WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.421
Volume 7, Issue 12, 1084-1091 Research Article ISSN 2278 – 4357

DRUG ADVERTISEMENTS IN MEDICAL JOURNALS: AN APPRAISAL

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Article Received on
22 October 2018,

Revised on 12 Nov. 2018,
Accepted on 02 Dec. 2018,

DOI: 10.20959/wjpps201812-12682

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INTRODUCTION

Medical journals are an important source of drug information especially for medical professionals. They have a large readership base which is growing over the years as they are vastly available online and also in institutional libraries. So the pharmaceutical companies target these medical journals and multiple drug advertisements per journal edition can be seen. Ideally, all drug advertisements should be reliable, accurate, informative, and with no misleading or unverifiable information and nothing should be withheld which may prove to be harmful for the patients.[1] New drugs are coming into the market every day and medical professionals need to appraise themselves with the latest developments. However due to their busy schedule, they are mostly dependent on media for updating their knowledge base like drug advertisements. Pharmaceutical companies exploit this scenario to the fullest and make huge profits by promoting their products by providing selective information. Studies indicate that doctors who are reliant on advertisements in medical journal may prescribe less appropriately and are associated with increased prescription cost.[2]

Even doctors who think that they obtain their knowledge from the scientific literature can be influenced by promotional sources without being aware of it. There are certain guidelines which have been laid down to govern these advertisements but due to lack of strong legal system they are mostly ignored. There is lack of mechanism to keep a check on the quality of advertisements. Most complaints are made when the advertisement is already in circulation. There is no strategy in place which prevents drug advertisements giving misleading information from getting published.[3]

There are certain guidelines which regulates these advertisements in electronic and print media for promotion of proper and rational use of drugs. Worldwide, the most followed guidelines are those laid down by WHO and by International Federation of Pharmaceutical Manufacturers Association (IFPMA). In 1988, the World Health Organization (WHO) laid down Ethical criteria for medicinal drug promotion. These guidelines consist of general principles for ethical standards that can be adapted by countries as per their circumstances. IFPMA Code of pharmaceutical marketing practices sets standard for the ethical promotion of medicines.[4] In India, medicinal drug promotion is guided by ethical criteria laid down by Organization of Pharmaceutical Producers of India (OPPI).[5] Although the guidelines has been framed but there is no good legal system in place to check the adherence to them. As a result of which these guidelines are not followed or ignored most of the times. The literature search has revealed that drug advertisements in India provide insufficient information, concealing the negative points and sometimes are also misleading.[6,7,8]

There is very limited data which looks at the completeness of advertisements available in medical journals in India. Taking into consideration the magnitude of drug use and the impact these journals can have on the prescribing behaviour of physicians, it becomes very important to look into this aspect whether the guidelines are being followed while advertising. So this study was undertaken to assess the compliance of these advertisements to WHO and OPPI guidelines.

Methods

This was a prospective, cross-sectional, observational study conducted in the department of pharmacology, Pt B D Sharma Post Graduate Institute of Medical Sciences, Rohtak, a tertiary care centre in North India. Drug advertisements pertaining to allopathic medication available in medical journals (print version) in the institute library were randomly selected during January 2017 to July 2017. Advertisements pertaining to those of medical devices, surgical appliances, nutritional supplements and Ayurveda drugs were excluded from the study. Duplicate advertisements were also not considered in the study.

Drugs in the advertisements were classified according to Anatomical Therapeutic Chemical (ATC) classification by World Health Organization collaborating centre for drug statistic methodology according to the action of the drug on the organ or system and their chemical, pharmacological and therapeutic properties.[9] The drug advertisements were then analysed

for compliance to ethical criteria for medicinal drug promotion guidelines laid down by WHO.[1]

The WHO guidelines consist of certain parameters to which the advertisements should be compatible. These are brand name, generic name, content of active ingredients, other ingredients known to cause problems, dosage forms, regimen, therapeutic uses, side effects and major ADRs, precautions, contraindications, warnings, major interactions, reference to medical literature, name of manufacturers or distributor, address of the manufacturer or distributor. These advertisements were also assessed for their compliance to OPPI guidelines. These guidelines state that all printed promotional materials other than short advertisements must be legible and include the name of the product (normally the brand name), the active ingredients, using approved names where they exist, the name and address of the pharmaceutical company or its agent responsible for marketing the product; date of production of the advertisement; and "abbreviated prescribing information" which includes an approved indication or indications for use together with the dosage and method of use, and a succinct statement of the contraindications, precautions and side effects.

Data collected is represented as number (no.) and percentage (%).

RESULTS

A total of 100 drug advertisements as per the inclusion and exclusion criteria were randomly selected and assessed as per the WHO and OPPI guidelines.

The organ system most commonly advertised in the medical journals in decreasing order were – drugs acting on dermatologicals (28%), anti–infectives for systemic use (25%), cardiovascular system (23%), systemic hormonal preparations excluding sex hormones and insulins (9%), nervous system (10%) and alimentary tract and metabolism (5%) as shown in table 1.

Table 1: Drug advertisements as per organ system based on ATC classification.

Sr No	Organ system	%
1	Dermatologicals	28
2	Cardiovascular system	25
3	Anti – infectives for systemic use	23
4	Systemic hormonal preparations excluding sex hormones and insulins	9
5	Nervous system	10
6	Alimentary tract and metabolism	5

Compliance to 'Ethical criteria for medicinal drug promotion' of WHO guidelines

The compliance to Ethical criteria for medicinal drug promotion of WHO by the advertisements published in medical journals is shown in table 2. 98% of the advertisements did not fulfil all the criteria as per WHO guidelines. All the advertisements mentioned brand name and generic name (100%) of the drugs. Most of the advertisements had listed active contents along with dosage form and manufacturer's name (97%), therapeutic indication/s (92%) while the address of the manufacturer/ distributor was there in 78%. Drug regimen was mentioned in 37% and a reference to literature was found in 30% of advertisements. Side effects, major ADRs and major interactions found mention in 27% of the advertisements. The least followed criteria, precautions, contraindications and warnings were mentioned in 25% of advertisements and other ingredients known to cause problem (15%). Overall, compliance of allopathic drug advertisements to WHO guidelines was 58.1%.

