Original Article

A Cross-Sectional Evidence-Based Review of Drug Promotional Literature (DPL) in a Government Medical College

Lavita Hazarika[1], Khanindra Nayan Kakoty[2], Geetamoni Dutta[3], Sahid Aziz[4], Rituparna Phukan Ray[5]

[1]Lavita Hazarika, Demonstrator, Department of Pharmacology, Jorhat Medical College, Jorhat, Assam, [2] Khanindra Nayan Kakoty, Demonstrator, Department of Pharmacology, Assam Medical College, Dibrugarh, Assam, [3] Geetamoni Dutta, Associate Professor. Department of Pharmacology, Jorhat Medical College, Jorhat, Assam, [4] Sahid Aziz, Assistant Professor. Department of Pharmacology, Jorhat Medical College, Jorhat, Assam, [5] Rituparna Phukan Ray, Professor and Head, Department of Pharmacology, Jorhat Medical College, Jorhat, Assam.

How to cite this article: Lavita Hazarika, Khanindra Nayan Kakoty, Geetamoni Dutta et. al. A Cross-Sectional Evidence-Based Review of Drug Promotional Literature (DPL) in a Government Medical College. Indian Journal of Public Health Research and Development / Vol. 15 No. 4, October-December 2024.

Abstract

With the increase in the number of new drugs and high competition among pharmaceutical companies, medical representatives use Drug promotional literature (DPL) to promote their drugs. DPLs are one of the most accessible means of drug information. Therefore, drug promotion by ethical means is important as it influences rational and ethical prescribing by clinicians. This study was undertaken to evaluate and analyze the various DPLs for their ethical and scientific status as per World Health Organization (WHO) Ethical Drug Promotion Guidelines. This is a cross-sectional, observational study, conducted by evaluating and analyzing 207 DPLs collected randomly over a period of 6 months from various out-patient departments (OPDs) of Jorhat Medical College and Hospital (JMCH). Of the 207 DPLs, a single drug was promoted in 48.31% and 51.69% were drug combinations. Only 60 (28.98%) of the DPLs fulfilled all 11 WHO criteria. References were mentioned in 75.85%; adverse drug reactions, contraindications, precautions, warnings, and drug interactions were listed in 32.85% of brochures, while dosage regimen was mentioned in 64.73% DPLs. The drug cost was highlighted in 7 DPLs (3.38%), while 2 DPLs (0.97%) did not mention the manufacturer's name. Although 21.74 % literature showed relevant graphs and tables, 3% of brochures had irrelevant pictures. The most commonly promoted drugs were those acting on CNS (15.94%), followed by drugs acting on the cardiovascular system and anti-diabetic drugs (13.04%). In conclusion, majority of the DPLs did not follow the WHO guidelines and hence inadequate and unreliable drug information was promoted; which may mislead and result in irrational or unethical prescriptions.

KEYWORDS: DPL, Drug Promotional Literature, Medical Representatives.

Corresponding Author: Sahid Aziz, Assistant Professor. Department of Pharmacology, Jorhat Medical College, Jorhat, Assam.

E-mail: drshahidaziz86@gmail.com

Submission date: Nov 5, 2023 **Revision date:** December 18, 2023 **Published date:September 20 , 2024**

Introduction

With the emergence new diseases and evolution of medical science, many novel drugs are launched into the market frequently. Also, older drugs have been tried and tested for both emerging and existing diseases. Most of the time, the initial source of information on these drugs to practicing clinicians is through Drug Promotional Literature (DPLs). These are supplied by the manufacturing companies, via their medical representatives, among clinicians to promote their drugs. All these promotional materials should contain reliable, accurate, and truthful information, which is updated and can be substantiated. In 1988, the WHO developed the "Ethical Criteria for Medicinal Drug Promotion", which defined 'drug promotion' as – "all informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs"[1]; to assist and encourage the improvement of healthcare via the rational use of drugs. In India, the promotional activities of pharmaceutical companies are governed by three bodies: the Organisation of Pharmaceutical Producers of India (OPPI), the self-regulatory code of pharmaceutical marketing practices, January 2007, and by the National Legislation.[2]

