

**KNOWLEDGE AND PRACTICE OF PRESCRIBERS REGARDING WHO ETHICAL  
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Article Received on 09/09/2016

Article Revised on 30/09/2016

Article Accepted on 20/10/2016

**ABSTRACT**

**Background:** Drug promotional advertisements (DPAs) provides bias and ambiguous information as pharmaceutical companies do not strictly follow the guidelines therefore promoting irrational prescribing by influencing prescriber's prescribing behaviour. Hence this study was planned to asses' knowledge and practice of prescribers regarding WHO ethical criteria for DPAs. **Material and method:** This cross-sectional questionnaire-based study containing 9 items regarding WHO criteria for rationality of the DPAs was conducted on 100 doctors posted in various outpatient departments of Lady Harding Medical College and associated hospitals. **Results:** It was found that 79% of respondents were not aware that false pharmaceutical advertisements are illegal under Drug and Magic remedies Act 1954 in India. Doctors preferred DPAs (40%) as a main source of drug information which influences their prescribing pattern. Originality and easiness of data & graphs of DPAs were never evaluated by 66 (85.7%) and 62 (80.5%) of prescribers respectively. Retrievability of the references was never evaluated by 86.5% of prescribers. Claims regarding efficacy was evaluated by 100% of prescribers. Bias in racial and ethical composition of people and social representation were not evaluated by 92.3% and 90.7% of prescribers respectively. **Conclusion:** Prescribers did not analyze DPAs as per WHO criteria for rationality because of lack of knowledge and practice. Hence there are strong need to improve knowledge and practice of prescribers regarding use of WHO criteria for rationality of the DPAs to promote rational prescribing.

**KEYWORDS:** Drug Promotional Advertisements, WHO, Prescribers, Knowledge, Practice.**INTRODUCTION**

In achievement or maintenance of health, medicine can play essential role if it is used rationally. As prescribers play key role in ensuring the appropriate use of medicines therefore they should be updated with new information and new drugs. For this purpose apart from other sources they depend upon drug promotional activities like Drug Promotional Advertisements (DPAs) of pharmaceutical industries.<sup>[1]</sup> To regulate the promotional activity of pharmaceutical industries World Health Organization (WHO) laid down ethical criteria for medicinal drug promotion in 1988 to improve rational use of drug. As per this criteria drug promotion refers to all informational and persuasive activities by manufacturers and distributors of the pharmaceutical industry, the effect of which is to induce a favourable prescription, supply, purchase, and/or use of medicinal drugs.<sup>[2-3]</sup> In India, Magic remedies (Objectionable Advertisement) Act 1954 prohibits false or misleading drug advertisements.<sup>[4]</sup> Self-regulatory regulations of Organization of Pharmaceutical Producers India (OPPI) and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) are also

available in India.<sup>[5]</sup> Despite the availability of regulation and controls of drug promotion in India, pharmaceutical companies have been criticized for publishing poor quality drug promoting literature and not implementing WHO ethical criteria. Numerous studies have been reported that information's given in DPAs are inconsistent with the code of ethics.<sup>[6-9]</sup>

It is evident that DPAs which exaggerate benefit and downplay the risk of drug, with poorly supported claims and promoting a drug for non approved benefit, are adversely affecting treatment. As these DPAs can influence the prescribing decision of the prescriber therefore may lead to irrational drug prescribing that endangers patient care.<sup>[10-16]</sup> Hence information provided in to the DPAs should be critically analyzed by prescribers.

On review of literature we were not able to find any study nationally or internationally which evaluated the knowledge and practice of prescriber about ethical criteria for DPAs. With this background we planned to evaluate knowledge and practice of prescriber regarding

WHO ethical criteria for medicinal drug promotion and about the existing regulations.

