

Evaluation of drug promotional brochures in a tertiary teaching hospital of Kannur, India

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ABSTRACT

Background: Pharmaceutical industries worldwide are heavily involved in aggressive drug promotions. WHO has framed guidelines for ethical drug promotion in 1988. The transparency of pharmaceutical advertisements is important because decision of the physician is likely to be influenced by the claims made by the pharmaceutical companies in the promotional drug brochures and pharmaceutical industries treat their marketing material as “educational material” for doctors. Authors did this study to analyze the information given on drug promotional brochures by the drug companies using ethical criteria of drug promotion by WHO 1988 and to verify the authenticity of the claims given by the pharmaceutical companies in drug promotional brochures.

Methods: Cross sectional study extending from 1/8/2012 to 31/7/2013. 612 drug promotional brochures satisfied our inclusion criteria. Drug brochures were analyzed with WHO ethical criteria 1988 and further categorizing the data into type of claims, number and source of references. Validity of journal articles were checked by using a validity measure developed by Cardarelli.

Results: Total 612 brochures satisfied inclusion criteria. INN was mentioned in 93.8% of collected brochures. Brand name was mentioned in 100% brochures. Content of active ingredients was mentioned in 92% of brochures. Name of the other ingredients known to cause problem 28.4% of brochures. Dosage form or regimen was mentioned in 23.2% of brochures. Approved therapeutic use mentioned in 65.7% brochures. Side effects and major adverse drug reactions were mentioned in 31.4% brochures. Precautions and contraindications and warnings were mentioned in 30.4% drug promotional brochures. Drug interactions were mentioned in 26.5% brochures. Name and address was mentioned by 69.1% brochures. There were 1144 claims and 739 references. Efficacy claims were 84.88% of the total claims. Main source of reference was from journal articles (74.1%) and among them 49.65% were randomized control trials. Only 47.94 % of the journal references were valid.

Conclusions: Brochures were lacking in vital information which included contraindication, warning, precaution, name of the other ingredients known to cause problem hence companies were found violating WHO ethical criteria. Claims were not well supported with references. Less than half of the given journal references were only valid. This study highlights the need of healthcare professionals to remain cautious about promotional material presented by pharmaceutical representatives.

Keywords: Brochures, Drug promotion, WHO criteria

INTRODUCTION

Medicines can play a crucial role in the attainment or maintenance of health, but it is vital that they are prescribed rationally. Doctors play a key role in ensuring

that medicines are used appropriately. However, in recent years, growing concern has focused attention on the relationship between health-care professionals and the pharmaceutical industry - particularly the industry's influence on prescribing and dispensing decisions through a range of promotional tools, which can influence treatment choices. Pharmaceutical industries worldwide are heavily involved in aggressive drug promotions.¹

New drugs in health care system are prescribed to the patients through doctors and the availability is of little value unless the prescribing doctor is aware of its existence and has important scientific information to effectively use it.² Promotional product literature is more selective. It is disseminated through a controlled means and has got a targeted audience. The initial readership is 100%.³

A study conducted in Boston school of public health shows that in United States 81% more people in their marketing department than research and development department.⁴ Most continuing medical education activities are primarily supported by drug companies who often use this opportunity to influence the prescribing habits of doctors. These activities are paid for from the advertising budgets of these corporations.^{5,6}

A recent study conducted by the Planning Commission's high-level expert group (HLEG) said the pharmaceutical industry spent more than 25% of its annual turnover on sales promotion alone as compared to 7% on research and development in 2008-09. Drug companies were recently caught red-handed writing scientific recommendations of their own products and submitting them to the Drug Controller General of India (DCGI) after getting them endorsed by top doctors for quicker marketing approval. Usually, scientific recommendations are submitted by experts after they have studied a drug's content. The endorsement is considered a crucial testimony that convinces the DCGI to trust the drug's effectiveness, in turn, allowing it to be launched in the market.⁷

