Research Article

Drug Promotional Literature – A Critical Appraisal in a Tertiary Care Teaching Hospital in Eastern India

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ABSTRACT

Drug promotional literatures (DPLs) are pamphlets or brochures printed by various pharmaceutical companies in order to promote the sale of products manufactured by them. DRPs can be highly informative and may contribute to practice of evidence-based medicine if it provides the true information including important drawbacks and if they are considered after critical analysis and review. But in most of the cases, they are misleading. Therefore, DPLs have to be critically analyzed for their content to prevent irrational prescribing pattern. This study was carried out to critically analyze the information content of drug advertisements in drug promotional literature available to the Medical Practitioners. Collected DPLs were assessed as per the WHO guidelines. Other additional analysis was also done such as whether cost was mentioned or not, validity, credibility and year of reference to scientific literature and picture or flowchart printed on the DPL. The data collected was summarized form using Microsoft Excel 365. Descriptive analysis was done to analyze and compare the data using percentages. A total of 543 DPLs were collected out of which only 393 were analyzed as per our inclusion and exclusion criteria. 213 (54.20%) DPLs were based on single drug formulation while 180 (45.80%) DPLs were on FDC. Drugs acting on cardiovascular system, antidiabetics and antimicrobials were among the top three groups of promoted drugs, indicating that drug companies are targeting diseases that are widespread. Approximately 70% of DPLs met only half of WHO's criteria for rational drug promotion. Based on the observations of this study, it is recommended that clinicians should be aware of the shortcomings in promotional literature before accepting it as source of valid information. When using drugs, especially new drugs on patients, the clinician should carefully analyze the results of research and draw conclusions, since misleading and incorrect information is now often found in promotional literature.

Keywords: Critical Appraisal, Drug Promotional Literature, WHO Guidelines, Evidence based medicine.

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INTRODUCTION

Major breakthroughs in medical science have resulted in a substantial increase in the number of drugs entering the market. This adds up to already existing information reservoir. There are various sources of drug information such as journals articles, medical textbooks, drug formulary or pharmacopeia, monograph, drug promotional literature, news articles, websites, seminar or conferences, and many more.[1]

New drugs are generally discovered, developed, manufactured and marketed by pharmaceutical companies.[2] To recover cost of development and making further profits, pharmaceutical companies are very much concerned on promoting the sale of new drugs manufactured by them by convincing physicians to prescribe their product. There are various modes of drug promotion such as audio-visual aids, flip charts, advertisements, messaging, leave behinds, drug promotional literatures or gifts.[3] For this, they spend huge amount of many which they usually recover from increasing cost of their products.[4]

Drug promotional literatures (DPLs) are pamphlets or brochures printed by various pharmaceutical companies in order to promote the sale of products manufactured by them. They form the major marketing techniques.[5] Due to the concise nature of DPLs, busy medical practitioners may sometimes rely on them as the primary source of drug information. DRPs can be highly informative and may contribute to practice of evidence-based medicine if it provides the true information including important drawbacks and if they are considered after critical analysis and review. But in most of the cases, they are misleading.[5] Therefore, DPLs have to be critically analyzed for their content to prevent irrational prescribing pattern.[6]

The ethical promotion of prescription medicines through DRPs is important for the pharmaceutical industry's aim of helping patients through the process of discovering,

developing and marketing new medicines. It helps to ensure that clinicians have access to updated information they need, and to ensure access of required medicines to patients and to ensure evidence-based practice of medicines to provides the maximum healthcare benefit and minimum risk to patients.[7] Pharmaceutical companies have to follow certain ethical guidelines, at the national and international levels, for drug promotional activities to ensure better healthcare through rational use of medicines.[8]

World Health Organization (WHO) ethical criteria for medicinal drug promotion defines the term promotion as "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 drug".[9] The "World Health Organization (WHO) criteria for ethical medicinal drug promotion 1988" and "the Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) 2012" are two guidelines at the international level.[7,9] In India, drug promotion is largely governed by the "Organization of Pharmaceutical Producers of India 2012(OPPI)". [10] World Health Organization criteria for "Ethical medicinal drug promotion, 1988" is the backbone of self-regulatory code of OPPI and IFPMA which is supposed to regulate the promotional activity of pharmaceutical industries.[5] All promotion making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, and capable of substantiation and in good taste.[9] Some countries have defined the minimum size of characters in which the generic non-proprietary name must be printed under the trade-mark labeling and advertising. In several countries the generic name must appear prominently in type at least half the size of that used for the proprietary or brand-name.[11] Therefore, this study was carried out to critically analyze the information content of drug advertisements in drug promotional literature available to the Medical Practitioners.