### MATERIALS AND METHODS

A cross-sectional questionnaire-based study was conducted on 100 doctors posted in various medical and surgical outpatient departments viz Surgery, Medicine, Paediatrics, Obstetrics and Gynaecology, Ophthalmology, Dermatology and Otorhinolaryngology of Lady Harding Medical College and associated hospitals from April 2016 to June 2016. Structured pretested questionnaire, based on the WHO criteria for rationality of the DPAs<sup>[2]</sup> contained 9 items to evaluate knowledge, perception and practices was used. Participants were explained the purpose of study and

were requested to complete and return the questionnaire within 30 minutes.

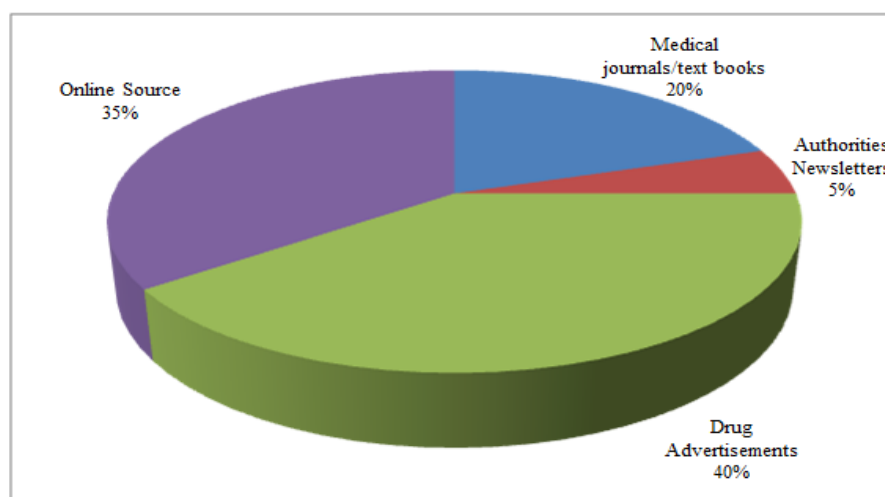
### RESULTS

In present study DPAs and related activities of pharmaceutical companies were preferred by 40% of doctors as a main source of drug information which influence their prescribing pattern followed by online sources (35%) (Fig-1). Two third (66%) of prescribers opined that DPAs are authentic source of drug information. Although 64% of doctors knew that ethical guidelines regarding pharmaceutical advertisements were framed by WHO but 79% of respondents were not aware that misleading pharmaceutical advertisements are illegal under Drug and Magic Remedies (Objectionable Advertisement) Act 1954 in India (Table-1).

**Table: 1 Knowledge and Perception of Prescribers regarding WHO's ethical criteria for DPAs\***

Sr. No.	Question	#Observation %
	<b>Knowledge</b>	
1.	Guidelines for DPAs were framed by:	
a.	Central Drugs Standard Control Organization (CDSCO)	23
b.	World Health Organization (WHO)	64
c.	Indian Medical Association (IMA)	0
d.	Indian Pharmacopoeia Commission (IPC)	13
2.	In India false DPAs are illegal under:	
a.	Drug and Cosmetic Act-1940	71
b.	Drugs and Magic Remedies Act- 1954	21
c.	Indian Medical Council Act-1956	2
d.	Narcotic Drug and Psychotropic Substance Act- 1985	6
	<b>Perception</b>	
3.	Source of drug information which influence your prescribing decision most:	
a.	Medical journals/text books	20
b.	Health authorities newsletters	5
c.	Pharmaceutical companies Activities (Drug promoting literature, Medical representatives etc.)	40
d.	Online sources	35
4.	DPAs are authenticated source of drug information:	
a.	Yes	66
b.	No	34

\*DPAs: Drug promotional advertisements, #Total number of participant =100 (n).



**Figure: 1 Sources of drug information which influence prescribing behaviour**

Among the various domains like text, data & graphs, claims, references and pictures & images of DPAs text and claims were observed by 100% of prescribers followed by data & graphs (77%), references (67%) and pictures & images (65%) (Table- 2 and Fig. 2).

