

Evaluation of drug promotional materials in a hospital setting in Nepal

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Abstract **Objectives:** Unethical drug promotion is a common problem worldwide. In, Nepal, there is limited vigilance on the quality of information supplied by the drug companies to the doctors. The objectives of this study were to analyze the promotional materials provided by the drug companies as per WHO ethical criteria for medicinal drug promotion. **Methods:** Promotional materials present in the Drug Information Center (DIC) during the period from September to December 2007 were collected. The collected promotional materials of different pharmaceutical companies were compared with WHO's Ethical Criteria for Medicinal Drug Promotion. **Results:** The name of active constituent(s) was mentioned in 87.87% (n=29) of promotional items. Therapeutic indication was mentioned in 87.88% (n=29) of promotional material but information on side effects [33.33% (n=11)], drug interactions [9.09% (n=3)] and use in pregnancy and lactation [12.12% (n=4)] were lacking in the majority of promotional materials. **Conclusion:** In a country like Nepal with limited drug information resources, the promotional materials provided by the manufacturers can largely influence the prescription behavior of the clinicians. Our findings suggest the need for interventions to improve the content of the promotional materials provided by the drug companies.

Keywords Drug Promotion, Nepal, Promotional Material, Ethics, Information.

Introduction

Drug promotion is an integral part of pharmaceutical marketing. The World Health Organization (WHO) defines promotion as all the informational and persuasive activities by manufacturers and distributors, the effect of which influence the prescription, supply, purchase and/or use of medicinal drugs. There are various methods by which pharmaceutical companies promote their drugs. The most common methods are drug promotion using medical representatives (MR), distributing free samples, advertisement through pamphlets, radio, TV and sponsoring medical

events¹. The monetary involvement in drug promotion is quite high. A study suggests that the amount of money involved in drug promotion by the manufacturers is at least 30 times more than the money spent on drug information by the government². In the booming pharmaceutical market with competitive and aggressive drug promotion by pharmaceutical companies there is every possibility of the promotion being unethical. At the same time, the information provided by the sales representatives is the only source of information about the medicine in developing countries³. Moreover, evidence suggests that promotion affects attitudes and behavior⁴.

Mushrooming in the number of drugs and vigorous promotional strategies by pharmaceutical companies causes biased information to be freely available to the medical practitioners and consumers. Lack of access to medical literature and poor information systems further complicate the access to unbiased Drug Information (DI) in developing countries like Nepal⁵. Doctors in Nepal have started to become targets for the pharmaceutical industry's promotional activities. Most hospitals in Nepal allow free access of MRs to doctors, and in the majority of cases independent academic detailing is absent. Studies from different countries have identified that printed material distributed by the drug companies is often biased^{7,8,9}.

The developed countries like the United States regulate of advertising and promotional materials regarding medicines¹⁰.

It was observed that in Nepal, unbiased and current drug references were not available in most clinical facilities for healthcare professionals and committees to develop drug lists and for making procurement decisions. Some examples of irrational use of drugs in Nepal include; polypharmacy, use of expired drugs, irrational combination of drugs, and overuse of antibiotics, vitamins & herbal remedies, brand prescribing, retail shop prescribing and unethical dispensing. Such irrational practices, combined with a lack of patient information on proper handling and use of drugs can lead to wastage of medicines as well as other serious consequences like adverse drug reactions and drug interactions¹¹.

In Nepal there is no mandatory law that regulates the contents of the promotional materials provided by the pharmaceutical companies. During 2007, the National Drug Regulatory Authority has come out with ethical guidelines for drug promotion however it is still in draft format¹². As of now there is no study from Nepal that has evaluated the scientific contents of the promotional materials provided by the pharmaceutical companies. Hence the present study was conducted with the objectives of comparing the drug advertisements (promotional material) of different pharmaceutical companies with the WHO guidelines on ethical drug promotion¹³. These guidelines address ethical concerns about advertisements, Medical

Representatives, Free samples of prescription and non-prescription drugs for promotional purposes, packaging and labelling information for patients¹³.

Methodology

The drug company representatives after visiting the doctors visit the Chief, Pharmaceutical Services at the Drug Information Center (DIC) located in the hospital. Often the companies leave similar literature to that provided to the doctors at the DIC. This is a cross sectional study and we identified the promotional materials present in the DIC during the period from September to December 2007. The data obtained were entered into a Microsoft® word document and were analyzed according to the WHO's ethical criteria on medicinal drug promotion¹³.

The guideline provides two different criteria for advertisements to healthcare professionals and to the general public. In this study we have looked at advertisements to physicians and health care professionals. WHO's Ethical Criteria for Medicinal drug Promotion states that the advertisement should include the name of the active ingredient, brand name, content of active ingredient per dosage form or regimen, other ingredients known to cause problems, approved therapeutic uses, dosage form or regimen, side effects, contraindications, major interactions, management in case of overdose or toxicity, storage conditions, pharmacokinetic profile, use in pregnancy and lactation, name and address of manufacturers or distributor, and reference to scientific literature.

