

Critical Analysis of Indian Drug Promotional Literature(DPL) Using World Health organization Criteria For Ethical Medicinal Drug Promotion.

*Shagupta A NAikwadi¹, Rupali B Jadhav², Amruta P Patil³

^{1,2,3}(Department of pharmacology, Dr V M Govt Medical College Solapur/ Maharashtra University of Health Sciences Nashik India)

Corresponding Author: Shagupta A NAikwadi

Abstract: Drug promotional literatures (DPLs) are a major marketing tool of pharmaceutical companies for promoting their products. According to WHO, promotional claims need to be reliable, truthful, informative, balanced, up to date. However, the pharmaceutical companies do not adhere to the required ethical guidelines while promoting their products. This study was aimed to evaluate collected drug promotional literature (DPL) as per World Health Organization (WHO) criteria for ethical medicinal drug promotion. This observational, cross-sectional study was conducted at outpatient department of a tertiary care center attached to a medical college in Maharashtra for a period of three months. Printed DPLs were collected as per selection criteria and were analyzed for the fulfillment of WHO criteria 1988. The collected DPLs were also analyzed for the type of claims, pictorial content, type of references quoted and their retrievability. In collected 81 DPLs, total 91 drugs were promoted out of which 38 DPLs were single drug whereas 53 DPLs were fixed drug combinations(FDCs). Cardiovascular drugs (26.37%) were the most promoted drugs. None of the DPL fulfilled all the 10 WHO criteria. Total 274 claims were made of which majority were about efficacy (63.86%) of the product. 68 DPLs provided 264 references for their claims. Majority references (87.5%) were from the journal articles.

Keywords: drug promotional literature, WHO criteria for ethical drug promotion.

Date of Submission: 14 -09-2017

Date of acceptance: 22-09-2017

I. Introduction

According to the “Ethical criteria for medicinal drug promotion” by WHO, “drug promotion refers to all informational and persuasive activities by manufactures and distributors of the pharmaceutical industry, the effect of which is to induce a favorable prescription, supply, purchase and /or use of medicinal drugs [1]. It includes activities of the medical representatives, drug advertisements and provision of gifts and free drug samples to prescribers, drug package inserts, direct-to-consumer advertisements, periodicals, telemarketing, holding of conferences, symposium, scientific meetings, sponsoring of medical education, and conduct of promotional trials [2]. Drug promotional advertisements (DPAs) are a major marketing tool of pharmaceutical companies for promoting their products and disseminating drug information for benefit of their own. These advertisements disperse the information regarding product name and its pharmacological properties, price, marketing claims, and references cited in support of these claims [3].

Pharmaceutical companies spend around one third of all sales revenue on marketing their products which is twice that spent on research and development [4]. Powerful influence of promotional advertisements on physicians prescribing preferences, dissemination of deceptive information, unsubstantiated claims, and lapses in the field of ethics is a matter of enormous concern worldwide for the past few decades. There is evidence that prescribers using the DPAs as the primary source of drug information tend to prescribe less appropriately, and in the process patients’ health can get compromised [5]. DPAs 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 behind 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 [6]. 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 [7].

In India, Promotional activities standards are formed by self-regulatory code of pharmaceutical marketing practices, January (2007), Organization of Pharmaceutical Producers of India, and by National legislation [8]. According to WHO, promotional claims need to be reliable, truthful, informative, balanced, up to date and capable of corroboration of authentic information. [9] However, the pharmaceutical companies do not adhere to the required ethical guidelines while promoting their products. [10] WHO has published ethical

criteria for medicinal drug promotion to support and improve health care by promoting rational use of medicines. [9] Drug promotional literatures DPLs can be highly informative when it provides the authentic information in essence as long as they have been critically appraised and reviewed. [11] However, many studies have been presented that information provided through drug promotional activities is not consistent with the code of Ethics [12]. Therefore, this study was conducted with the aim to analyze the fulfillment of WHO criteria in DPLs available in Indian market using WHO guidelines.

