

EVALUATION OF THE RATIONALITY OF CLAIMS MADE IN DRUG PROMOTIONAL LITERATURE IN WEST CHENNAI

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ABSTRACT

Objective: The study was aimed to evaluate the adequacy of information provided by drug promotional literature using WHO criteria. They were also evaluated for the quality, types of claims and the genuineness of these claims in this literature.

Methods: 412 drug promotional literature were collected from 20 busy physicians in the western part of Chennai from their private clinics. In addition to carrying out of "WHO criteria, 1988," the brochures were examined for the quality of coverage using a pre-tested and pre-validated checklist and types of claims and the genuineness of these claims were evaluated for their recoverability and accuracy.

Results: It was found that all the WHO criteria were not fulfilled by any of the promotional literature. 91.2% of leaflets satisfied the 4 WHO criteria namely, the brand name, generic name, approved therapeutic uses, name and address of the manufacturer. A most neglected aspect of drug promotion was information regarding drug interactions, precautions, Adverse drug reactions and overdosage (<10%). Of 412 leaflets collected, the quantitative research methods were mentioned in 67 (16.2%). Cardiovascular drugs and nutritional supplements were the most promoted drug groups (23% and 17%, respectively). 412 drugs promotional literature made a total of 954 claims. References were cited in 47% of the literature of which 96% were from the indexed journal and were retrievable.

Conclusion: Drug promotional literature analyzed by this study was inadequate in terms of their adequacy, quality and genuineness of coverage. Thus, the pharmaceutical companies did not follow the WHO guidelines while promoting their products, thus aiming to satisfy their commercial motive rather than fulfilling the educational aspect of promotion.

Keywords: Promotional literature, Ethical criteria for drug promotion, Pharmacy practice, marketing practice.

INTRODUCTION

The important sources of information on any new drug include textbooks, briefings by medical representatives, journal manuscripts, product monographs from pharmaceutical companies, drug promotional literature, etc. According to World Health Organization's (WHO) criteria for promotion of medical drugs, "promotion refers to all the informational and persuasive activities of manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs" [1]. Drug promotional literature distributed by pharmaceutical companies is an important source of prescribing information to the doctor, and the main aim of pharmaceutical advertisements is to persuade physicians to prescribe the product that is promoted, [2]. One of the major marketing strategies of pharmaceutical companies is "direct to physician marketing" [3,4]. The drug promotional literature should provide relevant research findings regarding the drug. The validity of research findings, its critical appraisal is often ascertained by the physician depending on the adequacy of the information provided in the promotional literature. There are ethical guidelines that need to be followed for the promotion of drugs at the national, as well as the international level. There are two important guidelines that are to be followed for the regulation of drug promotional activities at the international level; they are the Ethical criteria for medicinal drug promotion by WHO [1] and the Code of Pharmaceutical Marketing Practices by International Federation of Pharmaceutical Manufacturers Association [5]. The majority of the drug promotional activities in India are governed by the Organization of Pharmaceutical Producers of India, which is a self-regulatory code of pharmaceutical marketing practices [6]. The pharmaceutical companies targets doctors/prescribers through visits on a weekly or monthly basis, distributing attractive, eye-catching brochures that are often misleading and confusing [7]. Improper advertisement of drugs

encourages drug consumerism instead of the rational use of drugs. Moreover, a strong regulatory system is absent in developing countries to keep a check on such activities.

In India, very few studies regarding the quality, adequacy, and genuineness of the scientific information provided in the promotional literature of drugs that are being distributed by pharmaceutical companies have been carried out [8]. Therefore, this study has been taken up with the aim to analyze the drug promotional literature in terms of these three parameters.

Aims and objectives

With this background, this study was carried out to evaluate the drug promotional literature in accordance with the WHO criteria and also to evaluate the quality, types of claims and the genuineness of these claims with the hope that it might help the physicians to find out as to what extent they may rely on this source of information.