Results

Altogether thirty three promotional materials were evaluated from twenty different manufacturers. The majority of promotional materials were from Indian companies or multinational companies based in India. The manufacturer name was not mentioned in three of the promotional materials. The therapeutic classifications of the drugs promoted in the promotional material are listed in Table 1. Analysis of general pharmaceutical information present in the promotional materials is listed in Table 2. Table 3 describes the analysis of the pharmaceutical information in the promotional material.

Table 1. Therapeutic category of drugs promoted in promotional material (N=33)

Therapeutic classification	No. of drugs (33)	Percentage
Anti diabetic medicines	8	24.24
Drugs acting on cardiovascular, renal and blood forming agents	6	18.18
Antimicrobials	3	9.09
Drugs acting on respiratory system	3	9.09
Drugs acting on central nervous system	2	6.06
Vitamins, minerals and dietary supplements	1	3.03
Drugs acting on gastrointestinal tract	1	3.03
Hormone and hormone antagonists	1	3.03
Anti virals	1	3.03
Antiseptics	1	3.03
Enzyme preparations	1	3.03
Anti fungals	1	3.03
Vaccines	1	3.03
Miscellaneous	3	9.09

Table 2. Availability of general information in the promotional materials

Criteria	Present [%(n)]
Name of active ingredient(s)	87.87 (n=29)
Brand name	100 (n=33)
Reference to scientific literature	72.72 (n=24)

Table 3. Availability of pharmaceutical information in the promotional materials

Criteria	Present [%(n)]
Content of active ingredient(s) per dosage form	81.82 (n=27)
Other ingredients known to cause problems	0
Name and address of manufacturers or distributor	90.90 (n=30)
Dosage form or regimen	90.90 (n=30)
Storage conditions	9.09 (n=3)
Pharmacokinetic profile	18.18 (n=6)

Table 4. Availability of information related to clinical use of the medicine in the promotional materials

Criteria	Present [%(n)]
Approved therapeutic use	87.88 (n=29)
Side effects and major ADRs	33.33 (n=11)
Precautions, Contra-indications, Warnings	36.36 (n=12)
Major interactions	9.09 (n=3)
Management in case of over dose/toxicity	12.12 (n=4)
Use in pregnancy and lactation	12.12 (n=4)

Table 4 provides details of the analysis of the information related to clinical use of the medicines.

Discussion

In our study, general information like name of the active constituents was mentioned on the majority

of advertisements (n=29, 87.87%), however it was still missing in 13% of the advertisements. This is in line with Thailand, where it was observed that 88% of the advertisements have the name of active ingredient¹⁴.

In our study, dosage form and manufacturer name were mentioned in more than 90% of promotional materials which is more than Laos [dosage form (56.1%), manufacturer name (39.2%)] and Thailand [dosage form (59%), manufacturer name (76.2%)]¹⁴. Likewise, in our study, indications and side effects were outlined in 87.88% (n=29) and 33.33% (n=11) of promotional material respectively which is more or less similar to Laos [Indication (100%), Side effects (39.2%)], Thailand [Indication (91.2%), Side effects (43.6%)] and Vietnam [Indication (86.4%), Side effects (55.6%)].

A study from Brazil noted that approximately 75% of the advertisements did not comply with regulations in Brazil¹⁵. Similarly in our study none of the promotional materials had all the necessary information as per WHO's Ethical Criteria for Medicinal Drug Promotion.

A study from Argentina identified only eighteen (60%) of the thirty promotional materials had statements supported by cited references. Adverse reactions, warnings about drug interactions and contraindications were absent from all promotional material⁹. A study from Brazil also showed that 33% of promotional statements were either partially consistent or inconsistent. The study concluded that there was difficulty in accessing the references mentioned in the promotional materials and the messages on efficacy, safety and cost were not always supported by scientific studies⁸.

Effective drug regulation could be a sensible solution to the problem as unethical drug promotion is a worldwide problem. In Nepal with limited drug information sources, the promotional materials provided by the manufacturers can largely influence the prescribing behaviour of the clinicians. Interventions are needed to improve the content of the promotional materials provided by the drug companies in Nepal.

One of the strategies to overcome the unethical promotional strategies is to sensitize the medical students regarding the harmful nature of unethical drug promotion. In Manipal College of Medical Sciences (MCOMS), the medical school to which Manipal Teaching Hospital is affiliated, the students are taught to critically analyze drug advertisements and other promotional material against the WHO ethical criteria for medicinal drug promotion⁶. The students are also asked to perform role-plays with

the objectives of sensitizing them about ethical drug promotion and optimizing time spent with medical representatives¹⁷. We believe these initiatives could be quite helpful to sensitize the future prescribers on drug promotion.

Conclusion

It was observed that none of the promotional materials contained all of the essential information recommended by the WHO's Ethical Criteria for Medicinal Drug Promotion and essential information regarding active ingredients, dosage form or regimen, and drug interactions were absent in many promotional materials. In a country like Nepal, where MRs is considered one of the major sources of drug information, this issue is of major concern, however current study is preliminary in nature and suggests the need for more extensive studies on the issue.

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