WHO has framed guidelines for ethical drug promotion. Even Food and Drug Administration has code of conduct governing the control of drug promotional brochure. It is up to the pharmaceutical industry to follow the code of ethics. Following the code of conduct is one of the conditions of membership for manufactures association. Currently there are many code of practices out of which the important ones are International Pharmaceutical Association code of 2012 and Indian Pharmaceutical Associations code 2012 and WHO ethical criteria 1988.⁸⁻¹⁰

WHO defines drug promotion as "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." Pharmaceutical companies have several ways of drug promotion which include leave behind leaflets, emails and drug promotional brochure.¹⁰ The transparency of pharmaceutical advertisements is important because decision of the

physician is likely to be influenced by the claims made by the pharmaceutical companies in the promotional drug brochures and pharmaceutical industry treat their marketing material as "educational material" for doctors.¹¹⁻¹⁴ Many studies have shown that drug advertisements are inconsistent with the code of ethics. But, very few studies have been conducted in India.¹⁵⁻¹⁷ It is of utmost of importance to analyze the promotional material of the drugs in step with the growing popularity of evidence-based medicine.^{18,19} Hence with this background authors undertook this study to evaluate the drug promotional brochures in a tertiary teaching hospital in Kannur.

METHODS

The present cross sectional study was carried out in Kannur Medical College and Hospital from 1.8.2012 to 31.7.2013. The study was carried out after the approval of Institutional Ethical Committee of Kannur Medical College. All allopathic drug promotional brochures were collected from various outpatient departments of Kannur medical college hospital. Brochures containing ayurvedic preparations, brochures for medical devices, single brochures promoting more than two brands, reminder advertisements, repeat brochures, drug brochures promoting more than two brands on a single brochure were excluded. Reminder advertisements do not represent any therapeutic information and has different criteria for evaluation. Prior to the commencement of study Heads of all the clinical departments in the hospital were approached and the type of study was explained to them and verbal consent to conduct the study was taken. All the department heads were requested to preserve whatever drug promotional brochure were presented to them by the medical representatives. Every day at 4pm except Sunday, drug promotional brochures presented to the consultants were collected from the respective department. Among the collected brochures satisfying inclusion criteria were kept and analyzed. Further the brochures collected daily were entered in the semi structured self-validated profoma having WHO ethical criteria 1988 and validity score of Robert Cardarelli. As per WHO ethical criteria for drug promotion authors analysed all the collected drug promotional brochures for its authenticity and retrievability. The International Nonproprietary Name (INN) component of the WHO ethical criteria of drug promotion was verified using the published list of INN available from the Controller General of patents, designs and trade mark. Further the brochures were analyzed for brand name whether it was mentioned or not, and the content of active ingredient(s) per dosage form or regimen. The other points evaluated included name of other ingredients known to cause problems, approved therapeutic uses, dosage form or regimen, side effects and major adverse medicine reactions, precautions, contraindications and warnings, major interactions, name and address of manufacturer or distributor, reference to scientific literature as appropriate.

Claims if any were further categorised into the types of claims. A claim was defined as, any statement in drug promotional brochure concerning the safety or efficacy of a drug and other statements related to drug, patient or therapy presented with or without references. Further number of claims were noted down. Each claim was categorised into various types according to the nature of claim observed which included claims on cost, efficacy, safety, pharmacokinetic property, pharmaceutical property, and emotional claims. References in support of the claims were categorised into type of reference i.e, if the reference is quoted from a journal then source of reference is categorised as journal likewise into books, websites, data on file and others. Journal article was categorised into the type of scientific literature in it which included randomised control studies, meta analysis etc. Validity of the given journal references was checked using a validity score developed by Roberto Cardarelli et al. The reference in the drug promotional brochure was considered valid if it satisfied 3 out of 3 major criteria and at least 2 out of 3 minor criteria. Data analysis was done by using SPSS version 20. Results were expressed in numbers and percentages.

RESULTS

A total of 612 distinct drug promotional brochures were obtained from 1008 drug promotional brochures which were collected during our study period. In these brochures 67.8% were single dosage forms and 32.2% were fixed drug combinations. Out of the 612 brochures collected during our study period 180 (29.5%) comprised of chemotherapeutic drugs, followed by 86 (14.1%) non steroidal anti inflammatory drugs, 67 (10.9%) cardiovascular system, 55 (9%) central nervous system, 54 (8.8%) skin, 49 (8%) respiratory system, 32 (5.2%) gastrointestinal system, 20 (3.3%) antihistamines, 18 (2.9%) hormonal, 18 (2.9%) ocular drug, 14 (2.3%) blood, anaesthetic drugs 7 (1.1%) and others consisting of nutritional supplements 12 (2%).