METHODS

The study was conducted as an observational, cross-sectional study in the outpatient department of 20 busy physicians in the western part of Chennai. A total of 412 drug promotional literature (brochures) were collected randomly from 20 busy physicians from their private clinics for a period of 1-month starting from 1st June to 30th June 2014. The primary screening process was carried out on all promotional literature collected and literature that promotes modern medicines, where at least one therapeutic claim were observed, was taken for the analysis in this study. Those literatures promoting medicinal equipment's (blood glucometer, insulin pump, etc.) and devices (tongue depressors, medical thermometers, etc.) and orthopedic prosthesis, product monographs, Ayurvedic and Siddha medicines, reminder advertisements (they do

not present any therapeutic information), were all excluded from the analysis [9]. Ethical medicinal drug promotion criteria by WHO, which sites what information the drug promotional literature should contain was used for the analysis of the adequacy of coverage. A pre-tested and pre-validated checklist with nine parameters representing the quantitative analysis method was used for the analysis of the quality of the promotional literature [10]. The validity of the claims that were made in drug promotional literature were cross-checked by referring to standard literature online, listed in databases such as PubMed, Medline and Cochrane reviews, standard textbooks and peer-reviewed journals [11]. The references mentioned in this literature were also evaluated for their authenticity and retrievability.

RESULTS

A total of 486 drugs were promoted in 412 drug promotional literature. Of the 486 drugs promoted, 185 (38%) were single drug formulation and 301 (62%) fixed dose combinations (Fig. 1). Most commonly promoted group of drug was cardiovascular 112 (23%) followed by nutritional supplements 83 (17%), miscellaneous 59 (12.1%), antibiotics 56 (11.6%), hormones and antidiabetics 48 (9.8%), obstetrics and gynecology 41 (8.4%), non-steroidal anti-inflammatory drugs 35 (7.2%), gastrointestinal tract drugs 32 (6.6%) and respiratory system drugs 20 (4.1%) (Fig. 2).

From the 412 drug promotional literature collected, it was found that none of the brochures fulfilled all the 11 WHO criteria. The brand name was mentioned in all the drug promotional literature, whereas the generic name was found in 99.27%. Approved therapeutic use of the drug was mentioned in 393 (95.3%) drug promotional literature. 91.2% of leaflets satisfied the 4 WHO criteria, namely, the brand name, generic name, approved therapeutic uses, name and address of the manufacturer. Of all the literature, the most neglected aspects of drug promotion was information about drug interactions, precautions, adverse drug reactions and over dosage (<10%). Detailed analysis of fulfillment of WHO criteria are given in Table 1.

Of 412 drug promotional literature, research findings by quantitative methods were mentioned in only 67 (16.2%). Drug to drug

comparison and “p” value was mentioned in 51 and 44, respectively. The confidence interval for the samples was obtained using SPSS software. Randomization and blinding status were mentioned in 36 and 29, respectively. The power of the study was mentioned in six and confidence interval was mentioned in seven. The quality of coverage with reference to the reporting of quantitative research findings is shown in Table 2.

Pharmaceutical companies also made multiple claims in the literature, apart from giving therapeutic information, it was observed that on an average two claims were made per literature i.e., 954 claims were made in 412 drug promotional literature (2.31 per literature). Claims about efficacy were made in 91% of the literature. 72.08% claims were supported with scientific references. The majority of references cited were from journal articles followed by monographs, books, case reports. References were cited in 47% of the literature of which 96% were from the indexed journal. The genuineness of scientific information is shown in Table 3.

