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Perspective Study of Critical Appraisal of Drug Promotional Literature and Clinicians Attitude towards DPL Using WHO Ethical Criteria: At a Tertiary Care Centre

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Abstract

Drug promotional literature (DPL) is a vital method used by Pharmaceutical companies for promotion of pharmaceutical products to healthcare professionals. Medicalrepresentative (MR) visits to clinician, providing DPLs samples were eye-catching, fascinating , even though materials were very informative accepted as it is without critical appraised, they leads to irrational prescribing practices and increasing health care cast of patients.Aim of this study to evaluate drug promotional literature by using WHO ethical criteria and perception of physician regarding DPL. The study was conducted at Al-Ameen Medical College and Hospital Vijayapura, Karnataka India. A cross sectional, observational study was carried out between the months of October 2023 and February 2024. Study was approved by institutional ethics committee.DPLs in the form of brochures, calendars, pamphlets, flip-charts, flyers, and leaflets were collected from various Out Patients Department.Clinicians were included during period DPLs samples collection.Results obtained were tabulated and analyzed using mean, frequency, percentage, descriptive statistics. Total 319 DPLs samples were collected.Total 263 DPLs samples were assessed and among them only 8 DPLs met all the WHO criteria. Present study results have found less than 50% information about therapeutic uses (45.2%).DPLs were contained drug promotion of ophthalmic condition (n-12), otorhinolaryngology(n-11) and skin diseases(n-27).Single drug promotion (56.3%) and FDC drug promotion (46.8%).Present study analyzed that 84.6% of clinicians had knowledge regarding WHO criteria for DPLs evaluation. 92.3% of practitioners agreed that critical appraisal of DPLs will be helpful in rational prescribing of drugs. Present study shows pharmaceutical companies are trying to stick to guidelines; however DPLs are not fulfilled completely as criteria present in OPPI code and WHO ethical criteria. Government should take legal steps to regulate pharmaceutical companies to publish DPLs according to WHO criteria.

Keywords: Drug promotional, WHO, clinician, appraisal, medical representative.

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Introduction

Drug promotional literature (DPL) is defined by WHO "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]. Currently, there are two guidelines following for DPLs, 1) Ethical criteria for medicinal drug promotion established in 1988 by World Health Organization (WHO),2) Organization of Pharmaceutical Producers of India (OPPI) established in 1965, and OPPI Member Companies are committed to the ethical standards set out in this OPPI Code and it includes standards for the ethical promotion of pharmaceutical products[2].

For many years thepharmaceutical companies have been at the forefront in drug research and development (R&D) for public health care and get profit. Purpose of this company is to invest a billion of dollars, utilizing huge resources and manpower. Study mentioned that the estimate of the R&D per new drug from $113 million to just over $6 billion[3,4,5].

Multiple companies lack economical support and government fund, this put pressure on industry.High financial returns are necessary to induce companies to invest in drug R&D[3]. Moreover company gave importance to post marketing division to get profit from its own product sales by promoting drugs[4]. Many studies showed that lack drug promotion results in loss sale and less of profit[6].

Pharmaceutical companies are using different promotional methods such as audio visuals, drug reminders, and pamphlets and among them DPL is a crucial method utilized by industry for promotion of pharmaceutical products to healthcare professionals[4].

Drug promotional literature is a vital method used by medical representative (MR) being largely commercially-oriented, there is very little or no possibility of exchange of scientific information and MR keeps updating the clinician's knowledge about the latest drug information[5].

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) mentioned standard guidelines of drug promotional information to encourage and support the improvement of health care through the rational use medicinal products[7].

However pharmacy companies are promoting the information for their own brand of drugs, there is a possibility of prejudice. As MR visits to clinician, providing DPL samples were very attractive and fascinating , even though materials were very informative and accepted as it is without critical appraised ,resulting into irrational prescribing practices and increasing health care cast of patients[8].

