RESEARCH ARTICLE

Analysis of Rationality of Claims of Pharmaceutical Companies on Drug Promotional Literature (DPL) by 2nd Year Medical Students Using the WHO Guidelines

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Abstract

Background: Drug promotional literature (DPL) forms an integral part of drug promotion. But, many pharmaceutical companies promote their products unethically. This is dangerous for young graduates and medical students as the both cannot understand the consequences of irrational prescription. So, the planning of this study was done to evaluate the DPLs based on WHO criteria.

Materials and methods: A total of 162 DPLs were collected from the hospital attached to SGRDIMSR, Amritsar, Punjab, India for evaluation. A four-point pre-validated questionnaire-based checklist for critical evaluation of DPL was generated based on the objective structured practical examination (OSPE) skills development program of medical curriculum in the subject of pharmacology of in MBBS second year students.

Results: Out of 162, 58.6% had single drug and 41.4% had fixed-dose composition. Out of the all DPLs, only 16% of the DPL mentioned the major adverse drug reactions (ADRs). Only 15% of the DPLs mentioned about precaution, contraindications, warnings, and 1.8% of the DPLs mentioned about major interactions, 32.9% of DPLs made false claims about their product with catchy statement and 40.7%. Drug promotional literatures had irrelevant pictures. In contrast, 55.7 and 52.1% showed relevant charts and tables. The information about excipients was present in none of the DPL. The information about safety of the drug, such as ADRs, drug interaction, contraindications was not adequate.

Conclusion: The findings indicates that none of the DPLs fulfilled all the WHO criteria of DPL. Therefore, both physicians and medical students need to be educated during their primitive and formative years about evaluating DPLs.

Keywords: Drug promotional literatures, Objective structured practical examination, Pharmaceutical companies, WHO guidelines.

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Introduction

Drug promotional literature (DPL) drafted by majority of the pharmaceutical companies consists of pamphlets or brochures with an aim for promoting the sale of their products. According to the definition of World Health Organization[1] (WHO), drug promotion refers to "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 drugs." The various methods by which drug promotion is done are as using visual aids, medical leaflets, medical leave behinds, and audio visuals aids using communicative tools, such as internet, WhatsApp, e-mails, etc. Direct marketing approach to physician constitutes an important tool for increasing the product sales by drug manufacturers and drug product distributors.[2] So, it is prudent that the DPL about the superiority of the product should be latest, precise, and accurate. The validity of information and critical appraisal provided in the DPL is restricted to the information provided in the promotional literature as many a times there is no cross-checking of the information by the drug prescribers. Many studies are available showing that the increased marketing promotion of the products is directly related to increased sales of the products.[3] Ideally, pharmaceutical companies should follow the norms of ethical guidelines for drug promotional activities. Internationally, there are two guidelines, first is about the "Ethical criteria for medicinal drug promotion" as has been recommended by WHO.[1] The other guidelines are about the "Code of Pharmaceutical Marketing Practices" and this guideline is recommended by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).[4] Many a times, overworked or busy medical physicians/practitioners, depend on the information provided by DPLs as the primary sources of drug information with a presumption that the DPLs provide the up-to-date, abridged, authentic information in a nutshell. However, as long as the DPLs are not been analyzed and reviewed, DPLs can be misleading and can have false information. Many studies[5] are available concluding that the information given via DPLs is not as per the norms of medical code of ethics. Unfortunately, physicians' prescribing behavior is influenced by various factors, such as information provided by pharmaceutical companies, personal relationship build-up by company representatives as frequent visits, gifts, emotional blackmailing, etc. This affects the prescription of products and many times, without confirming the validity of the claims it results in adverse effects on the health of the patients

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such as irrational prescribing, failure of therapeutic response due to unindicated drug therapy, undesirable/adverse effects, multidrug antibiotic-resistant, and overall leading to an increase in health care costs of the patients.[6] The irrational advertisement of products directly increases drug utilization, drug consumerism but also add to irrational drug. In ideal situations, DPLs should have information about the safety and efficacy of the product consisting of important ADRs, warnings, contraindications, precautions, warnings, use in special situations, such as pregnancy, lactation, infants, children, and aged patients. However, DPLs do not provide such vital information or undermines the importance of such type of information using unprofessional means of making false claim of the product and thus diverting the prescription of the prescribers for their own selfish benefits. The main aim of pharmaceutical companies is to sell the product by convincing them that their product is superior to others. Thus, if prescribers only rely on the information from the pharmaceutical companies, the actual indication may be lost and this may result into detrimental consequences to patient health. Thus, there is an utter need to provide training, education to the drug prescribers about the critical analysis of drug advertisements. This can be achieved by educating the medical students regarding drug promotional advertisements during the primitive and formative years of medical curriculum especially during the 2nd year when they are taught the subject of pharmacology.[7] This will not only prevent medication error but also medical litigations arising in future as well.[8] The drug promotional activities are monitored and controlled by self-regulatory code of pharmaceutical marketing practices governed by the Organization of Pharmaceutical Producers of India (OPPI), and by National legislation of India (NLI).[9] So, the planning of this study was done with an aim to analyze the drug information present in the DPLs, and based on various predefined/preset parameters, the further planning to safeguard the prescription of the patients can be done. This will help the pharmaceutical companies to adhere the ethical marketing standards or norms and promote their products ethically.

