Original Research Article

Drug Promotional Literatures – a critical appraisal of their adherence to global guidelines

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Abstract

Background: Drug promotional literatures (DPL) distributed by various pharmaceutical companies are frequently reported to be inaccurate and not adhering to the relevant guidelines. The objective of the study was to evaluate various drug promotional literatures using criteria advocated by various national and global guidelines. **Methods:** This observational study was conducted with diverse DPLs collected from various OPDs using the World Health Organization and other guidelines. **Results:** Out of total 560 DPLs evaluated, majority of them were found to be lacking in adequate and accurate information with regard to various criteria like dosage, dosage schedule, adjuvants used, safety information and pharmaceutical safety data. **Conclusion:** Majority of the DPLs did not adhere to the ethical guidelines issued by any company and requires strict administrative monitoring. Prescribers also need to exercise utmost caution in believing those claims mentioned and judiciously incorporate information mentioned in DPLs.

Keywords: Drug promotional literature (DPL), IFMPA, WHO guidelines, pharmaceutical company, safety information

Introduction

According to the Ethical criteria for medicinal drug promotional by World Health Organization, drug promotion refers to all informational and persuasive activities by manufactures and distributors of the pharmaceutical industry, the effect of which is to induce a favorable prescription, supply, purchase and /or use of medicinal drugs [1]. It includes activities of the medical representatives, drug advertisements and provision of gifts and free drug samples to prescribers, drug package inserts, direct-to-consumer advertisements, periodicals, telemarketing, holding of conferences, symposium, scientific meetings, sponsoring of medical education, and conduct of promotional trials [2].

Drug promotional advertisements (DPAs) are a major marketing tool of pharmaceutical companies for promoting their products and disseminating drug information for benefit of their own. These advertisements disperse the information regarding product name and its pharmacological properties, price, marketing claims, and references cited in support of these claims [3]. Pharmaceutical companies spend around one third of all sales revenue on marketing their products which is twice that spent on research and

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development [4, 5]. Powerful influence of promotional advertisements on physicians prescribing preferences, dissemination of deceptive information, unsubstantiated claims, and lapses in the field of ethics is a matter of enormous concern worldwide for the past few decades. There is evidence that prescribers using the DPAs as the primary source of drug information tend to prescribe less appropriately, and in the process patients' health can get compromised [6]. DPAs are vital and needful source of drug information for medical practitioners as well as for patients. Different modes of drug promotion include visual aids, leave behind leaflets and audio visuals. In private or public clinic set-up, direct to physician (DTP) marketing is major method used by drug manufacturers and distributors [7].

Pharmaceuticals manufacturers must comply with International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code to ensure Ethical promotional practices. IFPMA code sets standards for Ethical promotion that member companies must follow [8]. In India, Promotional activities standards are formed by self-regulatory code of pharmaceutical marketing practices, January (2007), Organization of Pharmaceutical Producers of India (OPPI), and by National legislation [9]. According to WHO, promotional claims need to be reliable, truthful, informative, balanced, up to date and capable of corroboration of authentic information [9]. However, the pharmaceutical companies do not adhere to the required ethical guidelines while promoting their products [10]. WHO has published ethical criteria for medicinal drug promotion to support and improve health care by promoting rational use of medicines [9]. Drug promotional literatures DPLs can be highly informative when it provides the authentic information in essence as long as they have been critically appraised and reviewed [11]. However, many studies have been presented that information provided through drug promotional activities is not consistent with the code of Ethics [12]. Therefore, this study was conducted with the aim to analyze the fulfillment of WHO criteria in DPLs available in Indian market using WHO and other guidelines.

