(International Print/Online Journal)

SJIF IMPACT FACTOR: 4.617
PUBMED-National Library of Medicine ID-101739732

ISSN (Print): 2209-2870
ISSN (Online): 2209-2862

International Journal of Medical Science and Current Research (IJMSCR)
Available online at: www.ijmscr.com
Volume2, Issue 2, Page No: 323-331
March-April 2019

Study of Rationality of Promotional Drug Literature Received At a Cancer Hospital

Dr. Chaudhari VL[1], Dr. Chaudhari NL[2*]
[1]MBBS, MD Pharmacology Associate Professor,
Dept. of Pharmacology, SMBT IMS and RC, Dhamangaon
[2]MBBS, MD General Medicine, DM Medical Oncology
Consultant Physician, Jeevanjyoti Cancer Hospital, Jalgaon,
Maharashtra, India-425001

***Corresponding Author:**

Dr. Chaudhari NL
Add: 13, Vivekanand Nagar, Jilha Peth, Behind Hotel Rupali, Swatantra Chowk, Jalgaon, Maharashtra, India

Type of Publication: Original Research Paper
Conflicts of Interest: Nil

ABSTRACT

Introduction: The drug promotional literature (DPL) of the pharmaceutical companies is the most important sources of drug information. However, these DPLs are inaccurate and of poor educational value. Hence, we planned this study with the aim to evaluate the collected DPLs of anticancer drugs for accuracy, consistency, and validity of the information presented in it, using World Health organization (WHO) ethical criteria for medicinal drug promotion.

Materials and Methods: This observational study was conducted in six months duration. The DPLs were collected from out-patient department at Jeevanjyoti Cancer Hospital, Jalgaon and evaluated in department of Pharmacology in a medical institute in India. The literature was evaluated based on the WHO ethical criteria for drug promotion.

Results: Only 6% of the DPLs fulfilled all WHO criteria and 53% of DPLs were of anticancer drugs. 38% DPLs did not have any brief prescription information about the promoted drug. Majority (92%) of DPLs claimed about the efficacy of product. Out of132 references, 24% were not retrieved. Brochures presenting irrelevant pictures were48% where as statistically significant difference was found between the availability of printed side effects, precautions, contra-indications, warnings, drug interactions, number of quoted references before 2014 and brief prescription information on DPLs of anticancer and other drugs groups with p-value <0.05.

Conclusion: Pharmaceutical industries did not follow the WHO guidelines while promoting their products and to reduce this problem, government regulatory bodies must play a pre-emptive role where code of ethics is failing.

Keywords: Anticancer drugs, Brief prescription information, Drug brochures, Efficacy claims, Medicine promotion

INTRODUCTION

Pharmaceutical drug promotion refers to all informational and convincing activities by manufacturers and distributors, which lead to encourage the prescription, supply, purchase and/or use of medicinal drugs. The drug promotional literature (DPL) provided by the pharmaceutical companies is one of the most important sources of drug information to the clinicians. [1] In 2005, a pharmaceutical industry in the USA has spent more than 30 billion dollars in marketing and promoting to enlighten the clinicians about their products.[2] However, these DPLs at times are inaccurate and of

poor educational value[3-5]leading to inappropriate prescribing practices by inducing doctors prescribing behavior with or without benefitting the patient and further contributing to increased health care costs.[6] Promotional activities by pharmaceutical companies are governed by Organization of Pharmaceutical Producers of India (OPPI), self-regulatory code of pharmaceutical marketing practices, January (2007) and by National legislation which are derived from the 'World Health Organization's (WHO) Ethical criteria for the Medicinal drug promotion'.[7]Loyalty to the code of conduct is mandatory for the membership for manufacturers' association. However, many studies have reported that information spread through DPLs is varying with the code of ethics.[7-20]