DISCUSSION

It is observed that there is more of a commercial relationship between the prescriber and the pharmaceutical company, in the drug promotional activity that are being carried out [9]. The therapeutic information given in this literature was more of a bias than to help physicians reach a rationalized decision about the drug that was being promoted. These literature were full of claims regarding safety or efficacy that were not supported with proof or rather unsubstantiated, and the claims were therapeutically irrelevant also [3]. There is evidence that these kinds of drug promotional practices can negatively affect both patients and the healthcare professionals. The inferences from this study illustrated that the reporting quality of numerous parameters in the promotional

Table 1: Analysis of literature according to WHO criteria n=412 (adequacy of coverage)

Criteria	Number of samples	Mentioned (%)
INN	409	99.27
Brand name	412	100
Content of active ingredient (s)	359	87.1
Adjuvant	5	1.21
Approved therapeutic uses	393	95.3
Dosage form or regimen	365	88.6
Side effects and adverse reactions	37	9.8
Precautions, contraindications	34	8.25
Major interactions	22	5.33
Manufacturer’s name and address	381	92.4
Reference to scientific literature	194	47

INN: International non-proprietary name

Table 2: Analysis of various parameters of quantitative research (quality of coverage)

Parameter	Number of samples	n=412 (%)	n=67 (%)	95% confidence interval
Drug to drug comparison	51	12.38	76.12	74.35-77.89
Random assignment	36	8.74	53.73	51.96-55.5
Blinding status	29	7.04	43.28	41.51-45.05
p-value given	44	10.68	65.67	63.9-67.44
Comparability of groups	3	0.73	4.48	2.71-6.25
All accounted for or ITT	4	0.98	5.97	4.2-7.74
ARR/NNT reported	31	7.52	46.27	44.5-48.04
Power mentioned	6	1.46	8.95	7.18-10.72
Confidence interval mentioned	7	1.7	10.45	8.68-12.22

ITT: Intention to treat, ARR: Absolute risk reduction, NNT: Number needed to treat

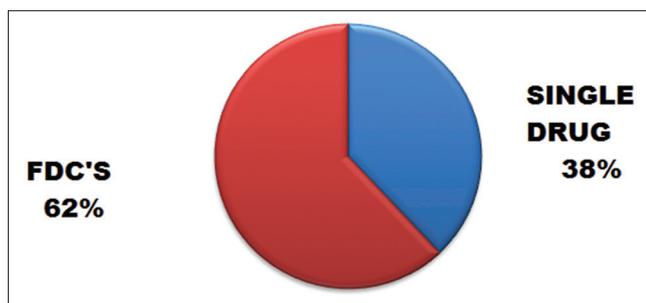


Fig. 1: Classification as per type of drug formulation (n=486)

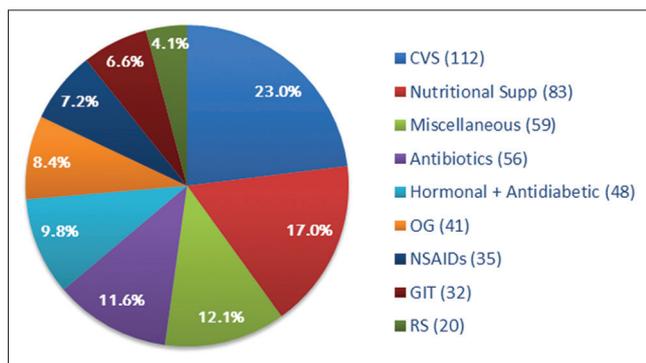


Fig. 2: Types of drugs promoted in the literature (n=486)

**Table 3: Analysis of genuineness of scientific information
n=412 (genuineness of coverage)**

Parameter	Number of samples	Percentage
Authentic	123	29.9
Exaggerated	114	27.67
Controversial	95	23.1
Misrepresentation	52	12.62
False	28	6.8

literature of drugs promoted by pharmaceutical companies is not in line with the standards. Therapeutically irrelevant information was printed, compromising space that would have been used to cite more important scientific information. This unethical drug promotional literature phenomenon is not confined only to India but has been under observation in medical journals of other countries also [12,13].