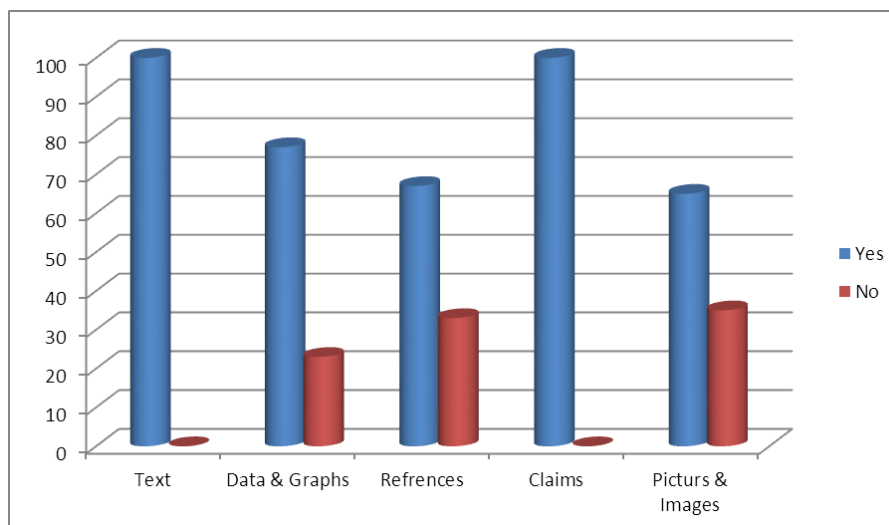


Figure: 2 Evaluation of domains of DPA by Prescribers as per WHO's ethical criteria.

Table: 2 Evaluation of DPAs by Prescribers as per WHO's ethical criteria.

SN	Question	Yes (n <sup>#</sup> )		No (n)
	<b>Text</b>			
1.	Have you ever read the text cited in DPAs	100		0
	<b>If Yes then have you ever evaluated the following:</b>	Yes	No	
1.1	Frequency of Generic names vs. Brand names	8 (8%)	92 (92%)	
1.2	Size of generic vs. brand name	4 (4%)	96 (96%)	
1.3	Safety get the equal prominence and placement as effectiveness	5 (5%)	95 (95%)	
1.4	Name and address of manufacturer	65 (65%)	35 (35%)	
	<b>Data &amp; Graphs</b>			
2.	Have you ever checked the data & graphs of DPAs	77		23
	<b>If Yes then have you ever evaluated the following:</b>	Yes	No	
2.1	Randomization, blinding and statistical significance	22 (28.6%)	55 (71.4%)	
2.2	Easiness of the data & graphs	15 (19.5%)	62 (80.5%)	
2.3	Simplicity of data & graphs	25 (32.5%)	52 (67.5%)	
2.4	Originality of data & graph	11 (14.3%)	66 (85.7%)	
	<b>References</b>			
3.	Have you ever checked the references in DPAs?	67		33
	<b>If Yes then have you ever evaluated the following</b>	Yes	No	
3.1	References for authors, title of study, journal etc.	55 (82%)	12 (18%)	
3.2	References were retrievable or not	9 (13.4%)	58 (86.5%)	
3.3	Source of references	14 (21%)	53 (79%)	
	<b>Claims</b>			
4.	Have you ever evaluated claims mentioned in DPAs	100		0
	<b>If Yes then have you ever evaluated the following</b>	Yes	No	
4.1	Claims regarding efficacy	100 (100%)	0 (0%)	
4.2	Claims regarding safety	98 (98%)	2 (2%)	
4.3	Claims regarding convenience	85 (85%)	15 (15%)	
4.4	Claims regarding cost	95 (95%)	5 (5%)	
4.5	Evidences for claims	95 (95%)	5 (5%)	
	<b>Pictures and Images</b>			
5.	Have you ever evaluated pictures & images in DPAs	65		35
	<b>If Yes then have you ever evaluated the following:</b>	Yes	No	
5.1	Relevance of picture of patient, doctor, drug etc.	45 (69.2%)	20 (30.8%)	
5.2	Bias in racial and ethical composition of people	5 (7.7%)	60 (92.3%)	

5.3	Symbols for association with drug or condition	13 (20%)	52 (80%)	
5.4	Bias in social representation	6 (9.2%)	59 (90.7%)	

