

Evaluation of Rationality of Drug Promotional Literature Using Who Ethical Criteria for Medicinal Drug Promotion

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ABSTRACT

Objective: To evaluate the rationality of drug promotional literature (DPL) using WHO criteria for ethical medicinal drug promotion.

Materials and Methods: 150 brochures for drug promotion were collected from physicians of various departments in Pandit B. D. Sharma University of health sciences randomly, to whom they were circulated by medical representatives. These promotional literatures were evaluated against the WHO ethical criteria for medicinal drug promotion.

Result: Only 2% of the drug promotional literature fulfilled all the WHO criteria and none fulfilled OPPI Code of Ethical Practice. DPL were highly compliant ($\geq 70\%$) about brand name, active ingredients & their contents, manufacturer's name and address. DPL showed moderate compliance (40-69%) regarding mention of approved indications and dosages but unfortunately majority of DPL were poorly compliant ($\leq 39\%$) for references, side effects, precautions, warnings, contraindications, interactions and name of other ingredients. Cost was mentioned in only 4% of literature and date of production of advertisement was not mentioned in any literature. Antibiotics (20%) were the most promoted group of drugs. 65% of promotional literature was designed for promotion of FDCs.

Conclusion: Drug promotion undoubtedly influences the prescribing behaviour of general physicians but their accuracy has always been questionable because the facts and figures in these literatures are often biased and distorted so as to highlight only the beneficial effect of the products and undermine the harmful effects. At national level, ethical committees and drug regulatory authorities need to maintain stringent control on the promotional activities of the pharmaceutical companies.

Keywords: Ethical drug promotion, WHO criteria, Drug promotion literature.

INTRODUCTION

Pharmaceutical 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 drug promotional literature provided by the pharmaceutical companies is one of the most important sources of drug information to the clinicians. ^[1] Medicine is one of the most rapidly advancing branch of science, with the constant need to reinvent

itself to suit the dynamic nature of the pathological agents, and grapple with the perpetual emergence of newer diseases. Perseverance of the knowledge of breakthroughs made in the science of medicine is mandatory for any practitioner, to better justify his role as a healer and minister the best medical care that he is capable of, which nevertheless is a challenging task because of multiple reasons. Pharmaceutical companies are the manufacturing units of drugs, with established conformity for dispersal into the public. [2]

According to an article published in the Forbes Magazine in 2013, the cost of introducing a new drug in the market is \$350 million, even before the drug is available for sale. [3] There are an estimated 20,000 pharmaceutical companies in India, competing for a share of Rs 4.5 billion dollar market growing at about 8 to 9 percent annually, in presumably a poorly regulated environment. India is now among top 5 pharmaceutical emerging markets and it is estimated that the healthcare market in India will reach US 31.59 billion dollar by 2020. [4] The picture is complicated by an uneducated customer base, [5] a highly privatised health system [6] and the prevalence of “cross practice” – the prescription of medicines in one system of medicine by doctors trained and certified in another system of medicine – though it is illegal in most states in India.

Number of new drugs and old drugs with some modification are entering every year in the Indian market. Very few among them are genuine innovations and rests are with altered formulation or me too drugs and FDCs which are added to more than 20,000 drug formulations present already in the market. [7] Drug manufactures spent more than \$ 11 billion each year drug in promotion and marketing. Around \$ 8000 to \$ 13000 per year is spent on each healthcare professional for drug promotional activities. [8] To increase their sales and hence, their shareholder value, these corporations need to make their product have earmarks of a

better formulation than those already available and stand out from their adversaries. Pharmaceutical companies being aware of it, try to target the physicians for promotion activities in the garb of providing the updated information. For this reason, a physician becomes a crucial target of the promotional activities of major pharmaceutical corporations, and in areas of scarcity of availability of sources of information, the Medical Representatives (MRs) or Pharmaceutical Sales Representatives (PSRs) becomes a major source of information for the doctors. [2] In developing countries where the influence of drug companies is high, promotional literature doled out by the drug companies forms a very important source of information dispersal. [9,10] A study done in Boston University in 2001 saw that advertisement department of pharmaceutical companies had 81% more employees than their research and development department. [11]