The 612 drug promotional brochures collected were analysed with the WHO ethical criteria 1988. The results are shown in Table 1.

Out of 612 brochures, 73.52% were having claims. There were a total of 1144 claims in the analyzed drug promotional brochures out of which 84.88% claims on efficacy of drugs, followed by 42% regarding extra emotional claims, 33.55% on safety of the drug, 31.11% claims on convenience, 25.7% claims on pharmaceutical property, 22% on pharmacokinetic claims, 14.88% claims on cost.

Authors observed maximum number of two claims per brochure contributing to 25% of total drug promotional brochures analyzed. Brochures having one claim per brochure contributed to 12.3% in this study. 18% of the brochures in this study were having 3 claims per brochure. 10.21% of the brochures in this study were

having 4 claims. 6% of the brochures in this study were having 5 claims per brochure. 2.1% of the brochures in this study were having 6 claims per brochure. Only 0.1% of the brochures in this study were having 7 claims per brochure.

Table 1: Analysis of drug promotional brochures with WHO ethical criteria.

| Criteria | Brochures fulfilling criteria (n=612) | Percentage |
|---|---------------------------------------|------------|
| International non proprietary name | 574 | 93.8 |
| Brand name | 612 | 100 |
| Content of active ingredient | 563 | 92 |
| Other ingredients known to cause problem | 438 | 71.6 |
| Dosage form or regimen | 470 | 76.8 |
| Approved therapeutic uses | 402 | 65.7 |
| Side effects and major adverse drug reactions | 420 | 68.6 |
| Precautions, contraindications and warnings | 186 | 30.4 |
| Interactions | 162 | 26.5 |
| Name and address of manufacturer/ distributor | 423 | 69.1 |

In this study authors observed that there were 739 references out of which 74.01% were from journals, 12.99% from websites, 8.11% were data on file, 0.81% reference from books and other sources were 4.05%. The other sources included treatment guidelines 1.3%, newspaper or magazine articles 2.1%, and clinical trial data 1.1%. Among the 739 references in the 612 drug promotional brochures, the type of study authors observed in the references were randomized control trial 49.65%, observational studies 13.92%, review articles 9.74%, meta analysis 8.35%, and others 9.97% which included correspondence, case reports and letters to editorial. Validity of the references of the journal article was analyzed using a scale developed by Robert Cardarelli. Authors observed that 47.94% of the references in the journal articles were valid.

DISCUSSION

Companies spend nearly 35% of sales on marketing of drugs and spend only one third on research and development.⁶ Promotion is nothing but one of the tactful ways to push the drugs into the market. Drug marketing does affect prescription habits of doctors and hence increases the sale. Physicians agree to the fact that meeting

with the medical representatives affect their prescribing behaviour. Inappropriate prescribing contributors will grave public health and increase health care costs of the community.⁶⁻¹⁰ In this study 93.8% of drug promotional brochures mentioned INN or generic name. Similar results also have been reported by Phoolgen et al, in Nepal found that 87.32% of drug promotion brochures mentioned INN name.¹⁵ Similarly Mali et al, in his study in Nagpur on 513 drug promotion brochures reported 95.9% of brochures to be containing INN or generic name. However there were some studies which reported lower number of INN or generic name. Vlassov et al, in their study on 207 drug promotional brochures in Russia found that, in 39% of brochures only were reporting INN or generic names.^{20,21}

Brand name was mentioned in 100% of brochures which was the same observation as in Mali et al study conducted in Nagpur, Phoolgen et al, study conducted in Nepal and Kasyap et al, study conducted in Bangalore.^{15,17,21}