Anticancer drugs either kill cancer cells or modify their growth. However, these drugs are one of the most toxic drugs used in allopathy. The toxicity is more severe on rapidly multiplying cells in host such as bone marrow, epithelial cells, reticuloendothelial system and gonads. Hence, the drug regimens and number of cycles of combined chemotherapy has to be planned accurately and wisely for which proper directions of drug use, possible adverse effects and contra-indications are necessarily printed on the DPLs of anticancer agents. However, very few studies have been carried out on DPLs of anticancer drugs and the reported observations are highly controversial [10]. Hence, we planned this study with the aim to evaluate the collected DPLs of anticancer drugs for accuracy, consistency, and validity of the information presented in it, using WHO ethical criteria for medicinal drug promotion.

MATERIALS AND METHODS:

The present study was an observational, cross-sectional study which was conducted by the Department of Pharmacology at SMBT Institute of Medical Sciences and Research Centre, Dhamangaon for a period of 6 months from October 2018 to March 2019. The study was commenced only after the protocol was approved by the Institutional Ethics Committee (SMBT/IEC/18/479). DPLs in the form of flyers, leaflets, and brochures were collected from the out-patient department (OPD) of Jeevanjyoti Cancer Hospital at Jalgaon which were available in the hospital through medical representatives and brought to study area by the Principal Investigator. The Collected DPLs were assessed as per the WHO guidelines. Literature promoting medicinal devices and equipment (insulin pump, blood glucometer, andorthopedic prosthesis), ayurvedic medications, drug monographs, reminder advertisements, and drugs' name list were excluded. The following are the WHO criteria to be followed by pharmaceutical industries for the completeness of DPLs:[1]

1. The names of the active ingredients using either international nonproprietary names or the approved generic names of the drug;
2. The brand name;
3. Content of active ingredient per dosage form or regime;
4. Name of other ingredients known to cause problems, i.e., adjuvant;
5. Approved therapeutic uses;
6. Dosage form or regimen;
7. Side effects and major adverse drug reaction;
8. Precautions, contraindications, and warnings;
9. Major interactions;
10. Name and address of the manufacturer or distributor; and
11. Reference to scientific literature as appropriate.

The DPLs were also analyzed for additional information such as various pictures printed, cost mentioned, and source and year of references used to defend the DPL claims. Descriptive statistics were used to analyze the data. The data were expressed as percentage. The comparison of various parameters between the DPLs of anticancer and other drugs was conducted using Fisher's exact test in Statistical Package for the Social Sciences (SPSS)version 24, IBM Corporation, Armonk, New York with a statistical significance set at p value <0.05.

RESULTS

Total 66 DPLs were collected from the Jeevanjyoti Cancer Hospital and analyzed, which revealed 58 (88%) were single drug formulation and 8 (12%) were fixed dose combination. Figure 1 represents the most commonly promoted drug categories arranged system wise as per Anatomical Therapeutic Chemical (ATC) classification. Total 35 (53%) DPLs were promoting anticancer drugs whereas 33(43%) DPLs were of other drugs such as analgesics (5%), antibiotics (9%) and drugs acting on- musculoskeletal system (6%), gastro-intestinal system (18%), and

Volume 2, Issue 2; March-April 2019; Page No. 323-331

hematology (9%). The extent to which DPLs followed the WHO criteria is shown in Table 1. All DPLs mentioned the generic, brand name and the active ingredient however, drug cost was not revealed in any of the DPLs. Pictures occupied considerable amount of space on all brochures while the drug administration information was not mentioned in 25 (38%) DPLs and occupied less than 10% of the total area of DPLs in 38 (58%). DPLs depicted photographs of drug formulation, woman, patient and other unrelated photographs were as shown in Figure 2. Only 34 (52%) DPLs had relevant pictures of drugs being promoted and 32 (48%) had irrelevant representation in the form of woman, patient, and others occupying major area. The pharmacological properties were represented in the form of graphs or scientific tables in 17 (26%) DPLs. The quality of paper used for DPLs were durable and the text was legible however the font size of brief prescription information was very less in all the DPLs.