The National Medical Commission has introduced DPL as part of CBME curriculum for MBBS and undergraduate students were exposed to drug promotion either during their medical course or during internship[9]. Scientific information provided in the drug promotional literature was inferiority and inadequacy. Many studies have encapsulated that information disseminated through DPLs and is inconsistent with the code of ethics[10,11].

Previous study has reported that 59.5% physicians were influenced by exaggerated claims used in promotional materials and gifts from the medical representative[12].However studies were insufficient to estimate standard parameters of DPLs and with this viewpoint the present study has been taken up with the aim to analyze the drug promotional literature using the ethical criteria laid out by the WHO and assess clinician's perceptions of the validity of such materials so that relevant

interventions can be made. Aim of this study to evaluate drug promotional literature by using WHO ethical criteria and perception of physicians regarding DPL and Objectives of the study are To evaluate DPL by using WHO criteria and To study the perception of physician regarding DPL by using questinnair

Method

Study Design, Site and Duration

The study was conducted at Al-Ameen Medical College and Hospital Vijayapura, Karnataka India. A cross sectional, observational study was carried out between the months of October 2023 and February 2024. Study was approved by the institutional ethics committee. AMCH/AMCE 2023-005/23

Sample Size and Sampling Method

Simple random sampling; at a confidence level of 95%, expected frequency (P) = 75% prevalence of DPLs adhering to WHO criteria by previous study 15 and at confidence limit (d) = 0.05, Z1–α/2 = 1.96, q = (1–p), the sample size (n) was calculated using study.

Eligibility Criteria

Inclusion Criteria

1. DPLs in the form of brochures, calendars, pamphlets, flip-charts, flyers, and leaflets were collected from various Out Patients Department.
2. Clinicians were included during period DPLs samples collection.

Exclusion Criteria

1. DPLs that promote devices and types of equipment and appliances in the orthopedic department were excluded and as our study focused on drugs.
2. Physicians attending the In Patient Department were excluded.

Source of Data

Samples of DPLs were collected from various Outpatients Departments in Al Ameen MC and Hospital and DPLs were assessed by using WHO ethical criteria guidelines using previous study done by K Chaithra et al[15]. At the same time clinicians were enrolled into the study and informed consent was taken. Study participants were assessed by pre validated questionnaires regarding DPLs. Questioners were taken from previous study done by A Kaur et al[16].

Statistical Analysis

Results obtained were tabulated and analyzed using mean, frequency, percentage, descriptive statistics, Statistical Package for the Social Science (SPSS) version 21 was used and a 'p' value <0.05 was considered significant.

Result and Discussion

Total 319 DPLs samples were collected and 56 samples were excluded from study and samples did not meet satisfactory WHO criteria. Total 263 DPLs samples were assessed and among them only 8 DPLs met all the WHO criteria. Result shows in (Table 1) and (Figure 2) scientific assessment components of DPL using WHO criteria and different sources of drug references respectively.

Table 2 shows perception of 65 clinicians regarding DPLs. Study also assessed by open questions to practitioners and 100% of clinicians had agreed to spend 10–15 min with the medical representatives. 64.6% of clinician updates their knowledge about novel drugs and existing drugs by attending continuing medical education (CME) and also by internet.32% of clinician analyses DPLs using WHO ethical criteria through journals and books.

Pharmaceutical companies use Printed promotional literature as a marketing

stategy to sell old drugs and publicize new medications. DPL is an important source of drug information with which both physicians and consumers are familiar[8,17]. Modern time most of DPL were not following sufficient information as mentioned in drug promotion criteria by WHO and OPPI code[18].

Our study result shows that 100% of DPLs were mentioned with active ingredients, brand name and approved generic name. Results were matches with study done by AV Sareetha et al[19]. Antimicrobial agents (21.7%), (endocrine-17%) corticosteroids, female hormones, antihypertensive, antidiabetics, antidepressants, opioides and anti-inflammatory (10%) were most class of drugs promoted in the present study (Figure 1).DPLs were contained drug promotion of ophthalmic condition (n-12) , otorhinolaryngology(n-11) and skin diseases (n-27). Previous study of P Sameer et al results were matched with present study[18,20].

