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Research Article

Critical appraisal of drug promotional literature in tertiary care hospital in rohtak haryana

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A R T I C L E I N F O

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A B S T R A C T

Introduction: Drug promotional literature (DPLs) is an integral part of pharmaceutical marketing strategy. The advertisement is a key element of marketing strategy in which the advertising messages consist of a combination of information and persuasion. The study was primarily aimed to evaluate the drug promotional literature of collected drug promotional brochures from different pharmaceutical companies on the basis of World Health Organization (WHO) guidelines on ethical drug promotion.

Material and Methods: This was an observational study conducted by Department of Pharmacology, UHSR, PGIMS, Rohtak, India. The study is conducted for a period of 6 months after collecting DPLs from the different outpatient department and analysed to see if they achieved objectives.

Results: A total of 411 drug promotional brochures were collected from the outpatient department of our hospital, out of which 310 were included in the study and 101 (reminder cards, drug list, brochures promoting equipment, orthopaedic prosthesis) were excluded from the study.

Conclusion: This study enabled us to find out to what extent the pharmaceutical industries follow the standard criteria for DPL and evaluate the claims made by them. Pharmaceutical industries did not follow the WHO guidelines while promoting their products, thus aiming to satisfying their commercial motive rather than fulfill the educational aspect of promotion.

INTRODUCTION

DPL consists of pamphlets or brochures printed by pharmaceutical companies whether national or multinational in order to promote the sale of their products. As such, DPLs represent an integral part of marketing strategy.[1]Drug promotional literature (DPL) or advertisement can be considered as necessary because whenever a new drug is introduced it is prescribed by the clinician only when they know about it. Due to their concise nature, busy medical practitioners may sometimes rely on DPLs as the primary sources of drug information. DPLs can be highly informative when they provide the authentic information in a nutshell, if they are in conformity with the norms as long as they have been critically analysed and reviewed, if not, they can be misleading.[2]

In addition, pharmaceutical companies have to follow certain ethical guidelines at the national and international level for drug promotional activities to ensure better health care through the rational use of medicines: for instance, WHO defines drug promotion as "all the informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."[3]Also, the World Health Organisation (WHO) states that "all promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up to date, capable of substantiation and in good taste".[3]

In current scenario, it is better to consider the drug advertisement as "necessary evil" because there is intense propaganda and tall claims with a lot of incentives to prescribers, in various forms or ways such as sponsoring events or very costly items as free gifts when achieving a particular target. Unfortunately, physicians may be influenced by extensive marketing and may hastily prescribe new products without confirming the validity of the claims, which can in turn result in possible detrimental health-related consequences, e.g.failure of treatment from the use of inappropriate drugs, undesirable/adverse effects, rise in antibiotic-resistant microorganisms or an increase in the national health care expenditure.[4]

Because DPLs influence the prescribing behaviour of medical practitioners, they have to be critically analysed for their

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content to prevent irrational prescribing patterns.[5] Medical practitioners should therefore play a significant role in the critical evaluation of the information provided in a DPL before considering it as a scientific source of information and forward more complaints about such non-compliant companies to regulatory authorities.[6]

Thus, ethical promotion of drugs and their rational prescription is possible with the combined efforts of medical practitioners, pharmaceutical companies and regulatory bodies. In turn, these efforts will ensure that promotional literature is not just a marketing strategy but also a useful, up to date and accurate source of drug information.[7]In teaching hospitals, the department of pharmacology can undertake the task of analysing the promotional literature before the medical representatives present the literature to the medical practitioners. Sessions on "Evaluation of Promotional Literature" should be conducted for interns and residents as they are the ones to interact with the pharmaceutical representatives. Also training in analysis of drug promotional literature should be imparted to undergraduate students to emphasize its importance.[8]

MATERIAL AND METHODS

This was an observational study conducted by Department of Pharmacology, PGIMS, Rohtak. The study is conducted for a period of 6 months from January 2021 to June 2021. The current study investigators collected those DPLs in the form of flyers, leaflets, and brochures from the various out-patient departments such as medicine, surgery, obstetrician-gynaecology, ophthalmology, orthopaedics, paediatrics and dermatology which were available in the hospital through medical representatives. Collected DPLs were assessed as per the WHO guidelines.