Methodology

An observational study was conducted across various out-patient departments by collecting drug promotional literatures provided by various medical representatives for a period of 6 months from January 2020 to June 2020. A total of five hundred sixty (560) different promotional literatures were collected and evaluated for different parameters with regards to the national and international guidelines for them. Promotional literatures from diverse drug categories like anti-diabetic drugs, anti-hypertensives, laxatives, antibiotics, diuretics, vitamins and minerals, gastrointestinal drugs, CNS drugs, genitourinary drugs etc were included for evaluation keeping in mind the heterogeneity of different drug and/or their combinations. The literatures were extensively studied to evaluate their completeness with respect to the guidelines like generic name, brand name, adjuvants, content per dosage form, indication for use, correct dose and regimen, safety information, manufacturer's address, reference for claims made, presence of any false claim and most importantly legibility of the promotional literatures. Data analysis were done using Microsoft Excel for windows. Descriptive statistics were used for analysis of the data.

Results

Out of the total 560 promotional literatures evaluated for completeness in various parameters, the categories of drugs that were included and their percentage are presented in Table 1. The brand names were present in all the literatures, while 36 of them did not have the generic names of the drugs. In majority of the promotional literatures (545 of 560), there was no mention of the adjuvants used in the formulation. In a total of 513 literatures, we found the content per dosage form were properly mentioned while 47 were found lacking in this aspect. 204 literatures contained the correct indication of the drugs while in 346 literatures the indication were not mentioned which is in contradiction to all the guidelines like those issued by IFPMA or WHO. Dosage forms were not mentioned in 128 literatures. Surprisingly, 514 of the literatures did not mention about the regimen for the use of the drug, while 524 of them did not even mention the safety information regarding the molecule. Another important criteria as per the WHO guidelines, i.e. the manufacturer's address which should be mentioned in all the promotional literatures were not found in 400 of the 560 evaluated literatures. We could not find any references for the scientific data properly mentioned in 428 of the literatures. 85 of the total evaluated literatures contained a false claim in contradiction to the WHO guidelines. Lastly, a very pertinent criteria as per the WHO guidelines is legibility of the fonts or letter size, were found to be deficient in 29 of the 560 literatures. The results of the evaluation are represented in tabular form in Tables. The comparative evaluation in terms of different assessment criteria are depicted in Figures respectively.

Table 1: Number of promotional literatures belonging to different categories of drugs

Classes of Drugs	Number of Promotional Literatures (n=560)	Percentage (%) (in round figures)
Anti-diabetic	70	13
Lipid lowering agents	60	11
Anti-hypertensives	80	14
Drug Affecting Gastrointestinal Functions	70	13
Drug Affecting Central Nervous System (CNS) Functions	30	5
Anti-microbial agents	90	16
Dietary Supplements	70	13
Drug Affecting Genitourinary System	30	5
Drug Affecting Respiratory System	50	9
Others	10	1

Table 2: Comparative results of different assessment criteria

Criteria	Yes	No
Generic name	524	36
Brand Name	560	0
Adjuvant	15	545
Content	513	47
Indications	204	356
Dosage form	432	128

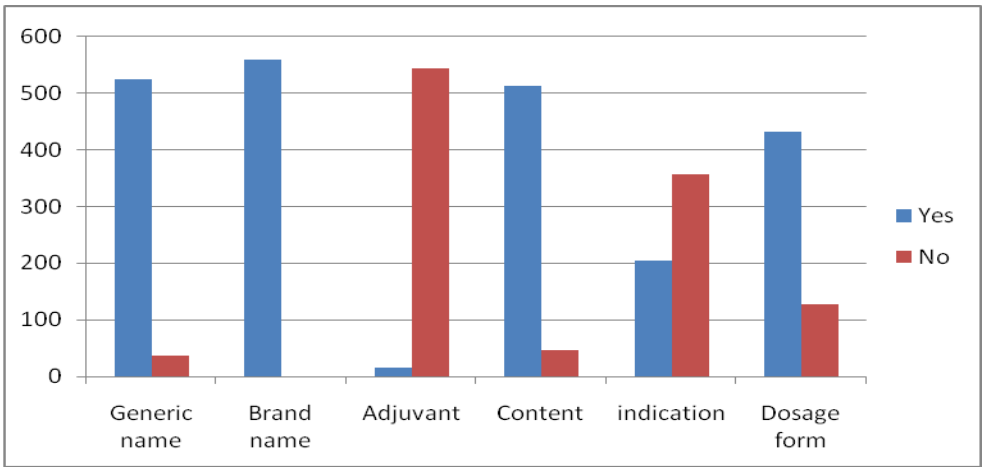

Fig 1: Adherence of DPLs to different assessment criteria

Table 3: Comparative results of different assessment criteria

Criteria	Yes	No
Dose	50	510
Regimen	46	514
Safety information	36	524
Manufacturer's address	160	400
Reference	132	428
False Claim	85	475
Legibility	531	29

