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A study of promotional advertisements of drugs in a medical journal: an ethics perspective

SARMILA NATH[1], SUBHROJYOTI BHOWMICK[2], TRAYAMBAK DUTTA[1], VR CHOWRASIA[2], SHIPRA BHATTACHARYA[3], RN CHATTERJEE[4], MANJULA SARKAR[4], AK RAM[5], PK MUKHERJEE[5]

[1] 2nd Year PGT, [2]Assistant Professor, [3]Professor & Head, [4]Professor, [5]Professor Emeritus, Department of Pharmacology, MGM Medical College & LSK Hospital, Kishanganj, Bihar 855107 INDIA Author for correspondence: Subhrojyoti Bhowmick, Flat No. 4, Prathama Apartments, 41/2 PGH Shah Road, Jadavpur, Kolkata 700032 INDIA e-mail: kolkataresearcher@gmail.com

Abstract

The study assessed 54 advertisements of 145 different drugs, published over one year (from December 2011 to November 2012) in an Indian medical journal, circulated widely mainly among general practitioners (GPs). The ethical guidelines of the World Health Organization (WHO) and Organisation of Pharmaceutical Producers of India (OPPI) for medicinal drug promotion were applied. The brand name was mentioned in all advertisements (100% compliance both with the WHO and OPPI criteria) and the names of the active ingredients were also mentioned in 128 (90.14%) advertisements. However, major adverse drug reactions were mentioned in only two advertisements (1.37%); precautions, contraindications and warnings in only two (1.37%); and major interactions in only one (0.68%). Only three advertisements (2.06%) were well substantiated with references. To ensure the ethical promotion of drugs among GPs, journals must introduce compulsory review and appraisal of promotional advertisements by a dedicated review board, including at least one member trained in pharmacology and one representative from the medical division of a pharmaceutical company.

Introduction

Physicians today are greatly concerned with the rational use of drugs. To follow safe medical practice, they have to keep themselves well informed about the hundreds of new drugs entering the market every year. For this, they often have to depend on the promotional practices followed by the pharmaceutical companies. Advertisements in different medical journals are one such source of information. Studies have revealed that what the physician prescribes is influenced by pharmaceutical advertisements (1–5). So, ideally, the information provided in such advertisements should be of high quality and help doctors to practise evidence-based medicine. However, the aim of pharmaceutical companies is not education, but commercial promotion of their product through advertisements.

Pharmaceutical companies are governed by certain ethical guidelines for drug promotional activities at the national and international levels. The "Ethical criteria for medicinal drug promotion" of the World Health Organization (WHO), 1988 (6) and the Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) (7) are two guidelines at the international level. In India, drug promotion is largely governed by the Organisation of Pharmaceutical Producers of India (OPPI) (8) and national legislation (9). However, the implementation of the code of ethics developed by the OPPI is a matter of self-regulation and self-discipline. Adherence to the code is in no way mandatory for the pharmaceutical companies.

There are 1.7 million family doctors in India. This works out to roughly 0.16 general practitioners (GPs) per 1000 people. Currently, the majority of patients in the country are managed by GPs (10). GPs are busy professionals who undergo less training than other doctors/physicians. They spend less time on enhancing their knowledge through continuing medical education (CMEs) and hence, depend on promotional literature on drugs in medical journals as an important source of information. This is why it is important that the quality of advertisements of pharmaceuticals in journals should be of a high standard. Maintaining such standards will help physicians prescribe drugs in a rational manner.

Our study was aimed at evaluating the quality of the promotional advertisements published in Indian journals and exploring whether there is any scope for improvement. We considered the WHO criteria for medicinal drug promotion and the OPPI code as our standard for evaluation.

GPs depend primarily on information obtained from pharmaceutical representatives and journals to bring their knowledge up to date. Journals catering to specific specialties

of medicine and surgery publish advertisements related mainly to those specialties, and there are not many advertisements that would be of interest to GPs. It is mostly the faculties and researchers of the respective fields who go through these journals. For this reason, we have selected an Indian journal which is specifically directed at and highly popular among GPs.

Materials and methods

After taking the permission of the institutional ethics committee, we conducted a cross-sectional, observational study of all advertisements on medicinal drugs published over one year (from December 2011 to November 2012) in the print version of an Indian medical journal (*Journal of Indian Medical Association*, JIMA), which was the world's most widely circulated medical journal with 1.7 lakh subscribers. This journal which was published monthly, and has recently stopped publication (11), featured advertisements of drugs and non-drug products apart from scientific articles. We considered 54 different advertisements for 145 different drugs. Advertisements for parenteral fluids, milk foods, laboratory equipments and the educational courses offered in different medical institutions were excluded. An assessment was made of whether the advertisements adhered to the guidelines of the WHO or the OPPI.

