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Research Article

An analytical survey of promotional drug literatures at C. U. Shah Medical College and Hospital, Surendranagar

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ABSTRACT

Background: The research and marketing of a new drug requires a lot of money by the pharmaceutical companies. Promotion through advertising brochures and leaflets is widely used to influence the physicians. Most of the times, this information is the only source of new drug information for the physicians. Hence, this study to analyze the appropriateness, accuracy, and validity of promotional drug literatures was undertaken.
Methods: Promotional materials were collected from outpatient departments of C. U. Shah Medical College and Hospital, Surendranagr. They were evaluated according to the "WHO criteria, 1988," and the references cited to support the claims were checked for their validity and authenticity. The images and the pictorial content were evaluated to find out any biased nature of gender representation.
Results: Evaluation of the total 486 brochures showed that none of them fulfilled all the nine criteria. Of the 308 claims, only 208 (42.79%) gave references to support the claims. Only 27 (39.13%) of the research articles among the 125 journal article cited were of high methodological quality. Among the 218 human figures, 144 were patients, and 103 were doctors. Female patients (62.5%) were depicted more than male patients (37.5%).
Conclusion: The present study showed that pharmaceutical companies do not strictly follow the WHO guidelines and majority of the research were sponsored by companies. Hence, more stringent regulations need to be implemented for the proper promotion and dissemination of information about the new drugs.

Keywords: Promotional literatures, World Health Organization criteria, Drug promotion

INTRODUCTION

The research of a new drug requires a lot of money by the pharmaceutical companies. However, even after the approval the pharmaceutical manufacturers invest a lot of money for the marketing and promotion of new drugs.[1] According to WHO, 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 drug.[2] The most widely used technique for promotion is "direct to physician" marketing. This type of marketing is done in the form of gifts, free samples, and drug brochures or through sponsored continued medical education.[3] Promotion through advertising brochures and leaflets is widely used to influence the physicians. Most of the times, the information given by the medical representatives through the promotional literatures is the only source of new drug information for the physicians.[1,4] Hence, the information provided by these promotional literatures can influence the prescribing decision of the physician and thus should be critically appraised.[5,6]

To evaluate the appropriateness of promotional drug literatures, WHO has published ethical criteria for medicinal drug promotion in 1988.[2] These criteria constitute general principles for ethical standards which can be adopted by governments according to their local needs. In India, with the help of the WHO criteria, a self-regulatory code of OPPI and IFPMA is available, which regulates the promotional activity of pharmaceutical industries.[7] In US, the FDA released a draft guidance in February 2008 for "good reprint practices" with regard to the distribution of medical/scientific journal articles or reference publications to healthcare professionals by drug/medical device manufacturers that discuss unapproved new uses for approved drugs or approved or cleared medical devices that are being marketed.[8]

METHODS

This observational cross-sectional study was based on critical evaluation of drug promotional literatures after getting approval from Scientific Research Committee.

The brochures were collected from various outpatient departments (OPD) running at C. U. Shah Medical College and Hospital, Surendranagar. The study was conducted over a period of 1-year from September 1st 2012 to August 31st 2013. From all the collected brochures, only those that were product advertisement and which marketed a single drug were included. Promotional material for various surgical instruments, medicinal devices, drug monographs, drugs' names list and reminder advertisements were excluded from the study. Reminder advertisements do not include therapeutic information and have different criteria for evaluation.[9]

The survey was done to analyze the promotional materials for their appropriateness, accuracy and ethical status according to "WHO criteria for ethical medicinal drug promotion, 1988."

WHO criteria for ethical medicinal drug promotion includes nine criterias,[2] which are:

1. The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug
2. The brand name
3. Amount of active ingredient(s) per dose
4. Other ingredients known to cause problems, i.e., adjuvant
5. Approved therapeutic uses
6. Dosage form or dosage schedule (while analyzing, dosage form and the schedule were evaluated separately)
7. Safety information including side effects and major adverse drug reactions, precautions, contraindications and warnings, and major drug interactions
8. Name and address of manufacturer or distributor
9. Reference to scientific literature as appropriate.

Whenever a claim is made in these advertisements, a reference should be included that reflects the scientific evidence. The claim must be consistent with the cited research and the research should be of proper methodology. The validity and authenticity of references were evaluated by answering the following five questions:

- Are all references cited retrievable?
- Are references of high methodological quality (which includes meta-analysis, systemic reviews and randomized controlled trials)?
- Did the company finance the research reported in the reference?

A reference was considered available if a soft copy of the cited material in the National Library of Medicine's PubMed or website of mentioned journal, freely in either full text or abstract format. References other than journal articles were searched through Google meta search engine.

The images and the pictorial content were evaluated for any type of gender bias, if any, in representing either doctors or patients in the promotional materials. The Chi-square test was applied to find the statistical significant difference and $p<0.01$ was considered statistically significant.

