

Drug promotional literatures (DPLs) evaluation as per World Health Organization (WHO) criteria

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ABSTRACT

This study was aimed to evaluate the drug promotional literatures (DPLs) as per World Health Organization (WHO) criteria and also to evaluate claims, references and pictures presented in DPLs. It was an observational, cross-sectional study conducted at the outpatient department of Civil Hospital, Ahmedabad, a tertiary care teaching hospital for period of 2 months. Printed drug promotional literatures for modern drugs were collected as per selection criteria and analyzed. WHO guidelines were not fulfilled in any of the 200 DPLs. Out of 299 claims, most commonly presented claim in 192 DPLs was efficacy (45.15%) followed by pharmaceutical properties (26.75%). 130 (65%) DPLs did not provide any references to support claims while only 70 (35%) DPLs provided references. Most commonly used reference was journal articles 66 (88%) followed by websites 5 (6.66%). Most common source of journal article reference was research article 53 (85.48%) followed by review article 7 (11.29%). 125 (78.61%) DPLs presented with irrelevant pictures while only 25 (15.72%) DPLs presented appropriate pictures. Information on adverse drug reactions, contraindications and drug interactions was missing in most of DPLs. None of the promotional literatures contained all of the information as per WHO guidelines for medicinal drug promotion. They were lacking with scientific and critical information.

INTRODUCTION

According to World Health Organization (WHO), medicinal drug promotion refers to “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” (WHO 1988). Drug manufacturers or distributors are interested in promoting the sale of new drugs and main goal of advertisements is to convince healthcare professionals to prescribe the particular product (Khakhkhar *et al.*, 2013). They are vital and needful source of drug information for medical practitioners as well as for patients. Different modes of drug promotion include visual aids, leave behinds, leaflets and audio visuals. In private or public clinic set-up direct to physician (DTP) marketing is major method used by drug manufacturers and distributors (Medhi B and Prakash A, 2010). Most of healthcare professionals currently get their information from commercial sources, usually through well set network of medical representatives (Gopalakrishnan and Murali, 2002).

Pharmaceuticals manufacturers must comply with International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code to ensure Ethical promotional practices. IFPMA code sets standards for Ethical promotion that member companies' must follow (IFPMA 2012). In India, Promotional activities standards are set by self regulatory code of pharmaceutical marketing practices, January (2007), Organization of Pharmaceutical Producers of India (OPPI 2012), and by National legislation. However, many studies have been presented that information provided through drug promotional activities is not consistent with the code of Ethics (Mali *et al.*, 2010). DTP method has influence on physicians' prescribing practices and studies have shown that pharmaceutical promotion influences physicians' behavior (Khakhkhar *et al.*, 2013). Most of healthcare professionals get commercial sources of drug information from medical representatives, drug brochures, leaflets etc., and it has huge impact on prescribing behavior (Gopalakrishnan and Murali, 2002). All promotion making claims about drugs should be accurate, informative, up to date and Ethical. They should not contain misleading, false and biased statements (WHO 1988). The pharmaceutical companies' claim that their products are better to existing and best to which prescriber are familiar.

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However, the information presented in DPLs may be inadequate, inaccurate, and false and can lead to irrational prescribing (Khakhkhar *et al.*, 2013). WHO has published ethical criteria for medicinal drug promotion to support and improve health care by promoting rational use of medicines. It is necessary to critically and scientifically evaluate the promotional material of the drugs as such promotional activities influence the prescribing behavior of the practitioners. Since last many years Ethical promotion and authenticity of such drug promotional considered as the subject of debate (Villanueva *et al.*, 2003). Therefore, this study has been taken up with the aim to analyze fulfillment WHO criteria in DPLs available in Indian market using WHO guidelines.

AIMS AND OBJECTIVES

The present study was designed to evaluate the drug promotional literature (DPL) as per World Health Organization (WHO) criteria and also to evaluate claims, references and pictures presented in DPLs.

MATERIALS AND METHODS

It was an observational, cross-sectional and single centre study conducted at the outpatient departments (OPDs) of Civil Hospital, Ahmedabad, a tertiary care teaching hospital in India for period of 2 months from April 2013 to May 2013. OPDs of medicine, skin, surgery, ophthalmology, orthopedics, pediatrics and psychiatry were visited daily from Monday to Saturday. Odd number unit of earlier mentioned OPDs was selected and printed DPLs (e.g. leaflets, brochures and visual aids etc.) were collected. While drug reminders, promotional literatures for medical devices and DPLs for drugs other than allopathic drugs were excluded. From collected DPLs, even number of DPL was selected for study. All DPLs were evaluated by WHO criteria for fulfillment of each of the following parameters (WHO 1988).