DPLs tend to have a powerful impact on physicians' prescribing behavior, affecting drug utilization patterns and rational/irrational use of drugs.[3] Many studies have shown that DPLs promote information inconsistent with the code of ethics and inaccurate and of poor educational value.[4] In India, very few studies have been carried out to access the quality, adequacy, and genuineness of the scientific information provided by these DPLs. Therefore, this study was conducted to evaluate and analyze the various Drug Promotional Literatures (DPLs) for their ethical and scientific status as per WHO Ethical Drug Promotion Guidelines, 1988.

Methodology

This was a cross-sectional, observational study performed at the Department of Pharmacology, by assessing and analyzing DPLs (in the form of flyers, brochures, pamphlets, etc.), collected randomly from various OPDs (Orthopaedics, General Medicine, Psychiatry, Surgery, Pulmonary Medicine, Pediatrics, Obstetrics and Gynecology) of Jorhat Medical College and Hospital, Jorhat, Assam; over a period of 6 months (June 2022 to November 2022). Literature promoting medicinal devices and equipments (like insulin pumps, glucometers, etc.), orthopedic prostheses, ayurvedic medicines, drug monographs, reminder advertisements, drug name lists, and brochures containing more than 2 brands were excluded. All the DPLs were evaluated for accuracy and completeness of the 11 WHO criteria for ethical drug promotion[1],

The DPLs used various pictures and methods of data representation to persuade the clinicians for prescribing the particular drug promoted in the DPL – thus, the pictorial contents of the promotional brochures were also analyzed using the following domain.

a. Type of picture (men, women, patient, doctor, others, etc.)

b. Graphical representation of facts and figures.

Apart from these, additional information like drug cost and drug composition (single or fixed-dose combination) were also analyzed. Further, the data were analyzed using descriptive statistics and all values were expressed in percentages.

Results

A total of 207 DPLs were included and considered for evaluation as per the selection criteria and analyzed according to WHO ethical drug promotion criteria. The majority of the DPLs (51.69%) promoted fixed dose combinations (FDCs), whereas 48.31% promoted single formulations (Figure 1).

Figure 1: Types of Drug formulation

The greater number of DPLs promoted drugs acting on the central nervous system (15.9%), followed by drugs acting on the cardiovascular

system (13.04%) and anti-diabetic drugs (13.04%). Other class of drugs promoted were antioxidants, analgesics, antimicrobials, nutraceuticals and drugs acting on gastrointestinal system, respiratory and endocrinal system. (Figure 2)

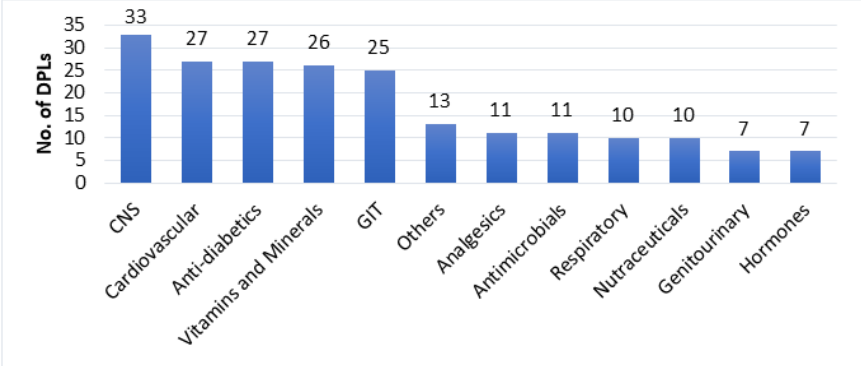

Figure 2: Class of Drugs

Only 60 (28.9%) DPLs fulfilled all the 11 WHO criteria of drug promotion (Figure 3). 100% DPLs had the brand name mentioned, whereas 99.03% had the generic name mentioned as well. The majority of the DPLs have mentioned the active drug per dosage form (95.65%) and approved therapeutic uses (96.14%) (Figure 4)