In this study, the generic name was mentioned in 99.27% drug promotional literature. In most of the literature, the generic name was mentioned in small letters than the brand name. The most neglected aspect of drug promotion was information about drug interactions, precautions, adverse drug reactions and overdosage (<10%), and also coincides with a similar study carried out in other parts of India [3]. The price of the drug was not mentioned in most of the literature. These findings suggest that unethical drug promotion is widespread in India, as well as all over the world and confuses the physician in making a decision regarding rational prescription of drugs. The quality of paper, print, and color were excellent in all (100%) literatures in our study. In India, there are regional Ethics Committees at Mumbai, Delhi, Chennai and Chandigarh to collect complaints against drugs that are promoted unethically by advertisements. These complaints are then forwarded to the drug controller authority which then takes necessary legal steps against drug manufacturers and distributors [7]. Therefore, it is the responsibility of a practicing physician to be aware of the downfalls in a drug promotional literature before taking it as a scientific source of information, and any flaws, if identified, should be reported to the appropriate authority [14].

This study evaluates the promotional activity of printed promotional literature used by pharmaceutical companies; however, interventional research is needed to verify the awareness levels of the physicians about these facts, and updating the physicians will help them gain ethical and only information that is accurate from promotional literature [3]. Combined efforts of physicians, regulatory authority and pharmaceutical industries can definitely help with ethical promotion of a drug and rational prescribing.

CONCLUSION

Drug promotional literature analyzed in this study was inadequate in terms of their adequacy, quality and genuineness of coverage. Hence, it can be concluded that the majority of the drug promotional literature that are given to the prescribers are not able to spread awareness towards rational prescribing, but only promote the drug and have commercial benefits.

REFERENCES

- Ethical Criteria for Medicinal Drug Promotion. World Health Organization. 1988 May 13; [8screens]. Available from: <http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip08e/whozip08e.pdf>. [Last accessed on 2006 Dec 10].
- Cooper RJ, Schriger DL. The availability of references and the sponsorship of original research cited in pharmaceutical advertisements. *CMAJ* 2005;172(4):487-91.
- Mali SN, Dudhgaonkar S, Bachewar NP. Evaluation of rationality of promotional drug literature using World Health Organization guidelines. *Indian J Pharmacol* 2010;42(5):267-72.
- Cardarelli R, Licciardone JC, Taylor LG. A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: Is what they tell us important and true? *BMC Fam Pract* 2006;7:13.
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Available from: <http://www.ifpma.org>.
- OPPI Code of Pharmaceutical Marketing Practices. Available from: <http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf>. 2007 Jan. [Last accessed on 2007 Mar 3].
- Gopalakrishnan S, Murali R. India: Campaign to Tackle Unethical Promotion. World Health Organization. *Essential Drugs Monitor*; 2002. p. 22. Available from: <http://www.apps.who.int/medicinedocs/pdf/s4937e/s4937e.pdf>. [Last accessed on 2010 Nov 10].
- Panda A, Bhagat A. Drug promotional literature: Will they promote rational drug prescribing. *Biomedicine* 2013;33(4):550-4.
- Khakhkar T, Mehta M, Shah R, Sharma D. Evaluation of drug promotional literatures using WHO guidelines. *J Pharm Negat Results* 2013;4:550-4.
- Jayakaran C, Saxena D, Yadav P, Kantharia ND. Drug promotional literature distributed by pharmaceutical companies: Do they provide enough information to ascertain their validity? *J Pharmacol Pharmacother* 2011;2(3):192-3.
- Murthy MB, Krishnamurthy B. Authenticity of claims made in drug promotional literature. *Indian J Pharmacol* 2010;42(1):59-60.
- Othman N, Vitry A, Roughead EE. Quality of pharmaceutical advertisements in medical journals: a systematic review. *PLoS One* 2009;4(7):e6350.
- Kessler DA. Addressing the problem of misleading advertising. *Ann Intern Med* 1992;116(11):950-1.
- Garje YA, Ghodke BV. Assessment of promotional drug literature using World Health Organization (WHO) Guidelines. *Indian J Appl Res* 2014;4(2):ISSN-2249-555X.