WHO criteria for ethical promotion of drugs

- The company should mention the name(s) of the active ingredient(s), using either the international non-proprietary names or the approved generic name of the drug.
- The brand name should be provided.
- The content of the active ingredient(s) per dosage form or regimen should be mentioned.
- Mention should be made of the names of ingredients known to cause problems.
- The advertisement should mention the approved therapeutic uses of the drug.
- Details of the dosage form or regimen must be provided.
- The side-effects or major adverse drug reactions should be mentioned.
- The precautions, contraindications, and warnings should be listed.
- The advertisement should mention major interactions with other drugs.
- The name and address of the manufacturer or distributor should be provided.
- Reference should be made to scientific literature, as appropriate

OPPI Code of Ethical Practice

All printed promotional materials other than reminder advertisements must be legible and include:

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

Claims should be substantiated through reference of appropriate scientific evidence. Such evidence should be available to healthcare professionals on request.

Results

We studied a total of 54 advertisements promoting 145 medicinal drugs. All the advertisements mentioned the brand name (100% compliance both with the WHO and OPPI criteria). The names of the active ingredients were also mentioned in most advertisements (128, or 90.14%). The content of active ingredients was given in 138 (95.17%), while the names of ingredients known to cause problems were mentioned in 2 (1.37%). Eighty-nine (61.37%) advertisements mentioned the approved therapeutic uses. The dosage form was provided in 118 (81.37%) and the therapeutic regimen in 3 (2.06%).

Only 2 (1.37%) advertisements mentioned the side-effects or major adverse drug reactions. Precautions, contraindications and warnings were listed in 2 (1.37%).Major interactions were mentioned in 1 (0.68%) advertisement. The name and address of the distributor was mentioned in 45 (83.33%) advertisements, and three advertisements (2.06%) gave references. None of the advertisements gave the date of publication of the advertisement. We graded the advertisements on the basis of the number of criteria they fulfilled. The grades were as follows:

Grade A: fulfilling 1–4 criteria

Grade B: fulfilling 5–8 criteria

Grade C: fulfilling 9–11 criteria.

It was found that 38 advertisements fell under grade A, 81 under grade B and 26 under grade C.

The advertisements were categorised according to whether they had been placed by Indian or multinational companies and analysed accordingly, as may be seen in Table 1. A majority of the companies (16 out of 19, or around 84%) were of Indian origin and the others were multinational. The fonts used in the advertisements of the companies Q, R and S were too small to read; only the brand names were legible. Surprisingly, in the case of 3 drugs, the advertisements mentioned only the names of the drugs and their active components without mentioning the names of the companies marketing them.

Discussion

From our study, it is evident that though most advertisements mention the brand name, generic name and content of

active ingredients of the drug, the pharmaceutical companies are very reluctant to list the adverse effects, the names of ingredients that may cause problems or the interactions of their products with other drugs. This is in keeping with the findings of other studies conducted in India and several developing countries (12, 13). A study based on the WHO criteria was carried out in 2011 to examine 882 advertisements from 12 Indian journals (12) catering to different specialties. It found that the brand names and generic names of the drugs were mentioned in 100% and 79.02% of the advertisements, respectively. However, only 45.35% provided information regarding the content of active ingredients. It is to be noted that our study found that there has been a vast improvement in this respect, the corresponding figure being 95.17%. The approved therapeutic uses were mentioned in 61.37% of the advertisements studied by us, compared to 47.61% of those studied by the previous study. Sadly, however, despite the continued emphasis on the improvement of the quality of advertisements, a significantly negative trend was observed with respect to the mention of adverse effects (1.37% in our study, compared to 38.54% in the previous one), precautions and contraindications (1.37% vs 34.01% in the previous study), and major drug interactions (0% vs 29.47% in the previous study). This finding is quite alarming.

The name of the pharmaceutical company was mentioned in 45 of the 54 advertisements, but the full contact address was mentioned in only a few. Five companies provided their web addresses from which information regarding their products could be obtained. The web addresses were verified and found to be authentic. Proper scientific references were given in a meagre 3 of the 145 drugs advertised. The references were mostly from journals.

In India, a few studies have been carried out on ethical issues related to advertisements published in medical journals. In 1997, Gitanjali *et al* conducted a study on drug advertisements published in the Indian edition of the *British Medical Journal* (*BMJ*) (14) and observed that many elements of ethical advertising, such as mentioning the generic name and price of the drug and the manufacturer's postal address, were often omitted. This is in line with the findings of our study.