Present study results have found less than 50% information about therapeutic uses (45.2%) Table 1, whereas similar study P Sameer et al 2022 found 98% of DPLs were therapeutic uses[20]. DPLs need complete information of therapeutic uses of drugs with valid references so that false prescriptions can be avoided. Chaithra KN et al 2023 study were matched with present study results that showed adverse drug reactions (15.6%), precaution and warning (10.3%) contraindication (10.3%) and drug interactions (10%)[15].

Name of the manufacturer 56% and address of the manufacturer 32.3% were mentioned in this study, however similar study done by S Rode et al 2022 showed that 100% of Name of the manufacturer and 65.6% of address of the manufacturer[17]. Figure 4 shows Single drug promotion (56.3%) and FDC drug promotion (46.8%), Single DPL with multiple drug promotion (48%) and Sekar P et al study were mentioned 38% of single drug formulation and 62% of FDC[11]. 22.1 % of drug cost, 21.3% of pharmacokinetic (PK) information and only 9.110% of DPLs had contained efficacy and storage information (17.1%) in present study and results were matches with previous study[15,8].

Clinicians were looking for cost effective and efficacy in their day today practice for the purpose not to burden patients economically. Patients were suffering from chronic conditions like hypertension and diabetes need lifelong treatment. Figure 3 and 4 results show that 48.1% of DPLs had Relevance pictures includes family, doctors, men and organs and similar study done by Jadava SS et al 2014 showed that 79.5% DPLs with relevance pictures[8].

Figure4 shown that 8.1% of DPLs mentioned exaggerated claims especially benefits, safety and statistical data in form graph and pictures, exaggerated explanation of one drug over other drug whereas previous study mentioned that 34.5% of exaggerated claims[15]. 58.5% of DPLs mentioned Reference to scientific literature among them 12.1% journal publication and 42.6% of website (Figure 2). Study done by Ganashree P et al 2016 showed that 75% of DPLs journal publication and 18% of website[21.]

Our study only 8 DPLs met all the WHO criteria whereas a similar study showed 5 (2.1%) DPLs met all guidelines[22]. Present study analyzed that 84.6% of clinicians were knowledgeable regarding WHO criteria for DPLs evaluation. 92.3% of practitioners agreed that critical appraisal of DPLs will be helpful in rational prescribing of drugs. Prasad, P et al study shown that 93.25% participants had awareness WHO criteria for DPL component and 64% faculties utilizes

DPLs general information and update their knowledge[15].

In the present study 30.1% of Clinicians look for statistical data/graphs in DPLs, 18.5% of clinician accepted the only source of knowledge updating about new drugs or reminders, 15.4% Clinicians of Prescribing pattern get influenced by DPLs and only 6.2% of Clinicians the integrity of prescribing can be compromised by incentives/ gratitude provided to prescribers by medical representatives. Results were matches with study done by similar study done by A Kaur et al, and Sharma S et al study mentioned that 79% of the clinicians have accepted prescribing pattern is influenced by DPLs[23,16].

Similar study also mentioned that critical appraisal of DPLs using WHO criteria helps clinician keeps update their knowledge, avoiding irrational prescribing pattern[22]. The National Medical Commission has introduced critical evaluation of DPL as part of CBME curriculum for MBBS and undergraduate students, which will help them in the future to do rational prescribing[24].

Limitation of study

DPLs samples were collected only from tertiary institution and present study needed different sources of data from private clinics for comparison and study physician samples were less to analyze the perception regarding DPLs appraisal with WHO ethical criteria. Present study required the involvement of more physicians from private as well as government hospital sectors for criticism.

