



EVALUATION OF RATIONALITY OF DRUG PROMOTIONAL LITERATURE IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA

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ABSTRACT

Pharmaceutical advertisements are one of the important methods of spreading the information about drugs to the concerned Physician. Misleading drug advertising encourages drug consumerism rather than rational use of drugs. To add to the problem, developing countries lack a strong system to keep a check on such activities. As there are few studies conducted in this region on rationality of drug promotional literature, the present study was carried out to evaluate the rationality of drug promotional literature. This was a cross sectional, observational study conducted in the department of Internal Medicine at tertiary care hospital in South India, from November 2014 to April 2015. A total of 132 advertisements were collected and tested against WHO criteria for ethical medicinal drug promotion. International non-proprietary names (INN) or the approved generic name of the drug was mentioned in most of advertisements (96%). The active ingredient was mentioned in 88.6% of the promotional materials and other ingredients causing adverse events was mentioned in 11%. Side effects, precautions, contraindications and drug interactions were mentioned in <30% of the promotional materials. The brand name was mentioned in all the promotional literature (100%). In this study, it is found that only 24.4% claims were supported by references. Most common reference used was journal articles and most common type of journal article was original article. Some promotional materials used case reports and editorial as the reference. Promotional materials does not follow the WHO's Ethical Criteria for Medicinal Drug Promotion. Physicians should not totally rely on these advertisements for prescribing information and other parallel sources should also be used.

Keywords: Drug promotional literature, Pharmaceutical promotion, WHO criteria, Brief prescription information.

INTRODUCTION

Pharmaceutical advertisements is one of the important methods of spreading the information about drugs to the concerned Physician or Prescribers"[1]. Besides personalized visits by designated representatives, various other methods are also used to spread the awareness about the drug like sample drugs, token gifts, drug brochures, reminder articles and advertisements in medical journals [2]. Misleading drug advertising encourages drug consumerism rather than rational use of drugs. To add to the problem, developing countries lack a strong system to keep a check on such activities [3, 4]. According to the World Health Organization (WHO),

medicinal drug promotion should be reliable, accurate, truthful, informative, balanced, up-to-date and capable of substantiation. Text and illustration contents should be consistent with scientific information [5]. Advertisement claims of pharmaceutical companies have been criticized for making exaggerated claims, emphasizing relative over absolute effect measures, omission of adverse effects, and for use of different standards for promoting drugs in resource limited countries [6, 7].

For rational use of drugs, it is very important for a physician to critically analyze research findings and draw conclusions as misleading and wrong information is not

uncommon in the literature used for drug promotion [8, 9]. As there are few studies conducted in this region on rationality of drug promotional literature, the present study was carried out to evaluate the rationality of drug promotional literature

MATERIAL AND METHODS

This was a cross sectional, observational study conducted in the department of Internal Medicine at tertiary care hospital in South India, from November 2014 to April 2015. Collected brochures were then explored to exclude the following materials: Literature promoting medicinal devices and equipments, ayurvedic medicines, drug monographs, reminder advertisements. A total of 132 advertisements were collected and tested against WHO criteria for ethical medicinal drug promotion as below

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
 7. Side effects and major adverse drug reactions
 8. Precautions, contraindications and warnings,
 9. Major drug interactions
 10. Name and address of manufacturer or distributor
 11. Reference to scientific literature as appropriate
- The data was recorded and analyzed using Microsoft Excel (2007 version). The results are explained in frequency and percentage

RESULTS

A total of 168 promotional literatures were collected from Internal Medicine department. analysis of the information present in the promotional literature is according to WHO criteria is shown in table 1.