- The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug
- The brand name
- Content of active ingredient(s) per dosage form or regimen
- Name of other ingredients known to cause problems;
- Approved therapeutic uses
- Dosage form or regimen
- Side-effects and major adverse drug reactions
- Precautions, contra-indications, and warnings
- Major interactions
- Name and address of manufacturer or distributor
- Reference to scientific literature as appropriate

All DPLs were evaluated for fulfillment for the each criterion mentioned above. References were analyzed as their type, source and retrievability. They were also analyzed for different type of claims used; type and space occupied by pictures, data

presentation and catchy terms/phrases used in DPLs. The data was entered in Microsoft Office Excel software (version 2007) and analyzed.

RESULTS

A total of 200 DPLs were collected in which 224 drugs were promoted. Out of 224 drugs, 122 (54%) were single drug formulation and 102 (46%) fixed dose combinations (FDCs) (Figure 1). Most commonly promoted group of drug was antimicrobials 37 (18%) followed by cardiovascular 33 (16%), non-steroidal anti-inflammatory drugs 26 (13%), gastrointestinal tract drugs 20 (10%) and miscellaneous 20 (10%) (Figure 2).

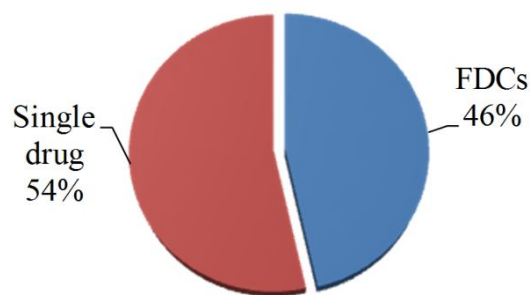


Fig. 1: Classification as per type of drug formulation (n=224).

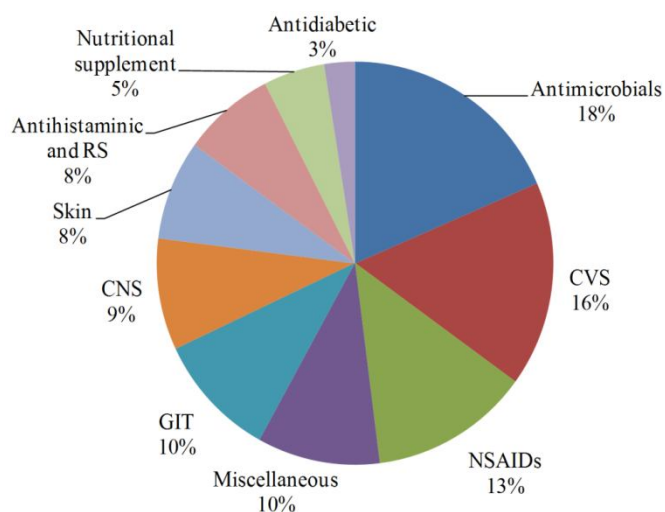


Fig. 2: Types of drugs promoted in DPLs (n=224).

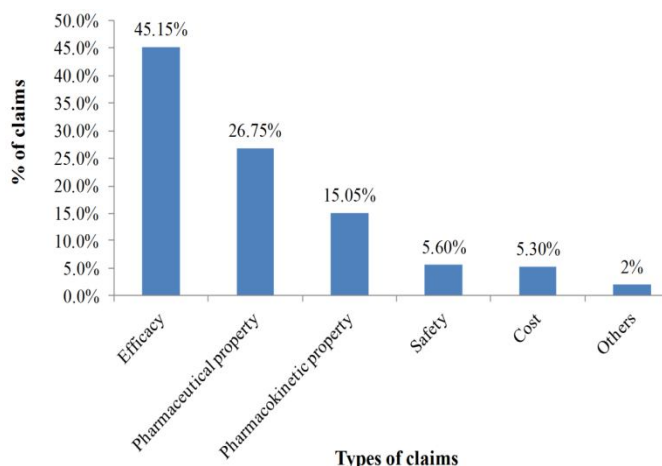
None of 200 DPLs fulfilled all the 10 criteria as given by WHO. 4 out of 200 DPLs fulfilled the criteria recommended by WHO excluding one criterion, i.e. other ingredients known to cause problems (Table 1). However, all DPLs mentioned about generic name, brand name, active drug per dosage form and therapeutic uses. Complete information of particular drug regimen was found only in 7 (3.5%) DPLs. Also complete safety information (side effects, contraindication, and drug interactions) was mentioned only in 3 (1.5%) DPLs. Detailed analysis of fulfillment of WHO criteria is given in Table 1.