Conclusion

Present study analyzed DPLs using WHO criteria, study showed most of DPLs material were followed only 6 standard guidelines that are branded name, active ingredient, name of manufacture, dosage form and meet more than 50% of DPLs. Present study shows pharmaceutical companies are trying to stick to guidelines; however DPLs are not fulfilled completely as criteria present in OPPI code and WHO ethical criteria. Government should take legal steps to regulate pharmaceutical companies to publish DPLs according to WHO criteria.

Ethical Approval

Ethical approval was obtained from the institutional ethics committee.

Informed Consent

The participant has consented to the submission of the article

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Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Table 1. Type of information contain in WHO Criteria.

Sr. No.	WHO Criteria	Frequency (n)	Percentage (%) (n=263)
1	INN or approved generic name	263	100%
2	Brand name	263	100%
3	Amount of active ingredient per dose	263	100%
4	Adjuvant	6	2.3%
5	Approved therapeutic use	119	45.2%
6a	Dosage form	232	88.2%
6b	Dosage schedule	49	18.6%
7a	Side effects and major adverse drug reactions	41	15.6%
7b	Precautions and warnings	27	10.3%
7c	Contraindications	27	10.3%
7d	Major drug interactions	26	10%
8a	Name of the manufacturer	147	56%
8b	Address of the manufacturer	85	32.3%
9	Reference to scientific literature	154	58.5%
	DPLs meeting more than 50% WHO criteria	220	83.6%

Table 2. Assessment of Perception of Clinicians regarding DPLs

Sl. No	Components of Perception of Clinicians	Frequency (n=65)	Percentage% (n=65)
1	The clinicians who read complete information in DPLs before prescribing	42	64.6%
2	Awareness amongst clinicians regarding WHO criteria for DPLs evaluation	55	84.6%
3	Prescribing pattern get influenced by DPLs	10	15.4%
4	The integrity of prescribing can be compromised by incentives/gratitude provided to prescribers by medical representatives	6	2.3%
5	Clinicians look for statistical data/graphs in DPLs	20	30.1%
6	DPLs are the only source of knowledge updation about new drugs or reminders	12	18.5%
7	Training regarding critical appraisal of DPLs at undergraduate	65	100 %
8	Critical appraisal of DPLs will be helpful in rational prescribing of drugs	60	92.3%
9	Help of books or journals for validating information provided in DPLs	58	89.2%

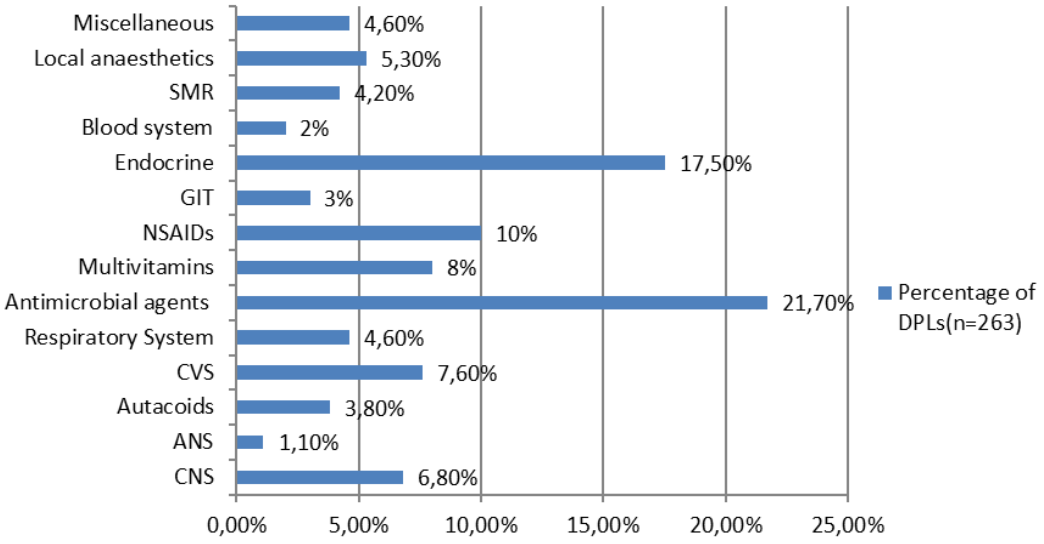

Figure 1. DPLs on Different Class of Drugs.