Table 1. Evaluation of promotional literature as per WHO criteria

| Criteria | Frequency | Percentage |
|---|-----------|------------|
| INN or approved generic name | 162 | 96.4 |
| Brand name | 168 | 100 |
| Amount of active ingredient(s) per dose | 149 | 88.6 |
| Other ingredients known to cause problems | 19 | 11.3 |
| Approved therapeutic uses | 150 | 89.2 |
| Dosage form or dosage schedule | 128 | 76.1 |
| Side effects and major adverse drug reactions | 52 | 30.9 |
| Precautions, contraindications and warnings | 41 | 24.4 |
| Major drug interactions | 22 | 13 |
| Name and address of manufacturer or distributor | 102 | 60.7 |
| Reference to scientific literature as appropriate | 41 | 24.4 |

INN = international nonproprietary name

The type of references mentioned in the promotional material is shown in table 2.

Table 2. Types reference mentioned in the promotional material

| Reference | Frequency | Percentage |
|------------------|-----------|------------|
| Journal article | 143 | 54.1 |
| Website | 39 | 30.9 |
| Books/monographs | 22 | 13 |
| Data on file | 33 | 52.3 |
| Others* | 49 | 55.3 |

* = Departmental study, prescribing information, newspaper articles, conference proceedings

Some materials mentioned more than one type of reference

The most reference was from journal articles

The type of journal articles mentioned in promotional literature is shown in table 3

Table 3: Type of journal articles mentioned as reference

| Article type | Frequency | Percentage |
|----------------------------|-----------|------------|
| Original article | 141 | 83.9 |
| Review article | 55 | 32.7 |
| Case report/series | 42 | 25 |
| Guideline | 23 | 13.6 |
| Meta-analysis | 18 | 10.7 |
| Letter to editor/Editorial | 11 | 6.5 |

Some promotional materials mentioned more than one type of journal articles

Most common journal article mentioned was original article.

DISCUSSION

Pharmaceutical companies did not follow the WHO criteria for drug promotional literature. Usually pharmaceutical companies make an attempt to highlight and present only the positive aspects and advantages of their products, but downplay any negative information [9, 10]. In this study, international nonproprietary names (INN) or the approved generic name of the drug was mentioned in most of advertisements (96%) and was a similar finding to the study performed in Nepal [10] and India [11].

The active ingredient was mentioned in 88.6% of the promotional materials and other ingredients causing adverse events was mentioned in 11% of the materials. This finding is higher when compared to other studies [11, 12]. Therapeutic indications were mentioned in 89% of the materials. This finding is similar to other studies [9-11]. The brand name was mentioned in all the promotional literature (100%). In other studies mentioned above, the brand name was mentioned in all the materials. Side effects, precautions, contraindications and drug interactions were mentioned in <30% of the promotional materials.

In this study, it is found that only 24.4% claims were supported by references; this is very less as compared with western studies, but similar to the studies done in developing countries [13]. Also the type of reference mentioned is similar with the other study [13]. But studies such as case report and editorial were mentioned in some the promotional literature which have low credibility. Promotional literature as far as possible should mention Meta-analysis or Randomized control trials as the main reference.

Promotional material is one of the important source of drug information to the physicians and physicians do get influenced by these materials [14]. One of the important reason may be the lack of time to critically

appraise the advertised drug is usually not available and they may lack the skills required [4]. Misleading drug promotion has appeared to be a vicious circle between the drug companies and health professionals that does more harm than good worldwide [15].

These unethical drug advertisements should be viewed seriously because of the past experiences like in the promotion of rofecoxib (Vioxx), “drug marketing got well ahead of the science” [16]. The successful hormone replacement therapy (HRT) marketing campaign “convinced physicians that so called HRT prevented cardiovascular disease before one single clinical trial with cardiovascular disease end points had ever been done [17].

Limitations of the study

This present study was conducted in a only one department and the sample size was small. Future studies should be done on large sample size and include additional criteria apart from WHO criteria for rationality of drug promotional literature.

CONCLUSION

Promotional materials does not follow the WHO’s Ethical Criteria for Medicinal Drug Promotion. Promotional literature concentrated more on commercial aspect rather than ethical and educational aspect. Physicians should not totally rely on these advertisements for prescribing information and other parallel sources should also be used.

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CONFLICT OF INTEREST

The author declares that he has no conflicts of interest.

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