RESULTS

A total of 765 promotional materials were collected from various OPDs running at C. U. Shah Medical College and Hospital, Surendranagar. Of them, only 486 promotional brochures satisfied the inclusion criteria and then analyzed and evaluated.

Type of drug promoted

The total number of drugs that were promoted was 486, of which drugs belonging to the cardiovascular group (140, 28.8%) were the most marketed. Antimicrobial agents (97, 19.9%) and nutritional agents (49, 10%) like multivitamins and probiotics followed next in marketing. The classification as per the type of drug promoted is shown in Table 1 (Figure 1).

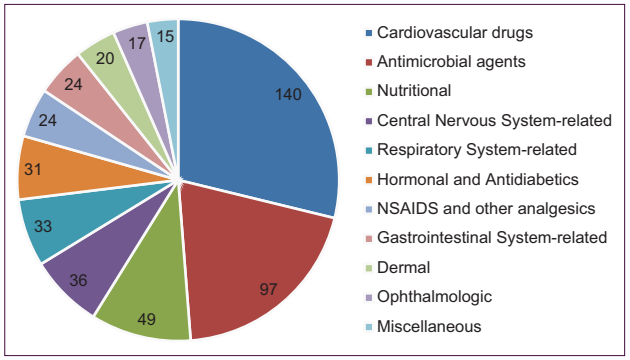

Figure 1: Classification as per the type of drug promoted (n=486).

Table 1: Classification as per type of drug promoted in literature (n=486).

Type of drug promoted	Number of promotional literatures, n (%)
Cardiovascular drugs	140 (28.8)
Antimicrobial agents	97 (19.9)
Nutritional	49 (10)
Central nervous system-related	36 (7.4)
Respiratory system-related	33 (6.8)
Hormonal and anti-diabetics	31 (6.4)
NSAIDS and other analgesics	24 (4.9)
Gastrointestinal system-related	24 (4.9)
Dermal	20 (4.2)
Ophthalmologic	17 (3.5)
Miscellaneous*	15 (3.1)

*Miscellaneous: Antiseptics, muscle relaxants, anticholinergics, etc., NSAIDS: Non-steroidal, anti-inflammatory drugs

Appraisal according to the WHO criteria

Evaluation of the total 486 brochures showed that none of them fulfilled all the nine criteria. The generic name and brand name were mentioned in all the collected brochures. However, information regarding references (52.5%), safety (30.5%) and adjuvant (9%) were mentioned in a lesser number of promotional materials. Information having only three criteria; namely INN, brand name, and amount of active ingredient per dose, were found in 4.2% of all the brochures (Table 2 and Figure 2).

Validity of references

Of the 486 brochures, 308 (63.37%) made claims about their respective drug. Only 208 (42.79%) gave references to support the claims. Retrievability of these references was checked and it was found that almost all (195, 93.75%) were retrievable. Among them, maximum references were from journal articles (125, 60.1%) of which research articles (69, 55.2%) had a major share. Rest of the references were from books, websites, and data on file. Among the research articles, only 27 (39.1%) were found to be of high methodological quality. It was also found 48 (69.6%) research articles referred were sponsored by the same company manufacturing the drug.

Images and pictures

Images in the form of human figures were found in 218 (44.9%) brochures. Overall 247 human figures were there in these 218 promotional materials, among which 144 (58.3%) were of patients and the rest 103 (41.7%) were representing physicians. This difference was found to be statistically not significant (p=0.0151). Of the 144 patients, 90 (62.5%) were females and 54 (37.5%) were males. The difference was statistically highly significant (p=0.062). Of the 103 physicians, 54 (52.4%) were males, and 49 (47.6%) were females. The difference in gender distribution among physician representation was statistically not significant (p=0.7646) (Figure 3).

DISCUSSION

The present study showed that pharmaceutical companies do not strictly follow any particular guideline in promotion of their drugs especially in the case of promotional literatures.

Table 2: Evaluation of promotional literature as per WHO criteria for ethical medicinal drug promotion, 1988 (n=486).

Criteria	Number of promotional literatures, n (%)
INN*	486 (100)
Brand name	486 (100)
Active drug per dose	465 (95.7)
Adjuvant	9 (1.8)
Approved therapeutic use**	432 (88.9)
Dosage form	486 (100)
Dosage schedule	350 (72.01)
Safety information	148 (30.5)
Name and address of the manufacturer	467 (96.1)
References to scientific information	255 (52.5)

*International non-proprietary name/approved generic name; **Drug use approved as per Central Drug Standard Control Organization, INN: International non-proprietary names