Table 2: Compliance as per 'Ethical criteria for medicinal drug promotion' of WHO.

Sr No	Criteria	% compliance
1	Brand name	100
2	Generic name	100
3	Content of Active ingredients	97
4	Other ingredients known to cause problems	15
5	Dosage form	97
6	Regimen	37
7	Therapeutic uses	92
8	Side effects and major ADRs	27
9	Precautions	25
10	Contraindications	25
11	Warnings	25
12	Major interactions	27
13	References to scientific literature	30
14	Name of manufacturer or distributor	97
15	Address of the manufacturer or distributor	78
	Overall compliance	58.1%

Compliance of advertisements to OPPI guidelines

None of the advertisements fulfilled all the criteria laid down in the OPPI guidelines (Table 3). All the advertisements mentioned the Brand name and most of them were compliant with listing of active ingredient/s (97%) and name of the manufacturer (97%) while 78% had mentioned the address of the manufacturer and only 51% gave abbreviated prescribing information. In the prescribing information, 97% had mentioned the dosage and 92% had approved indication/s written. Methods of use was mentioned in 37% of advertisements, side

effects in 27% while only 25% advertisements had mentioned precautions and contraindications. None of the advertisements had mentioned the date of advertisement.

Table 3: Compliance to ethical criteria for medicinal drug promotion of Organization of Pharmaceutical Producers of India (OPPI).

Sr no	*Criteria*	*% Compliance*
1	Brand name	100
2	Active ingredient/s	97
3	Name of manufacturer	97
4	Address of manufacturer	78
5	Date of advertisement	0
6	Abbreviated prescribing information Approved indication/s Dosage Method of use Contraindications Precautions Side effects	51 92 97 37 25 25 27
	Overall compliance	70.5%

DISCUSSION

In a study done to assess the impact of these advertisements in US revealed that during the first four years of a new medicine on the market, pharmaceutical companies may gain approximately US $2.43 for each dollar spent on medical journal advertisements for a medicine. The return on investment has been reported to increase to more than US $4 after that period.[10] These advertisements are more commonly for the drugs which give them huge profits or are used for longer duration of time like for chronic illnesses. In the present study, it was observed that the drugs most commonly prescribed were for dermatologicals, followed by drugs for cardiovascular system which are generally prescribed for longer duration and in some cases lifelong. Another group of drugs most commonly advertised were anti-infectives for systemic use as they are one of the most commonly used and also irrationally prescribed group of drugs.[11]

Most of the advertisements fared better in parameters like brand names, generic names and dosage form, content of active ingredients, therapeutic uses and name and address of manufacturer but other ingredients known to cause problems, side effects, major adverse drug reactions, precautions, contraindications, warnings, major interactions and references to scientific literature were among the least mentioned criteria in the advertisement. Not mentioning the parameters related to information on safety may be so as not to discourage

medical professionals from prescribing these drugs. This is in line with some of the studies done earlier which also opined that medical journals avoid mentioning the safety parameters related to the drugs.[12,13] The lack of mention of parameters such as contraindications, warnings and major drug interactions makes prescribing difficult and may prove to be detrimental to the health of the patient. Less than one third of the advertisements provided references to scientific literature which is consistent with another study done by Sharma AK et al.[14] This raises the risk of claims made by these drug advertisements regarding the benefits to appear as false. It was also observed that some of the references were not appropriate suggesting that even though references are present but they cannot be always trusted.

Overall the parameters which aid in selling the product were highlighted in majority of the advertisements and safety parameters were largely ignored. This selective passage of knowledge to medical professionals creates a gap in their knowledge regarding the benefits and risk of new drug for the patient. To avoid this, the critical appraisal of drug advertisements should be done more strictly before they are published in medical journals. For this purpose, they should have a panel of experts who may look into the scientific evidence for the benefit of the drugs. ADR Monitoring centres can also play a role by reporting adverse drug reactions due to these drugs so that more comprehensive information can be generated with latest data on the safety aspect of these drugs. Medical professionals must not rely solely on these advertisements but they should also have drug formularies available for their reference. In addition, medical professionals may also attend continuing medical education (CME) programs and conferences regularly to update their knowledge.

The regulatory authorities should be more vigilant in their surveillance of these advertisements and more stringent laws must be enforced to make the pharmaceutical companies accountable.

The authors are also of the opinion that there should be stringent scrutiny of these advertisements by a dedicated team which should include a trained pharmacologist before being published in the journals. The guidelines pertaining to drug advertisements should be strictly followed and the names of the habitual offenders may be published to act as deterrence for the companies which openly flout these regulations. Laws can be made more stringent to tackle with this menace. These few simple yet effective measures can go a long way in improving the quality of information circulated through medical journals in India.

CONCLUSION

Drug advertisements published in medical journals provide incomplete and selective information which is targeted to promote the sales of the drugs rather than provide full information necessary for the medical practitioners to make informed decision. The doctors on their part should be vigilant and not completely rely on them for information about the drugs.

Limitation

Only print advertisements in medical journals available in institutional library were considered for analysis. Online advertisements and Medical representatives promotional material was not considered.

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