MATERIALS AND METHODS

An observational study was done by the Department of Pharmacology at a tertiary care institute of eastern India, for a period of 6 months from February 2021 to September 2021, after the approval of the protocol by the Institutional Ethics Committee registered in CDSCO. DPLs which were usually available in various forms of flyers, leaflets, or brochures were collected from the randomly selected outpatient departments. The DPLs were usually handed over to clinicians through medical representatives. Collected DPLs were assessed as per the WHO guidelines. DPLs of medical devices or instruments (such as orthopedic prosthesis, surgical dressings, glucometer, syringes etc.), ayurvedic or homeopathic medications, literature having drug monographs or advertisements, literature having list of many drugs, and literature promoting more than one medicine or more than one fixed drug combination (FDC) were excluded.

DPLs were analyzed and assessed based on following WHO criteria for their completeness: [12]

1. The active ingredients name – Drug can be named either using international nonproprietary names or the generic names approved by regulatory authorities
2. The brand name of the drug
3. Dose of active ingredient per dosage form or regimen
4. Dosage form or regimen
5. Information of other ingredients or adjuvant known that can cause problems
6. Approved therapeutic indications
7. Adverse effects or other drug related problems
8. Precautions, contraindications, and warnings
9. Drug interactions
10. Name and address of the manufacturer or distributor
11. Reference to scientific literature as appropriate.

Other additional analysis was also done such as whether cost was mentioned or not, validity, credibility and year of reference to scientific literature and picture or flowchart printed on the DPL.

The data collected was summarized form using Microsoft Excel 365. Descriptive analysis was done to analyze and compare the data using percentages.

RESULTS

A total of 543 DPLs were collected out of which only 393 were analyzed as per our inclusion and exclusion criteria. 213 (54.20%) DPLs were based on single drug formulation while 180 (45.80%) DPLs were on FDC.

Table 1: Proportion of Various Drug Groups Promoted

Drug Groups	Number of DPLs (n=393)	Percentage
Antimicrobial Drugs	77	19.59
Anti-Diabetic Drugs and Drug acting on Endocrine System	62	15.78
Drugs acting on Cardiovascular System	57	14.50
Drugs acting on Central Nervous System	51	12.98
Anti-Inflammatory Drugs	47	11.96
Ophthalmic Preparation	31	7.89
Vitamins & Minerals	23	5.85

Drugs acting on Gastrointestinal Tract	21	5.34
Drugs acting on Respiratory System	15	3.82
Anti-Cancer Drugs	9	2.29

Table 2: Analysis of DPLs according to WHO Criteria[12]

WHO Criteria	Number of DPLs (n=393)	Percentage
1. The active ingredients name – Drug can be named either using international nonproprietary names or the generic names approved by regulatory authorities	381	96.95
2. The brand name of the drug	393	100.00
3. Dose of active ingredient per dosage form or regimen	374	95.17
4. Dosage form or regimen	366	93.13
5. Information of other ingredients or adjuvant known that can cause problems	2	0.51
6. Approved therapeutic indications	342	87.02
7. Adverse effects or other drug related problems	115	29.26
8. Precautions, contraindications, and warnings	112	28.50
9. Drug interactions	107	27.23
10. Name and address of the manufacturer or distributor	372	94.66
11. Reference to scientific literature as appropriate	95	24.17

Most of the DPLs on drugs acting on cardiovascular system had information about drug safety (53.13%) while reference to scientific literature was found in most of the DPLs on anti-diabetic drugs (42.24%).

Table 3: Result of Additional Analysis on DPLs

Criteria	Number of DPLs (n=393)	Percentage
Pictures or Flowchart on DPLs		
Pictures relevant to scientific drug promotion	86	21.88
Pictures irrelevant to scientific drug promotion	214	54.45
Picture of Drug Cover	77	19.59
Picture on pharmacological action of drug	48	12.21
Picture of healthy men or women	84	21.37
Cartoon	15	3.82
Picture of Doctor or Nurse	12	3.05
Cost		
Cost mentioned	101	25.70
Cost not mentioned	292	74.30

Table 4: Source of References Found in DPLs

Source of References	Number of DPLs having references to scientific literature	Percentage
Journal Articles	72	75.79
Published after 2022	4	4.21
Published 2016-2020	26	27.37
Published 2010-2015	19	20.00
Published 2006-2010	4	4.21
Published 2001-2005	6	6.32
Published before 2000	3	3.16
Pubmed Indexed	44	46.32
Website	16	16.84
Books	7	7.37