In 66 DPLs, total 132 references were mentioned. The details of references were shown in Table 2. Majority of references were quoted from journal articles, of which references published after 2014 were only 36 (37.5%) as represented in Table 2. A total of 45 (68%) DPLs satisfied 50% of the WHO criteria. Only 4 (6%) of the DPLs adhered to all the criteria and all of them belong to anticancer group.

When the DPLs of anticancer (n=35) and other drugs (n=31) were compared for meeting the WHO criteria, there was statistically significant difference between the availability of printed side effects, precautions, contra-indications, warnings, drug interactions, number of quoted references before 2014 and brief prescription information on DPLs of anticancer drugs with p-value <0.05 as shown in Table 1, Table 2 and Figure 2. However, no difference was noted in other WHO criteria and promotional claims raised in DPLs. All DPLs of anticancer drugs satisfied 50% of the WHO criteria while only 33% DPLs of other drugs satisfied 50% of the WHO criteria.

DISCUSSION

Promotional literatures by pharmaceutical companies forms an important source of information to the practicing physician, since they are not able to access other more reliable and authentic sources of drug information due to their hectic schedule, and other reasons. DPLs are sometimes the only source about new drugs/new indications for old drugs. However, many studies found that the claims and figures in these literatures are often misleading and biased so as to highlight only the positive aspects of the products and neglect the negative ones, leading the physician to prescribe the products which can be harmful to the patient and the community.

Marketing new drugs to physicians is an important strategy adopted by pharmaceutical companies making the principal objective of DPL is to promote their product. [2]However, it should be ethical. In our study, we observed that only 6% of the DPLs fulfilled all the criteria recommended by the WHO guidelines. Other studies reported similar finding. [2,7-12] This indicates that the pharmaceutical companies are more involved in building a commercial bond with the physicians in which the ethical educational aspect is highly compromised.[7] In the present study, only 12% of DPLs promoted fixed drug combination, which is much less than the other studies. This might be due to less fixed dose combinations are available to treat cancer patients. Anticancer drugs being the most promoted class in this study, indicating that pharmaceutical companies are developing new anticancer drugs rapidly and are targeting to promote these drugs meticulously.

It was observed that most of the DPLs had mentioned brand name, approved generic name, and active ingredient per dosage form, which is similar to other studies. In our study, only 10% of the DPLs had mentioned other ingredients that are known to cause problems. This suggests that pharmaceutical companies do not consider other ingredients as an important aspect of drug information and thus fail to fulfill the WHO criteria of ethical drug promotion. We observed that majority of DPLs quoted dosage form and therapeutic indications, but did not mention the adverse drug reactions, precautions, contraindications, and interactions particularly in the DPLs of other drugs group. The above criteria are certainly required for the care of the patient and also manage physician time from reviewing into other source of information. Similar findings were observed in other studies.[2,7-13]

All the DPLs were colorful, sturdy and attractive, but had irrelevant pictures related to the drugs being promoted. DPLs had used therapeutically unrelated matter and nonspecific depictions occupying major

Volume 2, Issue 2; March-April 2019; Page No. 323-331

area, which could have been used more properly for listing various characteristics of drugs. Other studies have reported similar finding. [2,7,10]