II. Aim And Objectives

The present study was undertaken to analyze the drug promotional literature as per WHO criteria and also to evaluate claims and pictorial content present in DPLs, and references quoted in support of these claims for their source, type and retrievability.

III. Materials And Methods

It was a prospective, observational, cross sectional, single centered study conducted at the outpatient department of a tertiary care center attached to a government medical college Solapur, Maharashtra. It was conducted for a period of three months from 1st November 2016 to 31st January 2017. The study was conducted after approval by institutional ethics committee. Printed DPLs promoting allopathic drugs were collected from OPDs of medicine, pediatrics, skin, psychiatry, ophthalmology, obstetrics and gynecology, otorhinolaryngology and orthopedics. DPLs promoting drugs other than allopathic drugs, medicinal devices and equipment, orthopedic prosthesis, drug reminders, drug monographs, drug name list were excluded.

All DPLs were evaluated by WHO criteria for fulfillment of each of the following parameters.

1. The names of the active ingredients using, either international nonproprietary names or approved generic names of the drugs.
2. The brand names
3. Amount of active ingredients per dose
4. Other ingredients known to cause problems i.e. adjuvant
5. Approved therapeutic uses
6. Dosage form or dosage schedule
7. Safety information including side effects and major adverse drug reactions, precautions, contraindications, and warnings and major drug interactions.
8. Name and address of manufacturer or distributor
9. References to scientific literature appropriate.

In addition to this information, DPLs were analyzed for different type of claims made, catchy terms/phrases used, data presentation. References quoted in support of claims made were analyzed for their source i.e. journal, website, books, data on file etc. Internet search was done to retrieve the references mentioned in the DPLs. Each reference was traced using all available database which involved all indexed and non-indexed journals, PUBMED, MEDLINE and other web search engines. In case of any inaccessibility of full paper, their abstracts were retrieved. References not available from search were considered non-retrievable.

The available journal references were grouped as per the type of article as follows-

Randomized clinical trial RCT

non-randomized clinical trial

Review

Observational study

Meta-analysis etc.

The data was entered in Microsoft excel and analyzed.

IV. Results

Total 81 DPLs were analyzed in which 91 drugs were promoted. Out of these 91 drugs, 38 (41.75%) were single drugs whereas 53 (58.25%) were fixed drug combinations. Most commonly promoted group of drugs was drugs affecting cardiovascular system 24 (26.37%) followed by drugs affecting endocrine system and nutritional supplements 17(18.68%) each, which was followed by antimicrobials 7 (7.69%). Detail classification of promoted drugs is given in Fig 1. None of the 81 DPLs fulfilled all the 10 WHO criteria. Information regarding the adjuvant was missing from all the DPLs. After excluding the adjuvant, rest nine WHO criteria were fulfilled by 20 DPLs. Information regarding brand name and manufacturer's name was present in all the 81 DPLs. Information regarding the safety was present only in 26 DPLs. Detail analysis of fulfillment of WHO criteria is given in Table 1. In these 81 DPLs, total 268 claims were made. Maximum claims were about the efficacy 175 (65.30 %), followed by safety 38 (14.18%). Claims about the pharmaceutical properties of the

drugs promoted, Pharmacokinetics, pharmacological properties, mechanism of action of drugs were 27 (10.07%), 16 (5.97%), 6 (2.23%), 6 (2.23%) respectively. (Fig. 2)

Out of 81 DPLs, 68 DPLs provided references to support their claims. In these 68 DPLs, total 264 references were quoted. Maximum references were from journal articles (87.5%). References from websites, books, data on file and study reports were 4.17%, 0.76%, 3.79%,1.14% respectively. Out of these 264 references 35 were non-retrievable, 22 from journal articles, 10 data on file and 3 study reports. (Fig 3) There was not uniformity in number of references quoted in these DPLs. Maximum references per DPL were found to be 23. Less than 3 references/DPL were present in 29 DPLs, while in 35 DPLs 3-7 references/DPL were found. In only 4 DPLs more than 7 references/DPL were quoted. References from journal articles were further classified according to type of article. Maximum were review articles (98) followed by randomized clinical trials (74). Other article types included non-randomized clinical trials (11), observational studies (7), metaanalysis (7), retrospective studies (5), cross sectional studies (4). (fig 4)