<sup>#</sup>n = 100 (Total number of participants)

All prescribers opined that they used to read the text mentioned in DPAs. Although name and address of manufacturers were observed by 65% of prescribers but the ratio of size of generic name vs. brand name of drug was evaluated by only 4% of prescribers. Majority (92%) of respondents never looked for the frequency of generic name of drug in compare to brand name of drug in DPAs. Seventy seven respondents stated that they usually examined the data and graphs mentioned in DPAs but 66 (85.7%), 62 (80.5%) and 55 (71.5%) of them never evaluated the originality of data, easiness of data and type of study respectively (Table-2).

In this study 67 doctors claimed that they used to check references given in DPAs. Of 67 doctors, 55 (82%) mentioned that they used to evaluate different components of references like author's name, title of the study, journal name etc. but 58 (86.5%) never evaluated that references were retrievable or not. Results have shown that all respondents used to evaluate claims mentioned in pharmaceutical advertisements. Claims regarding efficacy and safety were evaluated by 100% and 98% of prescribers respectively. Similarly 95% and 85% of prescribers evaluated the claims regarding cost and convenience respectively (Table-2).

Pictures and images given in DPAs were evaluated by 65 doctors. Of 65 prescribers, bias in racial and ethical composition of people, bias in social representation and symbols for kinds of association were not evaluated by 92.3%, 90.7% and 80% of them respectively. Further relevance of pictures in respect of patient, doctor, disease, drug etc. in advertisement was not evaluated by 30.8% % of prescribers (Table-2).

## DISCUSSION

Findings of our study were in agreement with other studies in which prescribers opined that drug promotional literatures are important, useful and convenient source of drug information.<sup>[2, 10, 17-18]</sup> Around 80% of participants of our study were in impression that false drug promoting literature is illegal under Drug and Cosmetic Act in India, which is wrong. In India false drug advertisements are illegal under Drugs and Magic Remedies Act- 1954.<sup>[4]</sup>

In present study various activities of pharmaceutical companies related to drug promotion like drug promoting advertisements (DPAs), visiting of medical representatives etc. are preferred by most of the prescribers as the main source for drug information which influence their prescribing behavior. Similarly Zipkin DA<sup>[19]</sup> and Manchanda P<sup>[20]</sup> also found that prescribing behaviour of doctors influenced by DPAs, pharmaceutical representative and pharmaceutical company sponsored meetings.

International and national studies have been reported that essential informations like generic name, adverse effects, precautions, contraindications and manufacturer's name and address were often omitted from drug promoting literatures.<sup>[9, 21-23]</sup> In one study Sekar P reported that the most neglected aspects of drug promotion were information about drug interactions, precautions, adverse drug reactions and over dosage.<sup>[24]</sup> In our study we found that prescribers are also not evaluate essential information if provided in DPAs e.g. majority of prescribers never evaluated the frequency and ratio of brand name in comparison with generic name of the drug in this study.

As data and graphs are often used in DPAs to provide scientific bases and explanations for the claims regarding efficacy and safety of the drug therefore they should be accurate, non-confusing and self-explanatory. In 2001, on analysis of 74 graphs that appeared in US medical journals Cooper found that 8% had errors, 5% were confusing, 12% used non-standard graphing techniques and only 36% of graphs were self-explanatory.<sup>[25]</sup>

Further it is evident that presentation style of data and graphs in DPAs affect physician's prescribing behaviour. In various studies it has been observe that the preference to use a particular medicine therapy is greatest when results are given as a relative risk reduction (RRR) and lowest when they are given as a number needed to treat (NNT). Therefore in many advertisements results are reported as a RRR and did not mention about NNT and absolute risk reduction (ARR). Similarly in many advertisements confidence intervals and references to randomization, blinding, power and NNT were omitted.<sup>[1]</sup>

In our study we observe that around half of prescribers never evaluated the data and graphs of DPAs for easiness and originality as well as they never looked for randomization and blinding in studies if mentioned in advertisement for providing strong evidence for claims. This is may be because of complex and incomplete data provided by pharmaceutical companies or may be because of lack of knowledge and practice of prescribers regarding WHO guidelines for drug promoting literature or both.