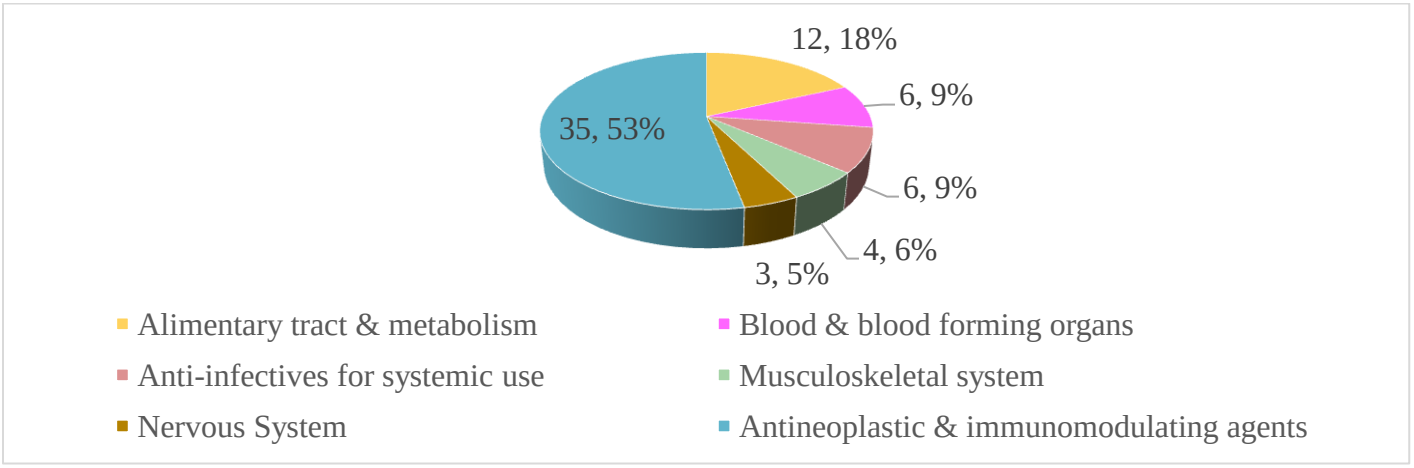
In this study, it was observed that unproven claims were made in the DPLs regarding efficacy and safety. Recent references were mentioned in very few DPLs, but this is necessary for updating the physicians so as to increase their existing knowledge and practice evidence-based medicine. In view of this study, it is of utmost importance for the treating physician to critically evaluate any source of drug information based on the established guidelines before accepting them as scientific piece of information. Sixty-eighty percent of the advertisements satisfied only half of the WHO criteria for rational drug promotion. Hence, the treating physicians should meticulously check the DPLs to provide and improve the quality care of the patients.

DPLs of anticancer drugs are more satisfying the WHO criteria as compared to other drugs. Similarly, the references cited in these DPLs were more recent, indicating that there is more recent data available on anticancer drugs and more research activities are focused on anticancer drugs.

There are some limitations in our study. One of the limitations of the study was small sample size. Also, the study was conducted only in a single centre. In this study only one type of promotional activity was analyzed, i.e. printed promotional literature. However, there is a prerequisite to evaluate the awareness of the physicians by intervention study and provides guidance about correct and ethical information from DPLs.

Finally to conclude, the pharmaceutical companies are promoting their products rather than providing the authentic information wherein one often comes across wrong, misleading or even false proclamations. [7] This problem is prevalent worldwide. As per a survey conducted by WHO in 2004, less than one-sixth of the countries had a well-developed regulation system for pharmaceuticals. One-third of national governments reported that they had little or no regulatory capacity. Some developed countries, such as the UK, Canada and Australia, have guidelines, codes, and regulations for printed material and material intended for broadcast. The UK provides an example of self-regulation and enforcement. [2] 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.[7,21] Forwarding more complaints about irrational promotion to regulatory authority by cautious physicians might lead pharmaceutical industry to incline toward self-regulation. Pharmaceutical industries did not follow the WHO guidelines while promoting their products and to reduce this problem, government regulatory bodies must play a pre-emptive role where code of ethics is failing. Wherever the hospitals are attached to the institutions, prior scrutiny of the promotional material for authenticity of the content could be done by the department of pharmacology.