Table. 1: Fulfillment of WHO criteria by DPLs (n=200).

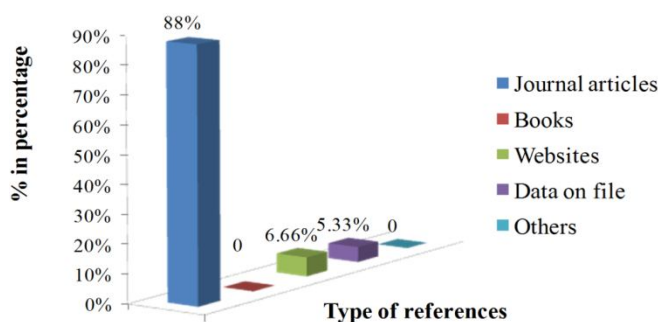
Sr. No.	WHO criteria	Complete information no. of DPLs (%)	Incomplete information no. of DPLs (%)	No information no. of DPLs (%)	Total
1	Generic name	200 (100%)	0	0	200
2	Brand name	200 (100%)	0	0	200
3	Active drug per dosage form	200 (100%)	0	0	200
4	Approved therapeutic use/s	200 (100%)	0	0	200
5	Other ingredients known to cause problems	0	0	0	200
6	Dosage form	196 (98%)	0	4 (2%)	200
7	Regimen	7 (3.5%)	193 (96.5%)	0	200
8	Safety information	3 (1.5%)	4 (2%)	193 (96.5%)	200
9	Manufacturer/Distributor's name and address	29 (14.5%)	0	171 (85.5%)	200
10	References	70 (35%)	0	130 (65%)	200

*DPLs: Drug promotional literatures, WHO: World Health Organization

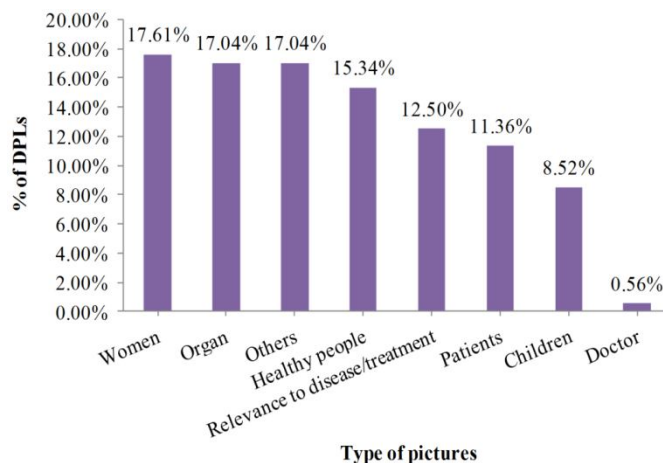
Out of 200 DPLs, 192 (96%) DPLs were presented with 299 claims. Also 16 (8.3%) DPLs were presented with 2 or more claims. Out of 299 claims, most common presented claim was efficacy 135 (45.15%) followed by pharmaceutical property 80 (26.75%), pharmacokinetic property 45 (15.05%), safety 17 (5.6%), cost 16 (5.3%) and others 6 (2%) (Figure 3). Out of total 299 claims, only 25.08% (75) were supported by references.

**Fig. 3:** Classification of claims made in DPLs (n=299).

Out of 200 DPLs, 130 (65%) DPLs did not provide any references while only 70 (35%) DPLs cited 75 references to support their claim. Also more than one reference per DPLs was found in 10 DPLs. After classification of references, most commonly used reference was journal articles 66 (88%) followed by websites 5 (6.66%) and data on file 4 (5.33%) (Figure 4). No references were given for books.