Exclusion criteria

1. Literature promoting medicinal devices and equipment (insulin pump, blood glucometer, and orthopaedic prosthesis)
2. Ayurvedic medications
3. Drug monographs
4. Reminder advertisements, drugs name list
5. Literature promoting more than one drug or more than one fixed drug combination

The following are the WHO criteria to be followed by pharmaceutical industries for the completeness of DPL[3]:

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 regimen
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
11. Reference to scientific literature as appropriate.

All the literature were then evaluated for completeness of information in the above mentioned aspects followed by their categorization on basis of their compliance shown to various criteria given by WHO.

Category	Percentage of compliance
High compliance	≥ 70%
Moderate compliance	40-69%
Poor compliance	≤ 39%

Statistical analysis: Descriptive statistics were used to analyze the data. The data were expressed as percentage.

RESULTS

A total of 411 drug promotional brochures were collected from the outpatient department of our hospital, out of which 310 were included in the study and 101 (reminder cards, drug list, brochures promoting equipment, orthopaedic prosthesis) were excluded from the study.

Groups of drugs promoted in drug promotional literatures

Table 1 Groups of drugs promoted in drug promotional literatures

Promoted groups of drugs	Frequency (%) (n=310)
Antimicrobials	53 (17.1)
Blood and cardiovascular	48(15.4)
Nutritional supplements	43(14)
anti-inflammatory drugs	41(13.2)
Gastrointestinal	25(8)
Respiratory drug	24(7.7)
Antidiabetic and other hormonal drugs	23(7.4)
Miscellaneous drugs	22(7.1)
CNS diseases	12(3.8)
Renal drugs	10(3.3)
Ophthalmic drugs	9(3.0)

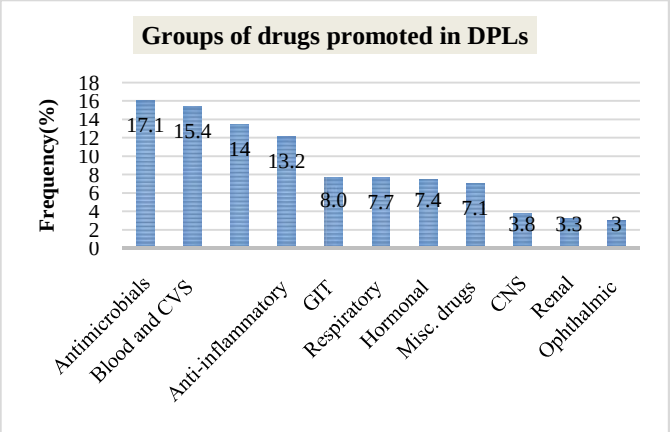

Figure 1 Groups of drugs promoted in drug promotional literatures

Among the brochures and pamphlets collected most commonly promoted a group of drugs was antimicrobials 17.1% and drugs for blood and cardiovascular 15.4% [Figure 1]. This was followed by nutritional supplements 14%, anti inflammatory drugs 13.2%, gastrointestinal 8%, respiratory drug 7.7%, antidiabetic and other hormonal drugs 7.4%, miscellaneous drugs 7.1%, CNS diseases 3.8%, renal drugs 3.3% then ophthalmic drugs 3.0%, [Figure1]. None of the 310 DPLs made complete fulfilment of all the criteria of WHO.