Different modes of drug promotion include visual aids, flip charts, leave-behinds, advertisements, gifts, and audio-visuals for promotion of drugs. [12] A major marketing technique used by pharmaceutical companies is direct-to physician (DTP) marketing [13] but there is a concern about the influence of DTP marketing on physician’s prescribing practices and its consequences, such as the physician’s ethical obligation to the patient and health care costs. Studies have repeatedly shown that pharmaceutical promotion influences physician’s behaviour. [14] Various reports archive unseemly effect of blatant promotion on the prescribing habits of the physicians, some of which can lower the quality of prescription or increase the prescription costs.

Another issue of rising concern is the authenticity of the research work, with the increasing involvement of the pharmaceutical companies in the funding, evaluation and other facets of the work, and the consequent probability of these studies to give positive outcomes, to selectively

report only the favourable findings or to implement post hoc data dredging. [2] It is known that intentionally inaccurate and selective information is effective for drug promotion. [15] It is also known that the quality of the drug information given to Indian doctors is poorer than that given to our western counterparts. [16] 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 behaviour 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. [17]

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. Pharmaceuticals manufacturers must comply with International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code to ensure ethical practices for drug promotion. IFPMA code sets standards for Ethical promotion that member companies' must follow. [18] It is a signatory condition for membership of the association to observe a code of practice in marketing activities in countries like UK, Australia and Canada. [14] In India, drug promotion is largely governed by the Organisation of Pharmaceutical Producers of India (OPPI). However, the implementation of the code of ethics developed by the OPPI is a matter of self regulation and self-discipline and adherence to the code is in no way mandatory for the pharmaceutical companies. In India, there are regional Ethics Committees in metropolitan cities like for complaints against unethical drug promotion advertisements. Drug controller authority

takes necessary legal steps in response to such complaints to against drug manufacturers and distributors. [7]

The accuracy and usefulness of drug advertisements has been the subject of debate for many years. 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 drug promotional literature available in Indian market using WHO criteria.

MATERIALS AND METHODS

This observational study was conducted by Department of Pharmacology of Pt B. D. Sharma University of health sciences, Rohtak. Approximately 180 drug promotional pamphlets and brochures were collected randomly from various outpatient departments namely medicine, surgery, otorhinolaryngology, ophthalmology, paediatrics, obstetrics & gynaecology, orthopaedics, skin & V.D., psychiatry, neurology, cardiology over a period of 6 months, that is July to December of 2016. Collected literatures were then explored to exclude following material: literature promoting medicinal devices and equipments (e.g. Insulin pump, blood glucometer, stents), orthopaedic prosthesis, reminder list. After excluding the above mentioned literature, a total of 150 pamphlets and brochures were included in the study. Included material was then assessed using WHO ethical criteria for medicinal drug promotion, which dictate that promotional literature should contain following information: [1]

1. The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug
2. The brand name
3. Amount of active ingredient(s)
4. Other ingredients known to cause problems, i.e. adjuvant
5. Approved therapeutic uses

6. Dosage form or dosage schedule
7. Safety information including side effects and major adverse reactions, precautions, contraindications and warnings and major drug interactions
8. Name and address of manufacturer or distributor
9. Reference to scientific literature as appropriate

Included material was also assessed using OPPI Code of Ethical Practice. According to this code all printed promotional materials other than reminder advertisements must be legible and include: [19]

- a) The name of the product (normally the brand name)
- b) The active ingredients
- c) The name and address of the pharmaceutical company or its marketing agent
- d) The date of production of the advertisement
- e) Abbreviated prescribing information
 - Approved indications
 - Dosage
 - Method of use