Figure 1: Type of drug promoted according to Anatomical Therapeutic and Chemical (ATC) Classification



Volume 2, Issue 2; March-April 2019; Page No. 323-331

Table 1: Evaluation of Drug Promotion Literatures (DPLs) as per World Health Organization (WHO) criteria of ethical drug promotion

WHO Criteria	Anticancer		Other		Total	
	No	%	No	%	No	%
International Nonproprietary Name	35	100.0	31	100.0	66	100.0
Brand Name	35	100.0	31	100.0	66	100.0
Active Ingredients	35	100.0	31	100.0	66	100.0
Other Ingredients	6	17.1	1	3.2	7	10.6
Appropriate indications	35	100.0	28	90.3	63	95.5
Dosage form	33	94.3	26	83.9	59	89.4
Side effects	21	60.0	5	16.1***	26	39.4
Precautions	22	62.9	5	16.1***	27	40.9
Contra-indications	24	68.6	7	22.6***	31	47.0
Warnings	22	62.9	5	16.1***	27	40.9
Interactions	15	42.9	5	16.1*	20	30.3
Name of Manufacturer/Distributor	35	100.0	29	93.5	64	97.0
Address of Manufacturer/Distributor	35	100.0	15	48.4	50	75.8
Reference to scientific literature	26	74.3	18	58.1	44	66.7

Fisher's exact test applied. *p value<0.05, ***p value<0.001

Table 2: Characteristics of references quoted in drug promotion literatures

Reference characteristics	Anticancer (n=69)		Other (n=63)		Total (n=132)	
	No	%	No	%	No	%
Retrievability	50	72.5	51	81.0	101	76.5
Journal	48	69.6	48	76.2	96	72.7
Web	2	2.9	3	4.8	5	3.8

Volume 2, Issue 2; March-April 2019; Page No. 323-331

Published before 2014	25	36.2	40	63.5**	65	49.2
Non-retrieved	19	27.5	12	19.0	31	23.5
Study	1	1.4	1	1.6	2	1.5
Data on file	7	10.1	2	3.2	9	6.8
Seminar	2	2.9	0	0.0	2	1.5
Guideline	3	4.3	2	3.2	5	3.8
Other	0	0.0	4	6.3	4	3.0
Book	1	1.4	2	3.2	3	2.3
Prescription by Pharmaceutical company	5	7.2	1	1.6	6	4.5

Fisher's exact test applied. **p value<0.01

Table 3: Evaluation of claims raised in the drug promotion literatures

Claims	Anticancer		Other		Total	
	No	%	No	%	No	%
Efficacy	34	97.1	28	90.3	62	93.9
Safety	19	54.3	10	32.3	29	43.9
Cost	1	2.9	4	12.9	5	7.6
Convenience	10	28.6	6	19.4	16	24.2
Pharmacokinetic	4	11.4	5	16.1	9	13.6
Pharmaceutical	11	31.4	8	25.8	19	28.8
Emotional	9	25.7	11	35.5	20	30.3

Figure 2: Categorization of pictorial content in the drug promotional literatures (n=71)