These promotional literatures were made striking using different pictures. Majority of these pictures were unrelated to the drug promoted or disease described in the DPLs. Such irrelevant images were present in 39 DPLs. Catchy terms like world's no 1, most effective analgesic etc were used in 47 DPLs. Four DPLs used tables for the presentation of data while 15 DPLs used various graphs. None of the DPL used tables and graphs both for the data presentation. Total 32 graphs were used and maximum were bar diagrams (23) followed by pseudo graphs (5), scatter diagram (3), and pie chart (1). Information regarding the price of the drug promoted was given only in 4 DPLs out of the 81.

Figures And Tables

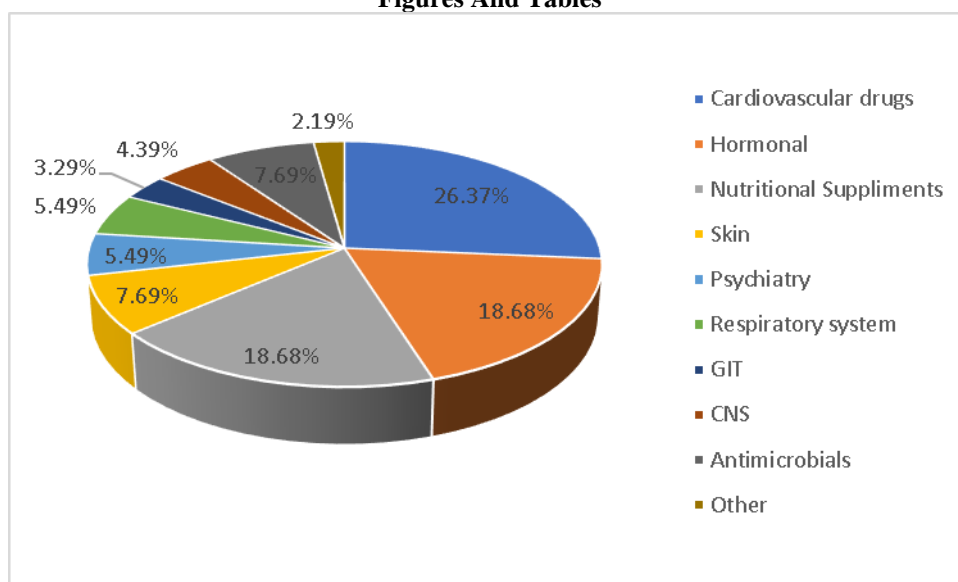


Fig. 1 classification as per the type of drug promoted

Table 1 Fulfillment of WHO criteria by DPL (n=81)

Criteria	Number mentioned (%)
International nonproprietary name	79 (97.53%)
Brand Name	81 (100%)
Amount of active ingredient per dose	77 (95.06)
Adjuvant	0 (0%)
Approved therapeutic uses	42 (51.85)
Dosage schedule	48 (59.25%)
Safety information	26 (32.09%)
Name of manufacturer	81 (100%)
Address of manufacturer	54 (66.67%)
References to scientific information	68 (83.95%)