**Fig. 4:** Classification of references in DPLs (n=75).

Out of 75 references, 10 references were not retrievable; 4 from journal article, 4 from data on file and 2 from websites. References from journal articles were then classified based on their presentation. Out of 66 journal article references, most common source of reference was research article 53 (85.48%) [Includes randomized control trial (21) (RCT), randomized placebo control trial (18) (RPCT)] followed by review article 7 (11.29%) and editorial article 2 (3.22%) (Table 2). Out of 200 DPLs, 159 (79.5%) DPLs were presented with 176 different pictures. Out of 159 DPLs, 125 (78.61%) were with irrelevant pictures, 25 (15.72%) with relevant pictures and 9 (5.66%) with mixed picture presentation. After classification of pictures in various categories; pictures of women, body organs and healthy people were found to be almost equal in number, i.e. 31 (17.61%), 30 (17.04%), 27 (15.34%) respectively (Figure 5).

**Fig. 5:** Classification of pictures in DPLs (n=176).

Out of 159 DPLs, 84 (52.83%) DPLs presented with pictures occupying space more than 50%. Brand name and generic name presentation in all DPLs was very dissimilar in relation to font size and color. Also various catchy terms/ phrases like 'KNACK for excellence', 'tested and trusted protector' were used in 190 (95%) DPLs. Out of 200 DPLs, 23 (11.5%) DPLs used 24 various graphical presentations to show various data information. Columns (11), bar (2) and others (2) were used for data presentation in 15 DPLs while comparative table (7) and scientific table (2) used for data presentation in 9 DPLs. Only 1 out of 23 DPLs presented with both tables and charts.

Table. 2: Classification of references as per its source (n=75).

Sr. No.	Type of references	Retrievable		
		Yes	No	
1	Journal article	RCT	21	
		RPCT	18	
		Retrospective study	6	
		NRCT	4	
		CCT	2	
		In-vitro study	1	
		Case report	1	
		Review article	7	
		Editorial article	2	
		Journal article not retrievable	-	4
2	Books	-	-	
3	Websites	3	2	
4	Data on file	-	4	
5	Others	-	-	
Total		75		

*RCT: Randomized control trial, RPCT: Randomized placebo control trial, NRCT: Non Randomized control trial, CCT: Case control study

DISCUSSION

Printed promotional literature is an easily available, accessible and important source of drug information. Number of new drugs and old drugs with some modification are entering every year in the Indian market. Very few among them are genuine innovations and rests are with altered formulation, FDCs which are added to more than 20,000 drug formulations present already in the market (Gopalakrishnan and Murali, 2002). Drug manufactures spent more than \$ 11 billion each year drug in promotion and marketing. Around \$ 8000 to \$ 13000 per year is spent on each healthcare professional for drug promotional activities (Rohra *et al.*, 2006).

We observed from this study that WHO guidelines were not followed by drug companies while promoting drug products. Similar finding has been observed in studies conducted in India (Mali *et al.*, 2010) and Nepal (Alam *et al.*, 2009).

In this study, it was observed that generic name of each active ingredient (100%) and recommended dosage form (100%), brand name (100%) and approved therapeutic uses (100%) was mentioned in all DPLs (n=200). Information about ADRs, drug interactions and precautions (>93%) was missing most of DPLs. Study conducted in Russia has shown similar findings which mentioned less than 5% of literatures mentioning ADRs (Vlassov *et al.*, 2001). Another study carried out in India showed similar observation about safety information presented in DPLs (Mali *et al.*, 2010).

Out of all the DPLs, 96% were containing one or more claims and 95% were containing catchy terms/phrases in this study. Claims presentation was found similar in study conducted in Pakistan (Rohra *et al.*, 2006). Similar finding was also noticed in three other studies (Mali *et al.*, 2010; Villanueva *et al.*, 2003; Stimson, 1975). The DPLs were full of unsubstantiated claims about efficacy or pharmaceutical property and those claims were irrelevant also. Practitioners may be easily misguided by such unsubstantiated and false claims and catchy terms/phrases.