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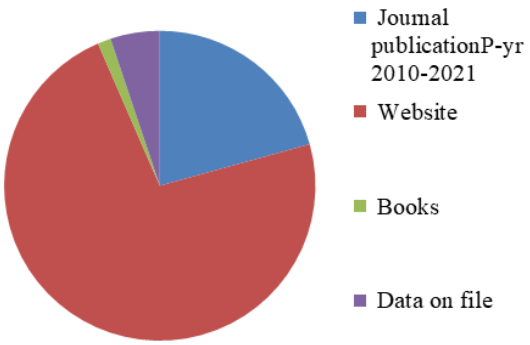

Figure 2. Different Sources of Drug References.

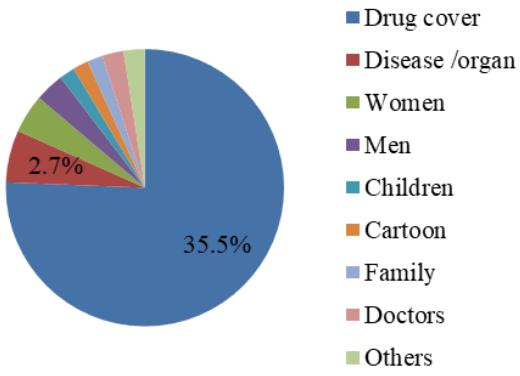

Figure 3. Types of Pictures Depicted on DPLs.

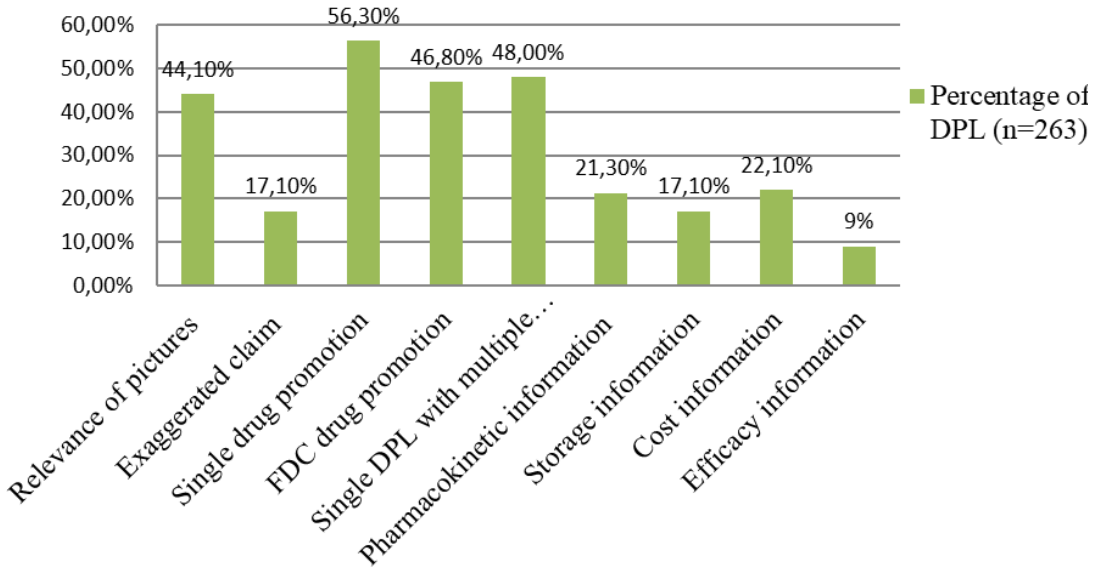

Figure 4. Assessment of Miscellaneous Features in DPLs.

about 56.3% of single drug promotion, 46.8% of Fixed Dose Combination d (FDC).