Professor SN Mali and his team had conducted a study on the promotional brochures supplied by pharmaceutical companies (15). Some aspects of our results are similar to their observations. Like them, we also found that the majority of the advertisements belonged to grade B (55.8% in our study and 48.7% in theirs). Another interesting aspect which both studies took note of was that most of the advertisements were concerned with marketing chemotherapeutic agents and drugs aimed at chronic diseases, such as cardiovascular, anti-diabetic and anti-neoplastic drugs. As the authors rightly pointed out, once these drugs are started, they are often continued lifelong, thus benefitting the company for a long time. Like the previous study, our study found that information regarding adjuvants was not mentioned in any of the advertisements.

A recent study by Charan et al (16), which evaluated the references given in advertisements to support the claims made, found that only 28% of the claims were supported by references. This figure is much lower than those in western studies and is similar to the results of our study, which found that references were given in only three advertisements (2.06%).

Various promotional activities undertaken by the pharmaceutical companies serve as an important source of information for the busy practitioner (17). However, as the aim of these companies is the promotion of their products rather than the provision of authentic information, one often comes across wrong, misleading or even false proclamations (18). 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 (19). 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.

Regulations in the UK are considered the standard, especially in countries with a weak regulatory system. Unfortunately, there is no regulatory code in developing countries such as India. Here, oversight of alleged unethical promotion is provided only through the code developed by the IFPMA, if the company involved is an IFPMA member.

Health professionals can play an active role in ensuring that high ethical standards are maintained and can report illegal marketing activities to the relevant regulatory authorities. The key requirements of ethical promotion are that it must be accurate, balanced, objective and based on up-to-date, relevant evidence. Evaluation of promotional literature may be emphasised in undergraduate studies, as recommended by VV Shetty et al (20). There is a need for stricter implementation of the codes for ethical promotion of medicinal drugs in India.

This study has a few limitations. Its duration was short and it assessed advertisements from a single medical journal. However, given the Indian context, this can be seen as a pilot study aimed at estimating the quality of promotional literature for drugs, primarily targeting GPs.

Conclusion

The authors strongly feel that all advertisements to be published in medical journals circulated among GPs must undergo a stringent process of assessment by a dedicated review board constituted within the editorial team of the journal. The board should include at least one member who is trained in pharmacology and one representative from the medical division of the pharmaceutical industry. This will help in estimating the rate of compliance with the standard recommended guidelines. Further, advertisements that do not comply with the standard guidelines should not be published and the editorial board should issue warning letters to the pharmaceutical companies concerned as a preventive measure. It would be a good idea for the review board to publish in the journals a list of the companies which constantly submit incomplete promotional advertisements. This would increase awareness among the readers of the unethical promotion of drugs. These few simple measures can help to improve the medical information spread through promotional advertisements in medical journals that are circulated among GPs in India.

Declaration

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Table 1
Company-wise analysis of drug advertisements

Company name (Indian/ multinational)	Active ingredients	Brand name	Content of active ingredients	Ingredients known to cause problems	Therapeutic uses	Dosage form/ regimen	A/E	D/I	Address	References
A (Indian)	No	Yes	No	No	Yes	No	No	No	Yes	No
B (MNC)	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
C (Indian)	Yes	Yes	Yes	No	Yes	No	No	No	No	No
D (Indian)	No	Yes	No	No	Yes	No	No	No	No	No
E (Indian)	Yes	Yes	Yes	No	Yes	No	No	No	No	No
F (Indian)	Yes	Yes	Yes	No	Yes	No	No	No	No	No
G (Indian)	No	Yes	Yes	No	Yes	No	No	No	No	No
H (Indian)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I (Indian)	Yes	Yes	No	No	Yes	No	No	No	Yes	Yes
J (MNC)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
K (Indian)	Yes	Yes	Yes	No	Yes	No	No	No	No	No
L (Indian)	Yes	Yes	Yes	No	Yes	Yes; no regimen	No	No	No	No
M (Indian)	Yes	Yes	Yes	No	No	No	No	No	Yes	No
N (Indian)	Yes	Yes	Yes	No	No	No	No	No	Yes	No
O (Indian)	Yes	Yes	Yes	No	No	No	No	No	No	No
P (Indian)	Yes	Yes	Yes	No	No	No	No	No	No	No
Q (Indian)	Yes	Yes	Yes	No	No	No	No	No	No	No
R (Indian)	Yes	Yes	Yes	No	No	No	No	No	Yes	No
S (MNC)	Yes	Yes	Yes	No	No	No	No	No	No	No

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