ISSN : e- ISSN 2395-3950, p-ISSN 2395-440X

Pharmaceutical Advertisement Claims Of Drug Promotional Literatures In India

[1]Sahila Khatun,[2]Prakash H. Bhabhor, [3]Tejas K. Patel, [4]Parvati B. Patel

[1]Tutor, [2]Associate Professor, [3&4]Assistant Professor, Department of Pharmacology, GMERS Medical College, Gotri, Vadodara, Gujarat, India

ABSTRACT:

Objective: To check the type of claims and reference provided in the drug promotional literature made available to the clinicians in a tertiary care teaching hospital by pharmaceutical companies

Methodology: In this cross-sectional study, drug promotional literature materials were collected from the various clinical departments of a tertiary care teaching hospital. We elucidate the type of claims and evidence provided in its categorized claims into 4 types- type A (unambiguous clinical outcome), B (vague clinical outcome), C (Emotive or immeasurable outcome) and D (non-clinical outcome). We also assessed the reference provided for each claim. **Result:** We observed total 282 claims from the 90 drug promotional literature materials. It contains average 3.04±1.71 claims per literature. The distribution of type A, B, C and D claims were 16.67%, 42.90%, 19.15% and 21.28%, respectively. The distribution of references for type A, B, C and D claims was 87.23%, 52.90%, and 3.70% and 18.33%, respectively. **Conclusion:** The majority of claims was based on vague, emotive or immeasurable and nonclinical outcome.

Key-words: Advertisment, Drug promotion, Pharmaceutical company.

Corresponding Author: Dr. Prakash H. Bhabhor, Associate Professor,
Department of Pharmacology, GMERS Medical College, Gotri, Vadodara, Gujarat, India.
E-mail: drbhabor@gmail.com M-9925014449.

INTRODUCTION

World Health Organization (WHO) defines the medicinal drug Promotion as a, "promotion refers to all the information 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 promotion claims the existence of the drug, promote its advantages, provides useful information to the clinician to decide whether and when to use the drug and get or induce a prescription. Ideally, it should provide scientific and critical information to the health care professionals.. Pharma companies promote drugs through advertisement in professional journals, non-professional magazines and drug information sheet and reminder to the clinician. However, it often emphasizes the positive aspects of the product and gives little coverage to the adverse aspects. In western countries, the analysis of drug promotional literature found that 31% of pharmaceutical advertisements contains "misleading" or "unjustifiable" information.[2-4] The literature is also not matching with the code of ethics.[3-8] The journal advertisements by pharmaceutical information also contain vague information and poor quality of claims. Most claims contain relative rather than absolute benefits which may leave doctors susceptible to misinterpreting information.[9] The literature is scarce in this field from India. So, the present study is conducted to elucidate the

type of claims and evidence provided in the drug promotional literature made available to the clinicians in a tertiary care teaching hospital by pharmaceutical company representatives.

METHODOLOGY

We conducted the cross-sectional study over a period of 2 months in a various clinical departments of the GMERS Medical College and General Hospital, Gotri, Vadodara. We collect a drug promotional literature materials and elucidate the type of claims and evidence provided in it as per the previous study with suitable modifications in a case record form.[10] We categorize claims into 4 types- type A (unambiguous clinical outcome), B (vague clinical outcome), C (Emotive or immeasurable outcome) and D (non-clinical outcome) as shown in Table 1. We also categorize type A and type B claims for the efficacy, safety, quality of life and economic and compliance related information as shown in Table 2. For each claim, we also checked that claim is supported by suitable reference. All categorization was performed by two pharmacologists. All decisions were made by consensus.

The data were entered in the excel sheet and accuracy was cross-checked by the other investigators. The data were presented in percentage for each category and subcategory of claims. All the statistical analysis was performed through Graph Pad Prism 6.0 version software.