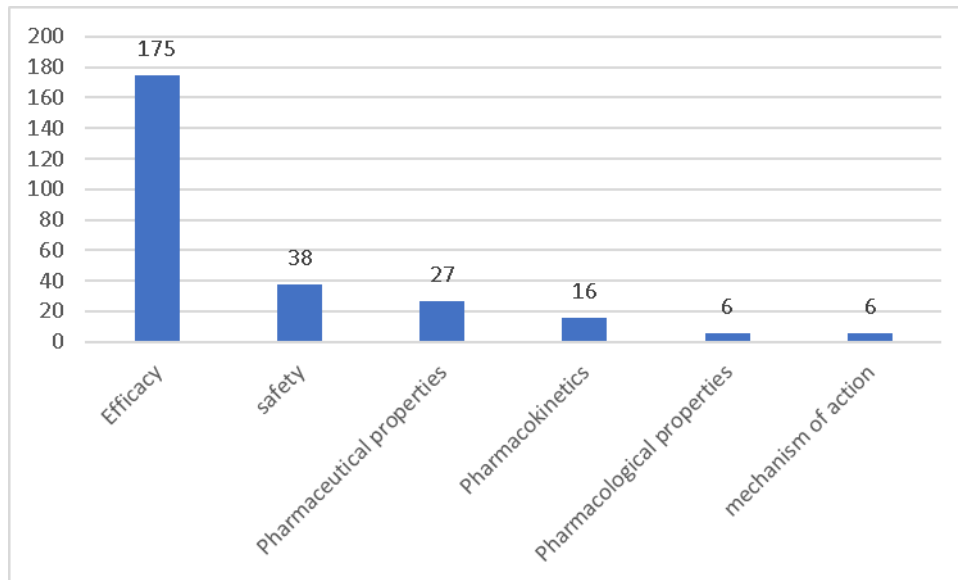


Fig. 2- classification of claims made in DPLs

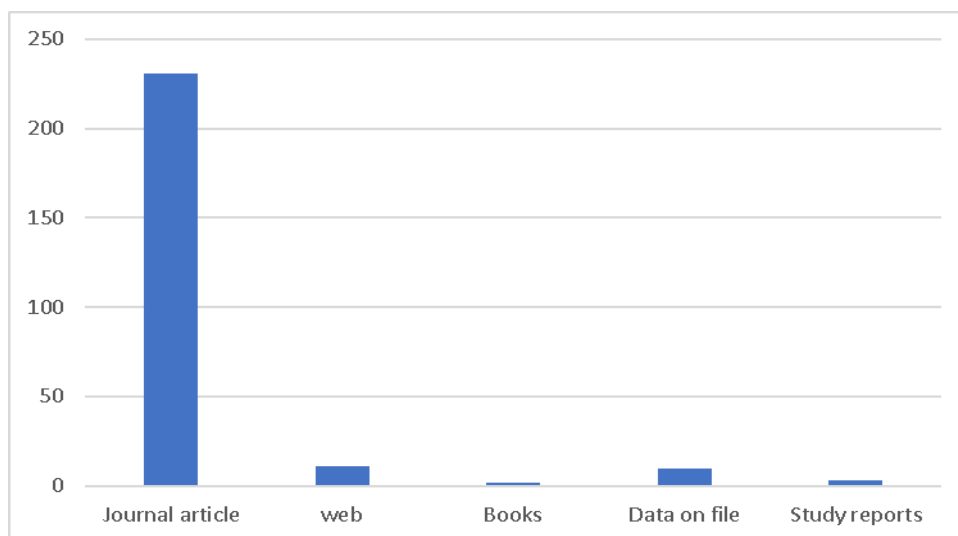


Fig.3- Classification of references according to their source

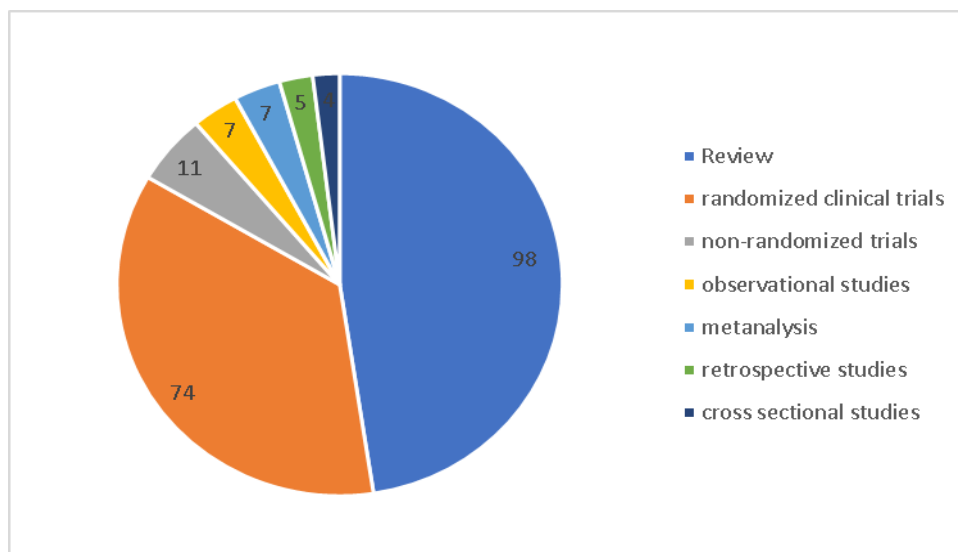


Fig 4- Classification of references from journal article according to type of studies

V. Discussion

Printed promotional literature is an easily available and important source of information. Every year many new drugs enter the Indian market. [13] The information provided for drug promotion should be accurate, scientific and evidence based to keep the doctors informed about the company's products and all related information. [12] Drug manufacturers spent more than \$11 billion each year in drug promotion and marketing. We observed from this study that pharmaceutical companies do not fulfill all the WHO criteria for ethical drug promotion. In our study, none of the DPL fulfilled all the ten WHO criteria and the information regarding adjuvant was missing from all the DPLs. This is similar to finding of other studies. [9,11,14] In our study, information regarding generic name of each active ingredient, brand name, amount of active ingredient, recommended dosage regimen was found in 97.53%, 100%, 95.06%, 59.25% respectively. Important information regarding safety of the drugs was present only in 32.09% DPLs. These findings are similar to other studies. [9,15]

These 81 DPLs contained 274 claims. Maximum claims were about the efficacy (63.86%). Claims about safety, pharmaceutical properties, pharmacokinetics were 13.87%, 9.85%, 5.84% respectively. Similar findings were found in another study. [14] We found 58.02% DPLs contained catchy terms/phrases. Irrelevant images were found in 48.14% DPL. Similar findings were noted in other studies. [9,14] In this study, 68 DPLs had provided 264 references for their claims. 13 DPLs were without references. Maximum were review articles 98 followed by randomized clinical trials. 