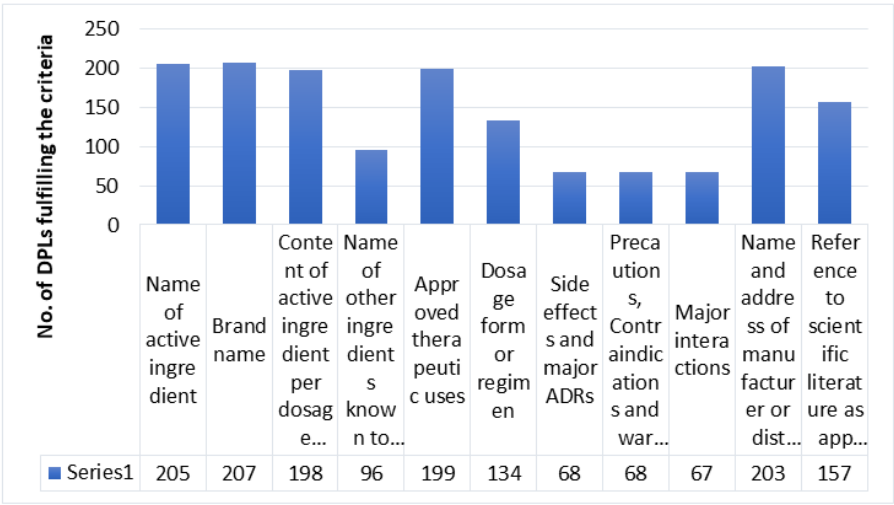

Figure 3: %WHO Criteria fulfillment

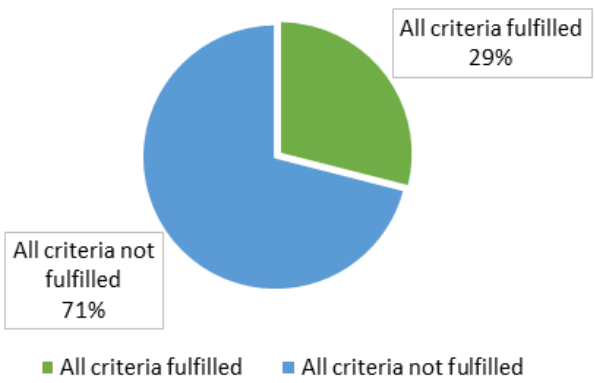

Fig.4: WHO criteria of ethical drug promotion

Among the most neglected information was regarding the safety information of the drug that has been promoted in the respective DPL. Side effects, major adverse drug reactions (ADRs), precautions, contraindications and warnings were absent from 67.15% and major interactions were lacking in 67.63% of the DPLs. Also, other ingredients known to cause problems was missing from 53.62% of the DPLs studied, thereby indicating the inadequate mention of the safety information. References to claims were lacking from 24.15%, while 1.93% DPLs lacked name and address of manufacturer (Table-1).

Table 1: Lacking information

Sl. No	WHO Criteria for ethical drug promotion	No. of DPLs lacking the information	% lacking the information
1	Name of active ingredient	2	0.97%
2	Brand name	0	0%
3	Content of active ingredient per dosage form or regimen	9	4.35%
4	Name of other ingredients known to cause problems	111	53.62%
5	Approved therapeutic uses	8	3.86%
6	Dosage form or regimen	73	35.27%
7	Side effects and major ADRs	139	67.15%
8	Precautions, contraindications and warnings	139	67.15%
9	Major interactions	140	67.63%
10	Name and address of the manufacturer	4	1.93%
11	Reference to scientific literature as appropriate	50	24.15%

Moreover, all the DPLs used small fonts to write the safety information. Brand names and generic names were very dissimilar in relation to font size and color. Apart from these, the cost of drug or dosage regimen was mentioned in only 3.38% (7) DPLs, and statistical representation of data using charts and graphs were seen in 21.74% (45) DPLs.