Table 1: Type of claim terminology with examples

Type	Terminology	Example
A	Unambiguous clinical outcome	Comparison with another drug: - When compared with drug X, drug Y delivers faster symptomatic relief
B	Vague clinical outcome	Without comparison: - Drug X is the new, effective 20mg pill with low incidence of discontinuation due to skin problem
C	Emotive or immeasurable outcome	Catchy terminology - Drug X : one of a kind - Drug X : a source of healing power - Only recommended by US FDA
D	Non-clinical outcome	Drug plasma half lives or bioavailability or biochemical markers - Using Drug X resulted in a 30% increase in arterial luminal diameter in postmortem dissection

Table 2: Analysis strategy of type A and B claims with parameters / measurements

Subtype	Parameter/Measurement	Claims for
Efficacy	Relative risk reduction, Absolute risk reduction, Number needed to treat Percentage of improvement	Mortality Morbidity Number of symptom free days, Incidence of stroke, MI Cardiovascular outcome, Faster improvement, etc.,
Safety	Adverse effects, Drug interaction, Pregnancy, Children, Vague	Local adverse effects, Systemic (CNS, CVS, etc.) Less drug interaction Safe in pregnancy Safe in children Specify the vague outcome in another category of CRF table
Quality of life	Physiological, functional → Overall, well being	Physical, social and psychological functioning
Pharmaco-economics	Cost, expenses	Cost difference, Cost effectiveness

RESULTS

We analyzed the 282 claims from the 90 drug promotional literature material from the different manufactures provided to the clinicians of our institute.

Number of claims in drug promotional literature

We observed average 3.04±1.71 (95% CI: 2.69, 3.40) claims per drug promotional literature. No drug promotional literature was without claims. The minimum and maximum claims per drug promotional literature were 1 and 10, respectively. The table 3 represents the distribution of number of claims per drug promotional literature. Every 4 out of 5 drug promotional literature was having more than one claim.

Table 3 Distribution of number of claims in the drug promotional literature

Number of claims	Drug promotional literature n (%)
1	18 (20.0)
2	20 (22.22)
3	23 (25.55)
4	10 (11.11)
5	12 (13.33)
> 5	07 (7.78)

Types of claims

Off 282 claims, maximum belonged to type B -121 (42.90%) clinical outcome followed by type D- 60 (21.28%), C- 54 (19.15%) and A- 47 (16.67%), respectively. Among 90 drug promotional literature, at least one A, B, C and D types of clinical outcome claims were present in 29

(32.22%), 62 (68.88%), 41 (45.55%) and 45 (50%), respectively. A total of 33 (66%) drug promotional literature was having efficacy data of either type A or B level. Only 15 (30%) of drug promotional literature provided safety data of either type A or B level.

A total of 17 (18.89%) drug promotional literatures expressed the claims based only on either type C or type D clinical outcomes. The table 4 represents the distribution of the average number of different types of claims in the drug promotional literature.

Table 4 distribution of average number of different types of claims

Types of claims	Mean (95% CI)
Unambiguous clinical outcome	0.5 (0.3-0.7)
Vague clinical outcome	1.27 (1.0-1.53)
Emotive or immeasurable outcome	0.61 (0.44-0.78)
Nonclinical outcome	0.67 (0.50-0.84)

Subgroup analysis of type A claims - Unambiguous clinical outcome

Off total 47 types A claims, 26 (55.31%) were based on the efficacy of promoted drugs. A total of 17 (36.17%) claims represented the safety of marketed drugs. The drug promotional claim was based on compliance and economics in 3 (6.38%) and 1 (2.12%) case, respectively. No drug promotional literature provided information to the clinicians based on the unambiguous clinical outcome for the quality of life.

Subgroup analysis of type B claims - Vague clinical outcome

Off total 121 type B claims, 78 (64.46%) were based on the efficacy of promoted drugs. A total of 29 (23.96%) claims represented the safety. The drug promotional claim was based on economics, compliance and quality of life 9 (7.43%),4 (3.30%) and 1 (0.82%) case, respectively.