In this study, references were cited in 35% (70) of DPLs only, showing that 65% DPLs were presented their claims without reference support. This is in accordance with a similar other Indian

study (Mali *et al.*, 2010). References giving the results of clinical trials of RCT were maximum (n=21) followed by RPCT (n=18). These findings were different to those of studies by Villanueva *et al.* (2003) and Cooper and Schriger (2005). 78.61% DPLs contained irrelevant pictures in our study. Similar finding was found in two other studies done by Stimson (1975) and Cooper and Schriger (2005). In another study irrelevant pictures was observed higher (90.2%) (Mali *et al.*, 2010). Pictures of women were commonly found which indicates to create attraction for particular product. In this study, less accurate and non scientific information was found in form of charts and tables which suggests toward the attraction and commercial purpose rather than educational or informative behavior. This study finding is similar with those of the study by Cooper and Schriger (2005).

It is a signatory condition for membership of the association to observe a code of practice in marketing activities in countries like UK and Canada (Khakhkhar *et al.*, 2013). In India, there are regional Ethics Committees for complaints against unethical drug promotion advertisements. Drug controller authority takes necessary legal steps in response to such complaints to against drug manufacturers and distributors (Gopalakrishnan and Murali, 2002).

One of limitation of the study was small sample size. Also study conducted only in government hospital and single centre. In this study only one type of promotional activity was analyzed, i.e. printed promotional literature; however, there is need to assess the awareness of the practitioners by intervention study and provide guidance about accurate and Ethical information from DPLs. DTP method of marketing may influence prescribing behavior with no benefit to the patient and also lead to irrational prescribing practices. Development of laws and their implementation by drug manufacturers, practitioners' awareness and strengthening of existing guidelines can be beneficial measures in this issue. It requires group efforts of practitioners, pharmaceutical companies and regulatory body which can ultimately to Ethical drug promotional activities and rational prescribing.

CONCLUSION

None of the drug promotional literatures contained all of the information recommended by the WHO's guideline for medicinal drug promotion. They were lacking with scientific and critical information. Therefore, healthcare professionals' awareness and responsibility is required to critically evaluate DPLs before accepting it as a scientific source of drug information and if any contradiction is recognized, should be reported to appropriate authority.

REFERENCES

Alam K, Shah AK, Ojha P, Palaian S, Shankar PR. Evaluation of drug promotional materials in a hospital setting in Nepal. *South Med Rev*, 2009; 2(1): 2-6.

Cooper RJ, Schriger DL. The availability of references and the sponsorship of original research cited in pharmaceutical advertisements. *CMAJ*, 2005; 172: 487–91.

Gopalakrishnan S, Murali R. 2002. India: Campaign to tackle unethical promotion. *Essential drugs monitor*. [ONLINE]. Available at: <http://www.apps.who.int/medicinedocs/pdf/s4937e/s4937e.pdf>. [Accessed 12 May 2013].

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), 2012. IFPMA code of practice. Available at: http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_Code_of_Practice_2012_new_logo.pdf. [Accessed 12 May 2013].

Khakhkhar T, Mehta M, Shah R, Sharma D. Evaluation of drug promotional literatures using WHO guidelines. *Journal of Pharmaceutical Negative Results*, 2013; 4(1).

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.

Medhi B, Prakash A. 2010. Ideal characteristics of promotional literature. In: Medhi B and Prakash A, ed. *Practical Manual of Experimental and Clinical Pharmacology*. 1st edition. India: JBPMP 342-45.

Organization of Pharmaceutical Producers of India (OPPI). 2012. OPPI code of pharmaceutical marketing practices. Available at: <http://www.indiaoppi.com/OPPI%20Code%20of%20Pharmaceutical%20Practices%20-%202012.pdf>. [Accessed 12 May 2013].

Rohra DK, Gilani AH, Memon IK, Perven G, Khan MT, Zafar H, Kumar R. Critical evaluation of claims made by pharmaceutical companies in drug promotional material in Pakistan. *J Pharm Pharmaceut Sci*, 2006; 9:50–9.

Stimson GV. Information contained in drug advertisements. *BMJ*, 1975; 4:508–9.

Villanueva P, Peiro S, Librero J, Pereiro I. Accuracy of pharmaceutical advertisements in medical journals. *The Lancet*, 2003; 361(9351):27-32.

Vlassov V, Mansfield P, Lexchin J, Vlassova A. Do drug advertisements in Russian medical journals provide essential information for safe prescribing? *West J Med*, 2001; 174:391-94.

World Health Organization (WHO). 1988. Ethical criteria for medicinal drug promotion. Available at: <http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip08e/whozip08e.pdf>. [Accessed 10 April 2013].

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