DISCUSSION

Marketing new drugs to clinicians is an important strategy adopted by pharmaceutical companies.[13] Sometimes, DPLs are the only source for new drugs/new indications for old drugs for clinicians due to time constrain. In our study, it was observed that none of the DPLs met all the criteria set by the WHO guidelines. A similar finding has been reported in previous studies also.[14, 15] This suggests that drug companies are more involved in establishing commercial

relationships with treating physicians, where ethical education is compromised. [14] In this study, 45.80% of DPL supported a fixed drug combination; therefore, physicians should consider the rationality of the drug combination before prescribing.

Drugs acting on cardiovascular system, anti-diabetics and antimicrobials were among the top three groups of promoted drugs, indicating that drug companies are targeting diseases that are widespread. This finding was consistent with a study conducted in Mumbai. [16] Treating clinicians should be very careful when prescribing drugs based on the information provided in the DPL to avoid irrational prescription, higher incidence of drug resistance, adverse drug reactions, and reduce patient costs. [16, 17]

It was observed that most DPLs listed the brand name, approved generic name and active ingredient per dosage form, which is similar to result of the study conducted in Nepal. [18] In our study, none of the DPLs mentioned other ingredients known to cause problems. We observed that most DPLs listed the dosage schedule and therapeutic indications, but did not emphasize drug side effects, precautions, contraindications, and interactions. The above criteria are certainly necessary for patient care and also for managing the clinician's time in searching for another source of information. Similar findings have been observed in other studies. [14, 15]

All brochures were colorful and attractive, but contained irrelevant images related to the advertised drugs. DPLs used non-specific representations occupying the main region, which could be conveniently used to enumerate different properties of drugs, other studies report a similar finding. [14, 15] In this study, it was observed that brochures made unsubstantiated claims regarding efficacy and safety. Recent references have been mentioned in very few DPLs, but this is necessary to update clinicians to expand their existing knowledge and practice evidence-based medicine.

In view of this study, it is of the utmost importance that the treating clinician critically evaluate any source of drug information against established guidelines before accepting it as scientific information. The Regional Ethics Committee in various metropolitan cities in India collects complaints of unethical promotion of drug and reports them to the Drug Controller General of India to take necessary legal action to regulate pharmaceutical companies to publish DPLs meeting WHO criteria.[14, 15, 19, 20]

Approximately 70% of DPLs met only half of WHO's criteria for rational drug promotion. Therefore, attending clinician should learn the art of analyzing DPL in order to provide quality care to patients and save them from un-necessary risk.

The most essential aspect of promotional literature is to look for reference sources that provide comprehensive updates for physicians from leading medical, national, or international journals. In our study, links presenting scientific information were included in 24.17% of brochures. In addition, several DPLs provided up-to-date references (most recent within the last five years). This is essential to update clinicians to improve their existing knowledge and practice of evidence-based medicine, so pharmaceutical companies should take care of this aspect.

During the review of various previous similar studies, we got the impression that the well-known pharmaceutical companies follow the WHO guidelines closely. In contrast, new and small pharmaceutical companies emphasize only positive points in their promotional literature. In our study, no brochure contained complete information according to WHO criteria. Because misleading and incorrect information is not uncommon in this literature, physicians should be aware of the limitations of current medical industry promotional methods and the influence of marketing on prescribing behavior. Educating prescribers, enforcing current regulations, creating guidelines and applying them by pharmaceutical corporations to promote drugs are some methods of correcting this problem.

A limitation of the study is that it only assesses one type of pharmaceutical company's promotional activities, namely printed promotional literature. However, promotion through social media, print media or audio-visual method of promotion should also be assessed.

CONCLUSION

Based on the observations of this study, it is recommended that clinicians should be aware of the shortcomings in promotional literature before accepting it as source of valid information. When using drugs, especially new drugs on patients, the clinician should carefully analyze the results of research and draw conclusions, since misleading and incorrect information is now often found in promotional literature. It might help to watch it with great vigilance. Further complaints of irrational advertising being forwarded to regulatory authorities by wary doctors could lead to the pharmaceutical industry leaning towards self-regulation. Government regulators must play a proactive role where the code of ethics fails. Wherever hospitals are attached to an academic ground, prior review of promotional material for content authenticity may be carried out by the relevant Pharmacology Department.

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