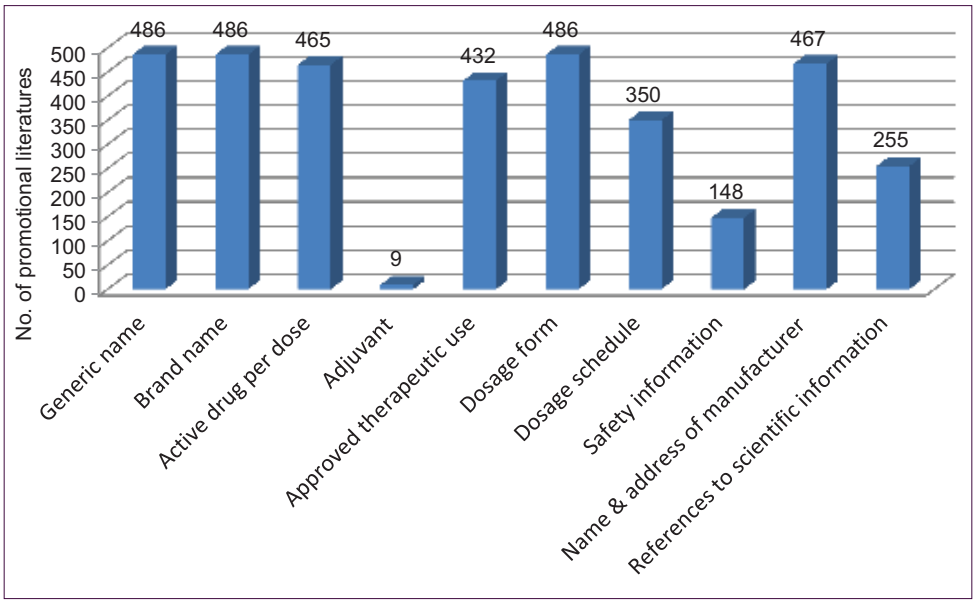

Figure 2: Evaluation of promotional literature as per World Health Organization criteria for ethical medicinal drug promotion, 1988.

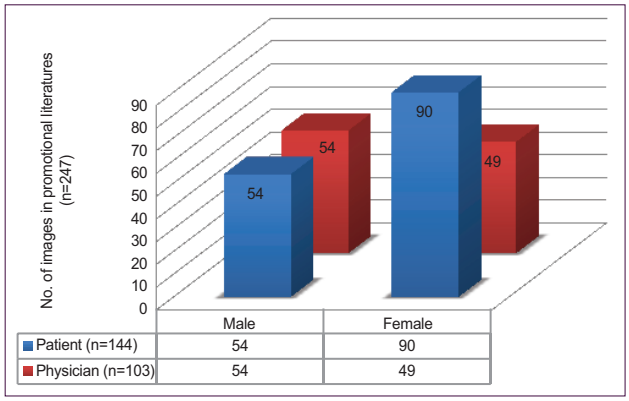

Figure 3: Difference in the gender representation in images shown in drug promotional literatures.

The cardiovascular group of drugs were the most promoted group of drugs, which might be due to the many fold rise in the incidence of cardiovascular related diseases. However, the increase in promotion of antimicrobial agents might be risky because of the development of drug resistance due to overuse. The WHO criteria were not fulfilled in all the brochures. Information regarding adjuvant and safety information which includes adverse drug reactions, contraindications, and drug interactions were neglected more often. More emphasis was given on attractive drug formulations and emotional claims regarding safety and efficacy. Our findings were found to be similar to those of previous studies.[10,11] Claims outnumbered the references provided in the promotional drug literatures, which were also reported by a study done by Islam and Farah.[12] Reference citations were found to be of poor quality and doubtful retrievability. The authenticity of the results of the references cited could not be justified as they were sponsored by the companies. Earlier studies done by Van Winkelen et al.[13] and Cooper and Schriger[14] have raised similar suspicions over the authenticity and reliability of the references. The images used in the brochures depicted both patients with the targeted disease and the treating physicians. Females with good looks were portrayed showing the effect of taking the marketed drug. A study by Curry and O'Brien[15] has shown that male heart patients and depressed female patients were represented more which strengthens our gender association. However, among the images of the treating doctor, female physicians were almost equally represented as the male physicians. This finding was in contrast to earlier studies regarding the gender bias of images in promotional material.[16,17] It is to be understood that drug promotional literatures are formed in such a way that physicians can be influenced to prescribe that drug. Hence, pharmaceutical companies use images of attractive persons as patients or physicians for marketing.

CONCLUSION

Given the present findings, physicians should remain cautious before prescribing the advertised drug solely on the basis of the information given in the promotional drug literatures. Further, physicians should practice the principles of evidence-based medicine in evaluating the validity of published studies. Since pharmaceutical companies do not strictly follow the WHO guidelines, more stringent regulations need to be implemented for the proper promotion and dissemination of information about the new drugs.

One major limitation of this study is that it is cross-sectional in nature, so the study design fails to measure any concrete outcome or cause and effect. Furthermore, the drug promotional materials' collected only from various OPDs of a tertiary level teaching hospital were analyzed, and those distributed to the private practitioners were not evaluated.

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