- Succinct statement of contraindications, precautions and side-effects

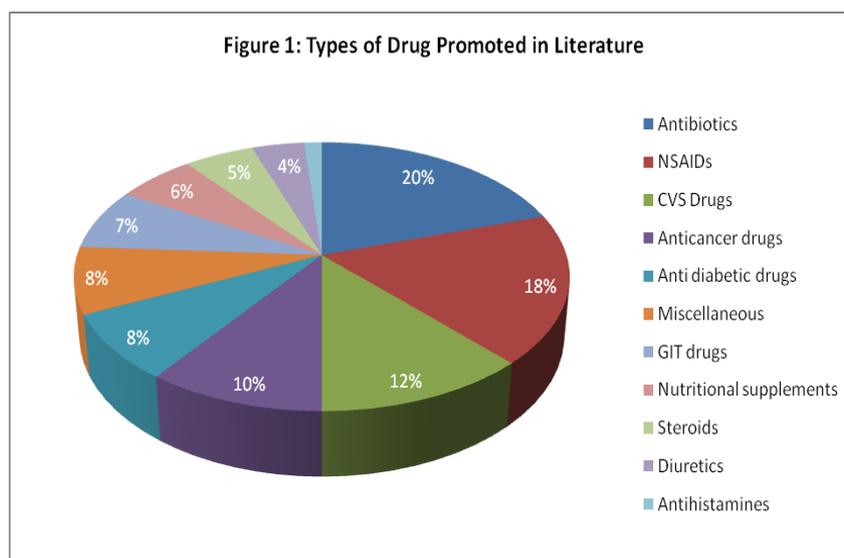
Apart from these they were also assessed for any mention about the cost. All the literature were then evaluated for completeness of information in the above mentioned aspects followed by their categorization on basis of their compliance shown to various criteria given by both WHO and OPPI.

Category	Percentage of compliance
High compliance	≥ 70%
Moderate compliance	40-69%
Poor compliance	≤ 39%

RESULT

Table 1: Evaluation of literature according to WHO ethical criteria for medicinal drug promotion

Criteria	Number of literature (%) n=150
Brand name	150(100)
Name of active ingredient	148(98.67)
Amount of active ingredient	142(94.67)
Name and address of manufacturer/distributor	132(88)
Approved therapeutic uses	96(64)
Dosage form / schedule	86(57.33)
References	42(28)
Side effects	17(11.33)
Warning	8(5.33)
Contraindications	8(5.33)
Precautions	8(5.33)
Major interactions	8(5.33)
Other ingredients known to cause problem	5(3.33)



Only 2% of the drug promotional literature fulfilled all the WHO criteria and none fulfilled OPPI Code of Ethical Practice. DPL were highly compliant (≥ 70%) about

brand name (100%), active ingredients (98.67%), content of active ingredients (94.67%) and manufacturer's name and address (88%). DPL showed moderate

compliance (40-69%) regarding mention of approved indications (64%) and dosages (57.3%) but unfortunately majority of DPL were poorly compliant ($\leq 39\%$) for references(28%), side effects (11.3%), precautions (5.33%), warnings (5.33%), contraindications (5.33%), interactions (5.33%) and name of other ingredients

(3.33%). Cost was mentioned in only 4% of literature and date of production of advertisement was not mentioned in any literature. Antibiotics (20%) were the most promoted group of drugs (Figure 1). 65% of promotional literature was designed for promotion of FDCs.

Table 2: Evaluation of Literature According to OPPI Code of Ethical Practice

Criteria	Number of literature (%) n=150
Brand name	150(100)
The active ingredients	148(98.67)
The name and address of the pharmaceutical company or its marketing agent	132(88)
Approved indications	96(64)
Dosage	86(57.33)
Method of use	86(57.33)
Side effects	17(11.33)
Contraindications	8(5.33)
Precautions	8(5.33)
The date of production of the advertisement	0(0)

DISCUSSION

Drug promotion undoubtedly influences the prescribing behaviour of general physicians but their accuracy has always been questionable. Physicians themselves universally agree on the fact that their prescribing habits are influenced by the data provided by the PSRs. In the study by Ziegler et al ^[20] 37% physicians and 61.2% in the study by Vencelik et al ^[21] said their decisions were influenced by the pharmaceutical drug information. Majority of DPL analysed in this study were focused on FDC (65%) rather than single drug but rationale for combination was justified only for few FDCs. Similar findings are also seen in study done by Saibhavana et al. ^[22] So physicians are advised to consider the rationality of drug combination before prescribing as this will not only increase the cost of treatment but also lead to unnecessary adverse drug reaction and interactions.