A total of 234 pictures were used in the 207 DPLs to make them convincing and attractive, of which 70 (29.91%) were drug package covers. (Figure 5)

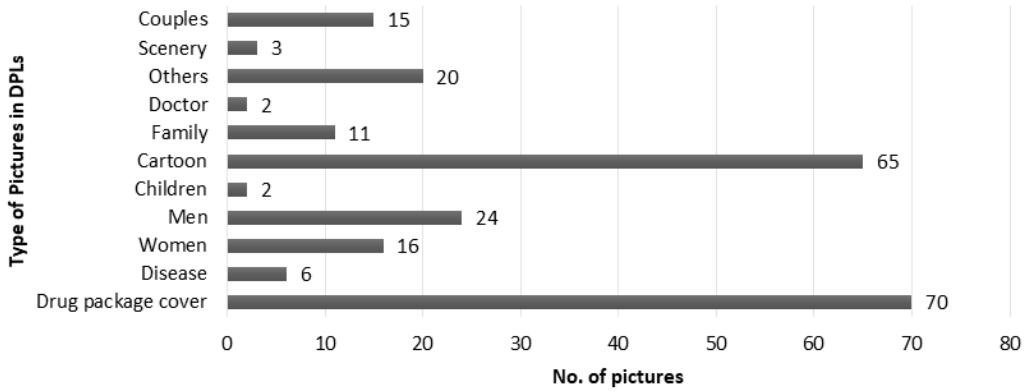

Fig.5: Type of Pictures used in DPLs

Discussion

A large number of brands are now available in the market for every formulation of the drug. Therefore, the intention of every manufacturer to acquire the growing market is of utmost importance. DPLs are one of the most common means of promotion used by pharmaceutical companies, and studies have shown that drug promotion does affect the prescribing pattern of the physicians[9]. Ideally it should abide by all the 11 criteria laid down by WHO for ethical drug promotion.

In our study, the majority of the DPLs promoted FDCs over single drugs, although the rationale for the combination was justified only for a few combinations with most of the FDCs being not WHO-recommended. This was also seen in studies by Sekar *et al*[11] and Mangla N *et al*[15]. Hence, physicians should consider the rationality of drug combination before prescribing as it shall increase the risk of ADRs and also the cost of treatment.

Among the most promoted class of drugs, drugs acting on the central nervous system, cardiovascular agents and anti-diabetic drugs were most common in this study. Similar observations were also made in several studies.[11,7,5,8,6,4,3,10] This suggests that most pharmaceutical companies are targeting drugs for chronic ailments, which ensures them huge profits for a longer period of time.

It was seen that 60 out of 207 (28.9%) DPLs fulfilled all the 11 WHO criteria for ethical drug promotion. Studies by Mangla N *et al* [15] and Rani SG *et al* [3] showed 2% and 5.8% DPLs following all the WHO criteria respectively. Whereas, many other studies have showed that none of the DPLs followed all the 11 criteria. [13,10,4,6,5,7,11] Though we found a higher proportion of DPLs following all the criteria ethical drug promotion compared to other studies, it still remains on the lower side. It can thus be inferred that the drug manufacturing companies are prioritizing on the marketing aspect, wherein the ethical and educational aspects were compromised. This not only creates a knowledge gap of updated information but also cause irrational prescribing and unwarranted inconvenience to patients.

A drug's safety information, including side effects, precautions, contraindications, warnings, major ADRs, and major interactions, were the most neglected information in the DPLs. Similar neglect was also observed in other studies[13,15,11,7,6,4,12,3,10]. This indicated that the safety information is highly overlooked despite being one of the most important criteria to consider before prescribing, and also to prevent drug-related adverse effects. Proper mention of these information in larger fonts should be made a standard for DPLs.

Pictorial representation in the DPLs occupied a large part of the DPLs, making them persuasive. This non-specific content not only compromises the font size of important therapeutic content but also deprives space for more relevant scientific drug-related information. Many studies have observed the same [13,10,3,4,6,5,7]. Very few studies [15,11,4] had observed the mention of drug cost in the DPLs evaluated, like with this study (3.38%). The cost of the drug being promoted, if mentioned in the DPLs provides the prescribing physician with a perspective of the feasibility from the patients' point of view and therefore compliance with the therapy.