Volume 2, Issue 2; March-April 2019; Page No. 323-331

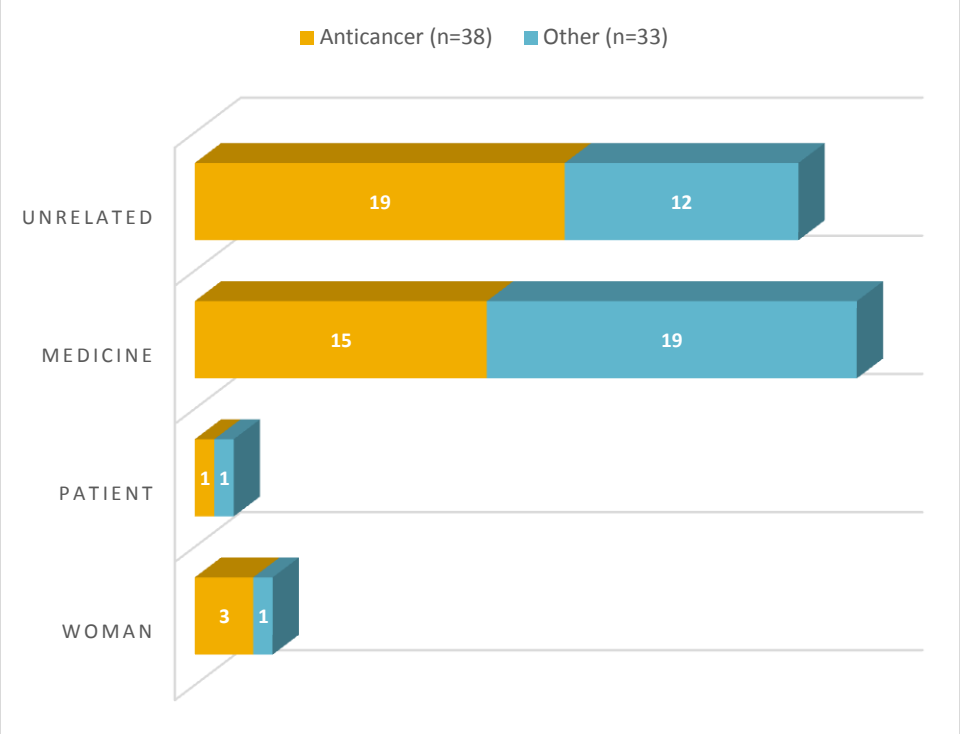
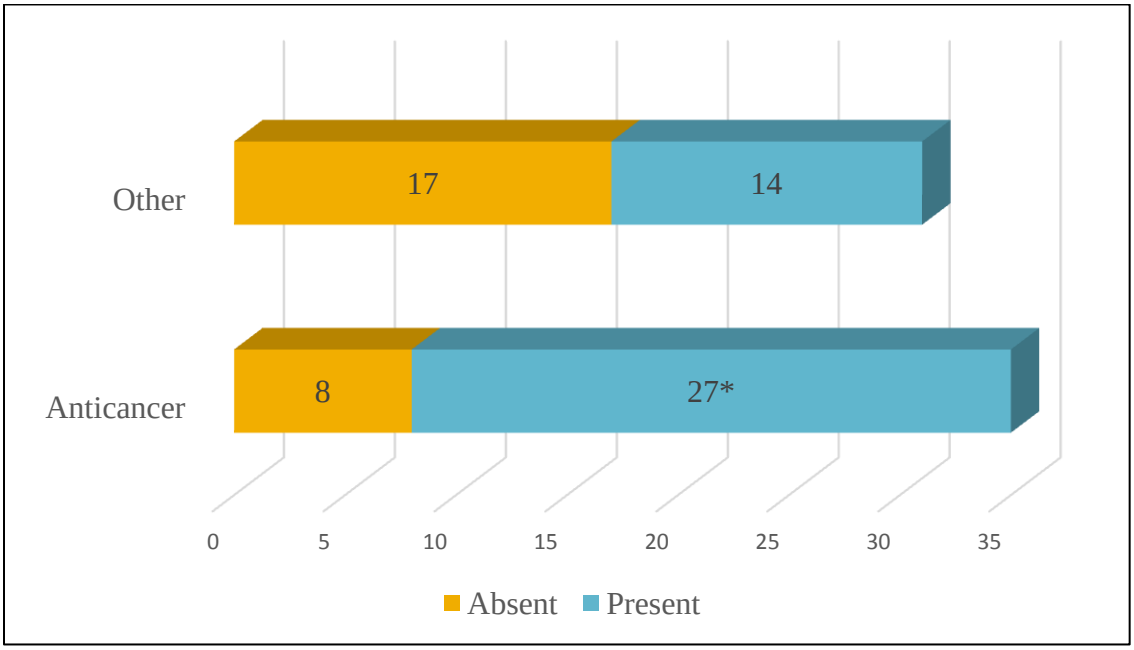


Figure 3: Evaluation of printed brief prescription information in the drug promotion literatures



Fisher's exact test applied. *p value<0.05.