In the present study antibiotics, NSAIDs and drugs acting on cardiovascular system were the most promoted drugs. Antidiabetic and anticancer drugs were also promoted in many literatures. Similar findings are also seen by Ganashree et al. ^[23] Above findings suggest that pharmaceutical

companies are targeting promotion of those drugs which are used most commonly in clinical practice and also for longer duration as in case of chronic diseases. Above trend of drug promotion ensures that pharmaceutical companies get huge profits for a sustained duration of time, as drugs for chronic diseases are prescribed for long duration and sometime for life-long.

In present study, out of 150 DPL only 2% (3) fulfilled all the WHO ethical criteria for medicinal drug promotion and none fulfilled OPPI Code of Ethical Practice. Similar findings are also reported by Mali et al. ^[13] This suggests that drug promotional companies are more involved in establishing a commercial relationship with the treating physicians wherein ethical educational aspect is compromised. The aim of these companies is promotion of their products rather than the provision of authentic information wherein one often comes across wrong, misleading or even false proclamations. ^[24] This problem is prevalent worldwide, in 2004, WHO conducted a survey of national governments and found that less than one-sixth of the countries had a well- developed regulation system for pharmaceuticals. One-third reported that they had little or no regulatory

capacity. Some developed countries, such as the UK, Canada and Australia, have guidelines, codes, and regulations for printed material and material intended for broadcast. The UK provides an example of self-regulation and enforcement. [25] There, the advertising of medicines is controlled by a combination of statutory measures (containing both criminal and civil sanctions), enforced by the medicines and healthcare Products Regulatory Agency, and self-regulation through the Code of Practice for the Pharmaceutical Industry, administered by the trade associations. Interestingly, our study found that the compliance of multinational companies with standard regulations was far superior to that of Indian companies. This can be due to the fact that the multinational companies follow a stringent process of having their promotional material screened in advance by dedicated medical colleagues, something which the majority of Indian companies do not do.

There are some limitations in our study. One of the limitations of the study was small sample size. Also, the study was conducted only in government hospital and in a single centre. In this study only one type of promotional activity was analyzed, i.e. printed promotional literature. However, there is a need to assess the awareness of the practitioners by intervention study and provides guidance about accurate and ethical information from DPL. DTP method of marketing may influence prescribing behaviour with no benefit to the patient and also lead to irrational prescribing practices. Development of laws and their implementation by drug manufacturers, practitioner's awareness and strengthening of existing guidelines can be a beneficial measure in this issue. It requires group efforts of practitioners, pharmaceutical companies and regulatory bodies which can ultimately lead to Ethical drug promotional activities and rational prescribing.

CONCLUSION

Literature by pharmaceutical companies forms a very important source of information to the practicing physician, who many-a-times are not able to access other more reliable sources of information due to their busy schedule, and other reasons. However, it has been found that the facts and figures in these literatures are often distorted and biased so as to highlight only the beneficial effect of the products and undermine the harmful effects, leading the physician to prescribe the products which can be detrimental to the patient and his community. Objective of DPL is to promote their product but an active approach by doctors can transform it into a useful and accurate source of information. Practicing physicians need to be able to judge the accuracy of the data presented to them, for which they exploit more than one source of information, preferably of unbiased authority. Pharmaceutical companies should provide undeterred access to their data, without manipulation and should present the data to the physicians in its entirety. At national levels, ethical committees and drug regulatory authorities need to maintain stringent control on the promotional activities of the pharmaceutical companies.

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