In drug promoting literatures claims about effectiveness, safety, quality of life, costs or convenience are important since these are the aims of pharmacotherapy but it should be free from any type of bias and ambiguity. It has been observed that the claims in around 70% of the cases laid emphasis on the efficacy and superiority while clinically relevant safety outcomes were negligibly highlighted.<sup>[9, 26]</sup> Further in one study author has shown that 42% of claims regarding quality of life were biased with too

much prominence given to medicine benefits as compared to harmful effects and in another study author found that most claims regarding cost- effectiveness were not supported by evidence.<sup>[1]</sup> Other studies also reported that majority of claims mentioned in DPAs are bias, unjustifiable, ambiguous and supported by irrelevant non-retrievable references.<sup>[14]</sup>

In our study most of the prescribers opined that they observed drug advertisements for claims regarding efficacy, safety, cost and convenience. As there are evidences that prescribers are using the drug advertisement as the primary source for drug information therefore these bias and ambiguous claims may leads to irrational prescribing and hence compromising the patients' health in the process.<sup>[26]</sup>

Drug advertisements should include references to support all claims or scientific information providing by it. In analysis of drug advertisement Randhawa GK found that 70% of the advertisements contain references and 70% of the total references were retrievable and out of them 17% were invalid. Among the valid references 83% were from research articles published in indexed journals.<sup>[26]</sup> In contrast to above other studies have been shown that in support of claims and scientific information either references were not mentioned, if mentioned then incomplete or quality was unacceptably low.<sup>[1, 9, 27-28]</sup> Further in some cases references were not available publically as those were unpublished (data on file) therefore prescribers could not able to analyze them.<sup>[14,18]</sup>

In many instance it has been found that authors of original research which was cited as a reference were affiliated with the product's manufacturer. Therefore authenticity of the references cited could not be verified as when pharmaceutical companies sponsor research on their medicine; the results are more likely to be in favour of the medicine.<sup>[1, 5, 18, 29]</sup>

In addition to the existing deficiencies in DPAs related to the references our study further added new perspective by showing that majority of prescribers had never evaluated the references for the source and retrievability.

In DPAs pictures and images are used to depict in such a way that physicians can be influenced to prescribe that drug. Along with that these pictures also either reinforce or challenge the common prejudices about different groups of people or society.<sup>[5,1]</sup>

In a study Bhatt PN reported that out of 247 images of human figures which appear in drug advertisements, 144 (58.3%) were of patients and the rest 103 (41.7%) were representing physicians. Author further added that females were portrayed as patient in 62.5% DPAs in compared to as physician in 47.6% of DPAs.<sup>[5]</sup> Numerous studies have been reported that gender bias of images in promotional material is very common issue

like heart disease was mainly represented by male and depression was predominantly represented by females.<sup>[1, 30]</sup> There are also racial biases in drug advertisements as predominance of whites both as health-care providers and as patients have been noted. Apart from gender and racial biases, drug advertisements also demonstrated age related biases as special needs of the elderly or children often did not appear to be taken into account. Similarly Symbols or metaphors in DPAs have complex and various meanings which may be not recognize by doctors because may be they unaware of the hidden messages or may be unwilling to know.<sup>[1]</sup>

In this study we found that although two third of the prescribers used to evaluate the pictures, images and symbols but majority of them were not in practice to analyze the pictures & images for racial, ethical and social representation bias and symbols for their meanings or purpose. Hence there are very much chance of irrational prescribing because of biased DPAs and ignorant prescribers.

## CONCLUSION

Prescribers use DPAs as an authenticated source of drug information which affects their prescribing behaviour but they did not analyze DPAs as per WHO criteria for rationality because of lack of knowledge and practice of same. Hence there are strong need to improve knowledge and practice of prescribers regarding use of WHO criteria for rationality of the DPAs to promote rational prescribing.

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