Name of other ingredients known to cause problems was mentioned in 28.4% of drug promotional brochures in this study while other authors (Kasyap et al, study observed 12%, Mali et al observed 1.9%) have observed less percentage of brochures mentioned this criteria. Phoolgen et al observed none of the drug promotional brochures mentioned other ingredients known to cause problem in their literature.^{15,17,21}

Regimen or drug dosage was mentioned in 76.8% of brochures in this study. This finding was bit lower when compared with the study of Phoolgen et al, Chirac et al, Khakhkhar et al where it was 83.10%, 87%, 84% respectively.¹⁴⁻¹⁶ But in the study by Mali et al only 32.2% of brochures mentioned drug dosage.²¹

Approved therapeutic use was mentioned in 65.7% of drug promotional brochures. The findings from other studies revealed that it was slightly more than our results. The study conducted by Mali et al in Nagpur government hospital observed that out of 513 total brochures collected only 86.3% of brochures had mentioned approved therapeutic use of the drugs.²¹ Similarly, in the study conducted by Phoolgen et al, in Nepal, out of 100 brochures collected from psychiatric outpatient department, 83.10% of brochures mentioned approved therapeutic usage.¹⁵

Side effects and major adverse drug reactions were mentioned in 31.4% of total drug promotional drug brochures collected in this study. Phoolgen et al, study showed that only 11.27%, Mali et al, and by Khakhkhar et al, in Gujarat, showed 8% of drug promotional brochures had mentioned side effects and adverse effects in both the studies.^{15,16,21}

In this study, 30.4% of the drug promotional brochures mentioned precautions; this percentage was less when compared to other studies. Khakhkhar et al, observed only 6%, Kasyap et al, observed 11% and Vlassov et al, had

observed of 11% of total promoted brochures mentioned precautions in their study.^{16,17,20} Major drug interactions were mentioned in 26.5% of the drug promotional brochures, which was more when compared to other studies. In the study by Phoolgen et al, and Vlassov et al, it was observed that only 8.45% of brochures mentioned major interactions.^{15,20} 69.1% of the drug brochures mentioned name and address of the manufacturer. But in the study by Mali et al, Phoolgen et al, and Khakhkhar et al, it was observed that 70.6%, 84.50% and 100% respectively mentioned the name and address of the manufacturer respectively.^{15,16,21}

Out of 612 brochures, 73.52% of the brochures had claims out of which, 84.88% of the brochures had efficacy claims. This was similar to the study conducted by Mali et al in Nagpur, where they found 92% of brochures mentioning efficacy claims.²¹

Safety claims were seen in 33.55% of the brochures studied. 42% of, 31.11% of, 25.7% of, 22% of and 14.88% of the brochures had extra emotional claims, claims on convenience, pharmaceutical property, pharmacokinetic property and costs respectively. The findings of our study was similar to study conducted in Nagpur, by Mali et al, where they observed 37.8% of claims on safety, 29.6% of on pharmaceutical property, 17.9% of on extra emotional claims, 17.7% of on cost effectiveness, 16.7% of on pharmacokinetic properties, 16.4% of on convenience.²¹

Pharmaceutical claims in this study were mentioning about authentic certification of manufacturing plant, GMP certification, various packaging characteristics or technologies of the drug production. These claims were not having any references. Claims were highlighted on the promoted brochures using maximum paper area and depriving the brochure of its therapeutic information. Cost effective claims in the drug promotional materials mentioned either in the price of the drug or compared its price with competitive brands. Pharmaceutical companies are very clever to make multiple claims in their drug promotional brochures. In this study 44.4% of the collected brochures were having references. A total of 1144 claims were made by 739 references, indicating paucity of references to the claims in the brochures studied.

CONCLUSION

From the study it is evident that promotional materials do not follow the WHO's Ethical Criteria for Medicinal Drug Promotion. Most claims in the brochures do highlight the selective part of information about the drug and frequency of misleading promotion is very much difficult to determine. This study highlights the need of health care professionals in Kerala to remain cautious about promotional materials presented by pharmaceutical representatives. Creating awareness to the consultant regarding the pitfalls in the information given in pharmaceutical drug promotional brochures and raising

complaints against the irrational drug promotion can be done to improve the scenario.

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