Table 5: Claim distribution tables in relation with references

Type of claims	Total claims	Claims with reference	Claims without reference
Unambiguous clinical outcome	47	41 (87.23)	06 (12.76)
Efficacy	26	26 (100)	00 (00)
Safety	17	14 (82.35)	03 (17.64)
Quality of life	00	00 (0.00)	00 (0.00)
Economics	01	00 (0.00)	01 (100)
Compliance	03	01 (33.33)	02 (66.67)
Vague clinical outcome	121	64 (52.90)	57 (47.10)
Efficacy	78	50 (64.10)	28 (35.90)
Safety	29	14 (48.27)	15 (51.73)
Quality of life	01	00 (0.00)	01 (100)
Economics	09	00 (0.00)	09 (100)
Compliance	04	00 (0.00)	04 (100)
Emotive or immeasurable outcome	54	02 (3.70)	52 (96.30)
Nonclinical outcome	60	11 (18.33)	49 (81.67)
Total	282	118 (41.84)	164 (58.16)

Types of claims supported by references

As shown in Table 5, maximum references were supported for type A (87.23%) followed by type B (52.90%), D (18.33%) and C (3.70). In case of type A claims, efficacy and safety were supported by references in 100% and 82.35% cases, respectively. In case of type B claims, efficacy and safety were supported by references in 64.10% and 48.27% cases, respectively.

DISCUSSION

We focused on the quality of the drug promotional practices carried out by the pharmaceutical companies in India through systematically analyzing the claims. Our study suggests that pharmaceutical companies often use the emotive or immeasurable and nonclinical outcome to promote the product. The use of unambiguous clinical outcome was the least for the promotion. Our study supports the Kasyap *et al*. Since the finding that the rationality of the drug is difficult to assess from the drug promotional literatures and it may lead to inappropriate prescribing.[11,12] The physician has to look at all aspects and should take their own judgments.

They predominantly use, the efficacy and safety claims for the promotion. The pharmaceutical companies neglect the important aspect of drug selection like quality of life, economics and compliance.

Our study also suggests the correlation between type of claims and use of the references. The unambiguous clinical outcome was mostly supported by the references. The Vague clinical outcomes were supported with reference in only 1 out of 2 cases. Only a few claims belonged to emotive or immeasurable and nonclinical outcome category were supported with the references. This type of claims may be for the purpose of commercial aspect rather than educational aspect. Clinicians should not only rely on drug promotional literature for prescribing information and other sources should also be used.[11]

This study has several limitations. We have not analyzed the level of evidence provided by the reference. This could further reduce the quality of evidence. Only presence or absence of reference should not be regarded as final proof. We had only evaluated the drug promotional literature used by medical representatives. We have not analyzed the advertisements in the journal.

CONCLUSION

The majority of claims was based on vague, emotive or immeasurable and nonclinical outcome.

Conflict of Interest: None.

Funding: Nil.

References:

1. Criteria for Medicinal Drug Promotion, World Health Organization. Endorsed by the 33rd World Health Assembly, May 1986, Resolution No. WHA21.41.
2. Moulds R, Bochner F, Wing L. Drug advertising. Med J Aust 1986; 145: 178-179.
3. Moulds R, Wing L, Shenfield G, Day R. Drug advertising [letter]. Med J Aust 1987; 147: 52.
4. Moulds R, Wing L. Drug advertising [letter]. Med J Aust 1989; 150: 410-411.
5. Alam K, Shah AK, OjhaP.et al. Evaluation of drug promotional materials in a hospital setting in Nepal. Southern Med Review 2009;2(1):2-6.
6. Angsulee NK. A participatory evaluation of the implementation of WHO's ethical criteria for medical drug promotion in multiple countries. Final Report, 2004.
7. 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.
8. Phoolgen S, Ajit Kumar S , Rajesh Kumar J. Evaluation of the rationality of psychotropic drug promotional literatures in Nepal. Journal of Drug Delivery & Therapeutics 2012;2(6):6-8.

9. Othman N, Vitry A, Roughead EE. Quality of claims, references and the presentation of risk results in medical journal advertising: a comparative study in Australia, Malaysia and the United States BMC Public Health 2010, 10:294.
10. Loke TM, Koh FC, Ward JE. Pharmaceutical advertisement claims in Australian medical publications. Is evidence accessible, compelling and communicated comprehensively? MJA 2000;177:291-93.
11. Kasyap S, Srikanth, Niveditha. Evaluation of the rationality of drug promotional literature in a tertiary care hospital. World Journal Of Pharmacy And Pharmaceutical Sciences. 2:1950-62.
12. Cardarelli R, Licciardone JC, Taylor LJ. 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.