REFERENCES

1. World Health Organization. Ethical criteria for medicinal drug promotion. World Health Organization. Geneva: WHO; 1988.
2. Mangla N, Gupta MC. Evaluation of rationality of drug promotional literature using WHO ethical criteria for medicinal drug promotion. Int J Health Sci Res. 2018; 8(4):55-62.

Volume 2, Issue 2; March-April 2019; Page No. 323-331

3. Loke TW, Koh FC, Ward JE. Pharmaceutical advertisement claims in Australian medical publications: Is evidence accessible, compelling and communicated comprehensively? Med J Aust. 2002;177(6):291-3.
4. 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.
5. Villanueva P, Peiro S, Librero J, Pereiro I. Accuracy of pharmaceutical advertisements in medical journals. Lancet 2003;361:27-32.
6. Cardarelli R, Licciardone JC, Taylor LG. A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underling studies:Is what they tell us important and true? BMC Fam Pract 2006;7:13-8.
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):267–272. doi:10.4103/0253-7613.70020
8. Randhawa GK, Singh NR, Rai J, Kaur G, Kashyap R. A Critical Analysis of Claims and Their Authenticity in Indian Drug Promotional Advertisements. Adv Med. 2015;2015:469147. doi:10.1155/2015/469147
9. Vachhani PM, Solanki MN, Desai MK. An evaluation of drug promotional literatures published in scientific medical journals. J Pharm Bioallied Sci. 2016;8(3):248–252. doi:10.4103/0975-7406.180769
10. Ganashree P, Bhuvana K, Sarala N. Critical review of drug promotional literature using the World Health Organization guidelines. J Res Pharm Pract. 2016;5(3):162–165. doi:10.4103/2279-042X.185711
11. Khakhkhar T, Mehta M, Sharma D. Evaluation of drug promotional literatures using WHO guidelines. J Pharm Negative Results. 2013;4:33–8.
12. Jadav SS, Dumatar CB, Dikshit RK. Drug promotional literatures (DPLs) evaluation as per World Health Organisation (WHO) criteria. J App Pharm Sci. 2014;4:84–8.
13. Naikwadi SA, Jadhav RB, Patil AP. "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.
14. Jaykaran, 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):192–194. doi:10.4103/0976-500X.83288

Volume 2, Issue 2; March-April 2019; Page No. 323-331

15. Sharif SI, Hassanein MM, Hassanein MM. Evaluation of drug promotional literature directed to consumers and physicians. Int J Basic Clin Pharmacol 2016;5:478-83.
16. Sharma AK, Dahiya N, Chuki P. Comparison of drug advertisements published in Indian and foreign journals. Int J Res Med Sci 2015;3:2630-4.
17. Parli K, Reema R, Devang R and Supriya M: Evaluation of promotional drug literature provided by medical representative at a tertiary care hospital. Int J Pharm Sci Res 2017; 8(4): 1744-50.doi: 10.13040/IJPSR.0975-8232.8(4).1744-50.
18. Santiago MG, Bucher HC, Nordmann AJ. Accuracy of drug advertisements in medical journals under new law regulating the marketing of pharmaceutical products in Switzerland. BMC Med Inform Decis Mak. 2008;8:61. Published 2008 Dec 31. doi:10.1186/1472-6947-8-61
19. Kornfield R, Donohue J, Berndt ER, Alexander GC. Promotion of prescription drugs to consumers and providers, 2001-2010. PLoS One. 2013;8:e55504.
20. Mikhael EM. Evaluating the reliability and accuracy of the promotional brochures for the generic pharmaceutical companies in Iraq using World Health Organization guidelines. J Pharm Bioallied Sci. 2015;7:65–8.
21. Gopalakrishnan S, Murali R. India: Campaign to tackle unethical promotion. World Health Organization. Essential drugs monitor [Online]. 2002 (31):22.

.

Volume 2, Issue 2; March-April 2019; Page No. 323-331