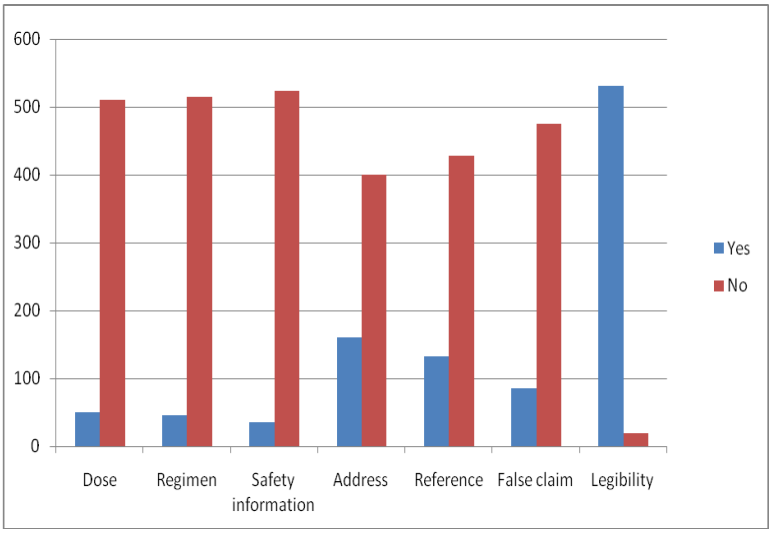

Fig 2: Adherence of DPLs to different assessment criteria

Discussion

Drug promotional literatures are important tools adopted by pharmaceutical manufacturers and marketing companies across the world to increase visibility and also serve as effective reminders to the prescribers. Many a times, it is observed that prescribers come to know of a new molecule from the DPLs for the very first time itself. Therefore it is very important that the DPLs are unbiased, informative and precise.Unfortunately it is observed in our study that most of the DPLsare not correct or complete with regard to various national and international guidelines laid down by the regulatory agencies like OPPI in India, and WHO, IFPMA and FDA globally. The same results were found in almost all the studies done on similar topics across the globe like those conducted in Nepal [13], Pakistan [14], Canada [15] and Russia [16]. In our study, majority of the DPLs mentioned about the adjuvants used in the brand. More importantly, safety information were found lacking in almost all the DPLs. Proper references to various claims made in the DPLs were not found and lots of false claims were observed in our study. A vast majority of the DPLs did not even have the correct dose and regimen of the product. While sincere attempt were made to promote the brand in every possible way by using unnecessarily graphics, colors etc, important information like the manufacturer's address were not part of many DPLs in

our study. Irrelevant and often misleading information which actually encourage the positive sides of the drugs but suppressing the adverse effects of the drugs were present in all the DPLs. From all the above findings it becomes very clear that the pharmaceutical companies are not adhering to the ethical promotional guidelines issued by the regulatory agencies. Rather this highly biased DPLs are actually promoting irrational prescribing and also might be the cause of many adverse reactions that are frequently encountered but never reported in resource poor third world countries like India. The prescribers should believe and incorporate the knowledges incurred from the DPLs in to their practice very judiciously. At the same time, strict administrative monitoring is needed to bring authentic data and reliability in the DPLs.

Conclusion

Although there are multiple guidelines for DPLs, yet very few of companies actually adhere to them. All the prescribers should maintain utmost caution while prescribing drugs based only on the knowledge gathered from DPLs. Biased and incorrect DPLs distributed by various pharmaceutical companies cannot and should not be a substitute for proper evidence based medicine and text book knowledge.

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