35 references were not retrievable. This is similar to the study carried out in Mumbai. [9] Printed promotional material an important source of information. On the basis of the observations of this study, it is found out that pharmaceutical companies do not fulfill all the WHO criteria for ethical drug promotion. Therefore, it is suggested that physicians should be aware of the flaws in promotional literature. In countries like UK, Australia and Canada, it is required to observe a code of practice in marketing as a signatory condition for membership of the association. [16] India has set up regional ethics committee to collect complaints against unethical drug promotion advertisements at Mumbai, New Delhi, Chennai, and Chandigarh which forward these complaints to drug controller authority to take necessary legal steps to discipline guilty companies. [13,17] Forwarding more complaints about irrational promotion to regulatory authority by cautious doctors might change the pharmaceutical industry's attitude towards drug promotion. It is responsibility of a practicing physician to evaluate the drug promotional literature before accepting it as a valid source of information and to report any flaws if they found to appropriate authority.

VI. Conclusion

From our study, it is found out that pharmaceutical companies do not follow ethical guidelines while promoting their products. Therefore, it is responsibility of the physicians to critically analyze these DPLs before using them as a valid source of drug information. Small sample size was the limitation of present study. Study conducted only at single government hospital. In this study, only one type of promotional activity ie printed promotional drug literature was analyzed. Larger studies targeting all the activities of drug promotion are needed covering both government and private hospitals. Combined efforts of physicians, pharmaceutical industry and regulatory authority will help in ethical drug promotion and rational prescribing.

