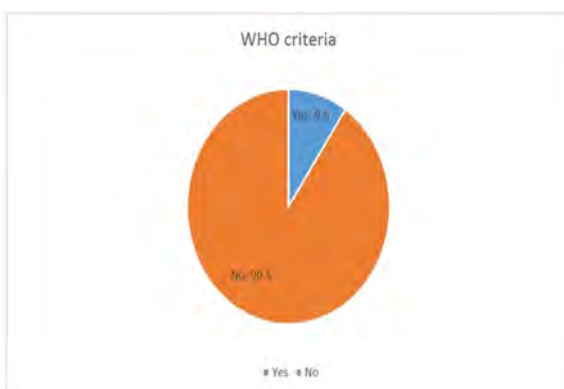


Figure 3: Drug promotional literature following WHO criteria

Brief prescribing information

Out of 750 drug promotional literatures, brief prescribing information was present in 142 drug promotional literature (18.9%).

Table 1: Evaluation of drug promotional literature as per WHO criteria

Criteria	Mentioned Number (%)
Inn	750 (100)
Brand Name	750 (100)
Pharmacological Data	370 (49.3)
Clinical Information	
Indications	750 (100)
Dosage Regimen	450 (60)
Contraindication	250 (33.3)
Precaution	245 (32.6)
Adverse Effects	260 (34.6)
Drug Interactions	110 (14.6)
Overdosage	90 (1.2)
Pharmaceutical Information	
Dosage Form	740 (98.7)
Strength of Dosage Form	740 (98.7)
Excipients	54 (0.72)
Storage Conditions & Shelf Life (Expiry Date)	125 (16.6)
Pack Size	314 (41.9)
Description of the Product & Package	750 (100)
Legal Category	620 (82.6)
Manufacturer	730 (97.3)
Reference	360 (48)

DISCUSSION

Printed drug promotional literature is an easily available, accessible and important source of drug information. We observed from this study that WHO guidelines were not followed by drug companies while promoting drug products. A total of 750 drugs was presented in the same number of drug promotional literatures. Information related to drugs like INN name, Brand name, indications, description of the product and the package were present in all the drug promotional literatures. But, important information related to safety information were missing in most of the DPL. Only 71 out of 750 DPL (9.5%) had all the information mentioned in the WHO criteria (9.5%), which is a sad fact to digest. Previous study published by Tejas Khakhkar, reported that none of the drug promotional literature followed WHO guidelines after analyzing 142 drug promotional literatures.¹⁹

In addition to this, we checked for the presence of brief prescribing information (BPI) in these 750 drug promotional literature and only 18.9% of the literature provided BPI. This information acts as a brief summary which can guide doctors in prescribing the drug in the right way.

One limitation of the study was it was conducted only in one tertiary hospital which may not correlate with drug

promotional literature distributed in other places (government hospitals, private clinics etc.)

Development of laws and their implementation by drug manufacturers, practitioners' awareness and strengthening of existing guidelines can be beneficial measures in this issue. It requires group efforts of practitioners, pharmaceutical companies and regulatory body which can ultimately lead to ethical drug promotional activities and rational prescribing.

CONCLUSION

Few of the drug promotional literature contained all of the information recommended by the WHO's guideline for medicinal drug promotion. They were lacking in scientific and critical information. Therefore, healthcare professionals' awareness and responsibility are required to critically evaluate DPLs before accepting it as a scientific source of drug information and if any contradiction is recognized, should be reported to appropriate authority.

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