Fulfilment of WHO criteria

It was observed during the study that none of the brochures fulfilled all the criteria's laid down by WHO, the ethical guidelines for drug promotion. Pharmaceutical marketing was

primarily focused on highlighting the strengths of the drug or formulation and were most reluctant to provide information regarding drug interactions (3.22%), and warnings/ contraindications/precautions (8.0%). Likewise information regarding cited references and side effects were outlined in only 12.5% and 8.7% of brochures respectively, so they are moderately compliant. It was found that most of the evaluated brochures were satisfying only six criteria and highly compliant are namely brand name (100%), name of the active ingredients (98.3%), approved therapeutic uses (95.8%),amount of the active ingredients (90.6%), dosage form (85.4%) and address of the manufacturer (81.2%) as shown in Table 2. To conclude, the therapeutic information provided in the promotional literature was not found to be sufficient for the prescriber to make a rational decision to use the promoted drug.

Table 2 Evaluation of literature according to WHO ethical criteria for medicinal drug promotion

Criteria (n=150)	Number of literature (%)
Brand name	310 (100)
Name of active ingredient	305 (98.3)
Amount of active ingredient	281 (90.6)
Name and address of manufacturer/distributor	252 (81.2)
Approved therapeutic uses	297 (95.8)
Dosage form / schedule	265 (85.4)
References	39 (12.5)
Side effects	27 (8.7)
Warning/Contraindications/Precautions	25 (8)
Major interactions	10 (3.2)
Other ingredients known to cause problem	00 (0)

Types of pictures in drug promotional literatures

Out of 310 DPLs, 180 presented with pictures, 15 have scientific tables and 25 included scientific graphs [Figure 2].

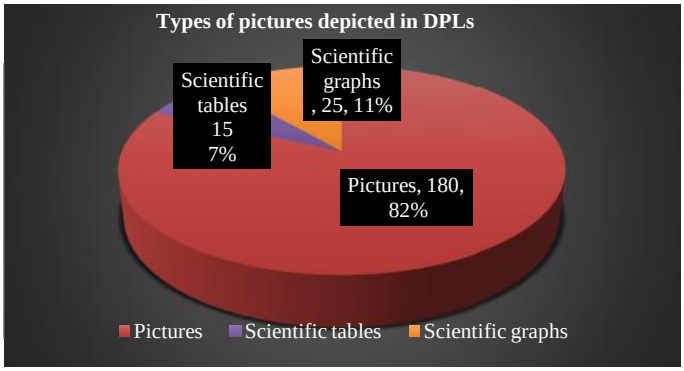

Figure 2 Types of pictures in drug promotional literatures

DISCUSSION

It was concluded from this study that pharmaceutical industries did not follow WHO guidelines while promoting their drug products, thus accelerated their commercial motive rather than ethical educational aspect. Little therapeutic information was provided to help physicians reach any rational decision about promoted drug.[1]In our study, none of the brochures had mentioned other ingredients that are known to cause problems. The promotional brochures lack important information regarding adverse drug reactions, contraindications, or drug interactions. This suggests that drug promotional companies are more involved in establishing a commercial relationship with the treating physicians wherein ethical educational aspect is compromised.[9] Also this indicates that the companies are less focussing on providing essential information regarding the safety of the patients. Similar observations on omission of these important criteria's were reported from previous studies also. So, it was difficult to trust them because of ambiguous presentation, poor quality, and questionable retrievability.

Clinicians need to keep themselves well informed and updated about the hundreds of new drugs entering the market every year. There is an urgent need to draw the inference and respond to the pharmaceutical promotional tactics and pressures in a much more responsible and diligent manner. Printed promotional material is an important source of information. On the basis of the observations of this study, it is suggested that physicians need to be aware of the flaws in promotional literature before accepting it as valid information. This could help monitor it with great vigilance. The association of pharmaceutical companies in developed countries, e.g. UK, Australia, and Canada are required to observe a code of practice in marketing as a signatory condition for membership of the association.[9] 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.[10]For warding more complaints about irrational promotion to regulatory authority by cautious doctors might lead pharmaceutical industry to incline toward self-regulation. Government regulatory bodies must play a proactive role where code of ethics is failing. Wherever the hospitals are attached to the academicia, prior scrutiny of the promotional material for authenticity of the content could be done by respective department of pharmacology.

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