References

- [1]. Sahne B J, Yegenoglu S, Uner M, and Wertheimer A I. Adherence of drug advertisements to the international marketing Codes. Hacettepe University Journal of the Faculty of Pharmacy. 2012;32(1):53–66
- [2]. Lal A. Pharmaceutical Drug Promotion: How it is being Practiced in India? Vol. 47, Journal of Association of Physicians of India. 999. p. 266–373.
- [3]. Cooper RJ, Schriger DL, Wallace RC, Mikulich VJ, Wilkes MS. The quantity and quality of scientific graphs in pharmaceutical advertisements. J Gen Intern Med. 2003;18(4):294–7.
- [4]. [Internet]. 2017 [cited 11 September 2017]. Available from: <http://www.who.int/trade/glossary/story073/en#main>
- [5]. [Internet]. 2017 [cited 11 September 2017]. Available from: B. Mintzes, D. Mangin, and L. Hayes, Eds., Understanding and
- [6]. Responding to Pharmaceutical Promotion—A Practical Guide, vol. 4, World Health Organization/Health Action International, 1st edition, 2013, <http://www.haiweb.org/11062009/drugpromotion-manual-CAP-3-090610.pdf>.
- [7]. Medhi BPrakash A. Practical manual of experimental and clinical pharmacology. New Delhi: Jaypee Bros. Medical Publishers; 2010. P. 342–45.
- [8]. [Internet]. 2017 [cited 11 September 2017]. Available from: http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Code_of_Practice_2012_new_logo.pdf
- [9]. [Internet]. 2017 [cited 11 September 2017]. Available from: https://www.indiaoppi.com/sites/default/files/PDF%20files/OPPI%20Code%20of%20Pharmaceutical%20Practices%20-%202012_0.pdf
- [10]. 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.
- [11]. World Health organization (WHO). 1988 Ethical criteria for medicinal drug promotion. [Internet] 2017. [cited 11 September 2017] Available from: <http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip08e/whozip08e.pdf> Khakhkar T, Mehta M, Shah R, Sharma D. Evaluation of drug promotional literatures using WHO guidelines. J Pharm Negat Results [Internet]. 2013;4(1):33. Available from: <http://www.scopus.com/inward/record.url?eid=2-s2.0-84883660359&partnerID=tZOtx3y1>
- [12]. Results [Internet]. 2013;4(1):33. Available from: <http://www.scopus.com/inward/record.url?eid=2-s2.0-84883660359&partnerID=tZOtx3y1>

- [13]. Villanueva P, Peir?? S, Librero J, Pereir?? I. Accuracy of pharmaceutical advertisements in medical journals. *Lancet*. 2003;361(9351):27-32.
- [14]. S Gopalakrishnan. India: campaign to tackle. *Essent Drugs Monit* [Internet]. 2002;(31):2002. Available from: <http://www.healthyskepticism.org/files/WHOEDM/31/Page22.pdf>
- [15]. Jadhav S S, Dumatar C B, Dikshit R K. Drug promotional literatures (DPLs) evaluation as per World Health Organization (WHO) criteria. *Journal of Applied Pharmaceutical Science*, 2014; 4(06):084-088
- [16]. Alam K, Shah A, Ojha P, palaian S, Shankar P R. Evaluation of drug promotional materials in a hospital setting in Nepal. *Southern Medical Review*, 2009;2(1):2-6.
- [17]. Gitanjali B, Shashindran Ch, Tripathi KD, Sethuraman KR. Are drug advertisements in Indian edition of *BMJ* unethical? *BMJ* [serial online] 1997. Available from:<http://www.bmj.com/cgi/content/full/315/7106/459> Aug 23
- [18]. 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(6):391-4.

*Shagupta A NAIkwadi. "Critical Analysis of Indian Drug Promotional Literature(DPL) Using World Health organization Criteria For Ethical Medicinal Drug Promotion." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)* 16.9 (2017): 49-54