Though this study provides new information on the present trend on DPLs provided by pharmaceutical companies, it has certain inherent limitations. This has been a small, single-centered, government hospital-based study, with a small sample size, and only the printed type of drug promotional activities was analyzed within a short period of time.. Pharmaceutical companies use a variety of other lucrative activities to influence the prescribing pattern of physicians which could not be assessed in this study.

Conclusion

DPL availability is of little importance unless the prescriber is aware of its existence and knows the art of analyzing it and using it effectively to prescribe rationally for patients. It is essential to sensitize the medical fraternity regarding the harmful effects of unethical drug promotion, which can lead to unethical, irrational prescribing, affecting the patient physically and financially. A good quality DPL can prove to be helpful in providing necessary information regarding a drug and help in educating practicing clinicians. Improper advertisement of drugs encourages drug consumerism, self-

medication, drug misuse, and drug abuse. Irrational prescribing also led to poor treatment outcomes, increased ADRs, and increased health care costs with wastage of resources. With proper implementation of a code of ethics in drug promotion, it can not only rationalize the therapy for the individual patient, but also reduce drug resistance and adverse events and cut down the costs of healthcare.

Ethical clearance: Not taken (No confidential data invloved)

Source of funding: Self

Conflict of Interest: Nil

References

1. Ethical criteria for medicinal drug promotion. World Health Organization [Online]. 1988 May 13.
2. OPPI code of pharmaceutical marketing practices. Available from: URL:http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf [Online]. 2007 Jan [last cited on 2007 Mar 3];[32 screens].
3. Rani SG, Chugh PK, Sah RK, Tripathi CD. Critical appraisal of drug promotional literature using World Health Organisation guidelines. Int J Basic Clin Pharmacol 2017; 6:2014-9.
4. Ganashree P, Bhuvana K, Sarala N. Critical review of drug promotional literature using the World Health Organization guidelines. J Res Pharm Pract 2016; 5:162-5.
5. Mali SN, Dudhgaonkar S, Bachewar NP. Evaluation of rationality of promotional drug literature using World Health Organization guidelines. Indian J Pharmacol 2010; 42:267-72
6. 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.
7. Khakhkhar, Tejas& Mehta, Maulin& Shah, Rima & Sharma, Dineshchandra. Evaluation of drug promotional literatures using WHO guidelines. Journal of Pharmaceutical Negative Results (2013). 4. 33.
8. Cardarelli R, Licciardone JC, Taylor LG. 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 Mar 3;7:13.
9. Sharif, Suleiman I.; Hassanein, Mohammed M.; Hassanein, Mai M.. Evaluation of drug promotional literature directed to consumers and physicians. International Journal of Basic & Clinical Pharmacology, [S.l.] 2016, v. 5, n. 2, p. 478-483.
10. Chaudhari A, Zaveri J. A Study on Critical Review of Drug Promotional Literature Using the WHO Guidelines. Int J Sci Stud 2019;7(2):1-4.
11. Sekar, P., P. Sekar, and K. Punnagai. "Evaluation Of The Rationality Of Claims Made In Drug Promotional Literature In West Chennai". Asian Journal of Pharmaceutical and Clinical Research, vol. 8, no. 5, Sept. 2015, pp. 107-9,
12. Abubakar AR, Sheikh SA, Haque M. Drug promotional literatures: Educative or misleading for young medical graduates and students? Natl J Physiol Pharm Pharmacol 2015;5: 318-322.
13. Hailu HG, Gobezie MY, Yesuf TA, Workneh BD. Critical evaluation of the validity of drug promotion materials in Ethiopia. Drug Health Patient Saf. 2019;11:47-54
14. Prasad, P., Bajracharya, S. R., Deo, S., Lamichhane, S., Pradhan, P. M. S., Ghimire, R., & Pokharel, A. Adherence of Drug Promotional Literatures Distributed by Pharmaceutical Companies to World Health Organization Ethical Criteria for Medicinal Drug Promotion. Journal of Nepal Health Research Council 2019, 17(3), 345-350.
15. 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.