Aims and Objectives

With this background information, this study was planned and carried out to evaluate the DPLs as per the standards of WHO criteria, and in addition, evaluation of the quality of the product, various types of claims and their genuineness, were also assessed.

Materials and Methods

This was an observational, cross-sectional study conducted by the Department of Pharmacology, Sri Guru Ram Das Institute of Medical Sciences & Research (SGRDIMSR), Amritsar, Punjab, India. Drug promotional literatures were collected from the outpatient department (OPD) of SGRD hospital attached to SGRDIMSR teaching institute. Printed DPLs provided by various companies promoting their products were collected from the various departments of OPDs of SGRDIMSR. The various departments included were medicine, cardiology, nephrology, surgery, obstetrics and gynecology, pediatrics, dermatology, otorhinolaryngology, psychiatry, ophthalmology, and orthopedics, etc. After approval from the Institutional Ethics Committee, the study was carried out by the second year students, in the Department of Pharmacology, studying the subject of Pharmacology at SGRDIMSR. A checklist questionnaire was developed focusing on the concept of DPL, knowledge about DPL and attitude toward DPLs.[10] Various types of DPLs were collected consisting of small leaflets, drug review literature made by the companies, brochures, and flyers. The data were collected from the various OPD of the hospital through sales representatives of the companies. A four-point pre-validated questionnaire-based checklist for the critical evaluation of DPL was generated based on objective structured practical examination (OSPE) skills development program of medical curriculum in the subject of pharmacology of second year MBBS students. Pre-validated questionnaire consisted of a preformed questions based on the information, such as international non-proprietary name (INN), knowledge (based brief information on pharmacological effects and mode of action), clinical information, and pharmaceutical information (Table 1). Data were collected and analyzed based on the number and percentage of the DPLs showing various results out of the total collected DPLs. Evaluation was done as per the pre-validated questionnaire comprised two sections regarding knowledge and attitude. The additional evaluation of DPLs was meant for the information present in printed pictures, comparative costs mentioned in tabulated forms, and authenticity of the references, such as source and year. However, the non-DPL consisting of medicinal devices, medical/surgical equipment (ventilators, blood glucometer, and orthopedic prosthesis, etc.), Ayurvedic medical literatures, reminders, published scientific articles were excluded from the study. The following parameters were used for study evaluation as given in Table 1:

- Product names, generic names, dosage based on INNs or approved generic names of the drugs.
- Dose of active ingredients per tablet/formulation.
- The brand/proprietary names.
- Dosage form or dosage schedule as per the recommendation of any approved society.
- Approved therapeutic uses, such as from Drug Controller general of India.
- Other ingredients known to cause adverse drug problems, that is, adjuvant/excipients.
- Adequate information on drug safety, for example, serious ADEs, common ADRs, precautions, contraindications, use in special situations, product warnings, and major drug interactions.
- Name and address of manufacturer/head office of the company.
- Authentic scientific reference/literature for the claims.

Exclusion Criteria

DPLs promoting.

- Drugs other than allopathic drugs, for example, Herbal/Unani/Siddha, etc.
- Medical devices/equipment/techniques.

Statistical Analysis

Descriptive statistics were used to analyze the data. The data were tabulated and were expressed as percentage for result evaluation and comparison and final interpretation.

Results

The total number of DPLs collected were 162 from the OPDs of various departments and were analyzed as per the WHO checklist.[10] It was observed that the distribution of DPL out of 162 as per the system was as antimicrobial (16.6%), multivitamins (14.8%), cardiovascular system (12.9%), hepatology (4.1%), and was less than 10% in other systems as endocrinology, gastrointestinal

Table 1: Checklist of drug promotional literature[10]

Sr. No.	*Check points*	*Yes (Y)/No (N)*
1.	International non-propriety name (INN)	Y/N
2.	Brief pharmacological information	Y/N
3.	Clinical information	
	a. Indications (based on diagnosis)	Y/N
	b. Dosage regimen and relevant pharmacokinetic data	
	• Dosage for adults/children	Y/N
	• Dosing interval	Y/N
	• Treatment duration	Y/N
	• Dosage in special situation, for example, renal, hepatic, cardiac disease, elderly, pregnancy, etc.	Y/N
	c. Contraindications	Y/N
	d. Precautions/warnings (reference to kidney, liver disease, pregnancy, elderly, etc.)	Y/N
	e. Adverse effects	Y/N
	f. Drug interaction	Y/N
	g. Drug overdose information	Y/N
4.	Pharmaceutical Information	
	Dosage forms	Y/N
	Strength	Y/N
	Storage conditions and shelf life	Y/N
	Product description	Y/N
	Legal category	Y/N
	Name and address of manufacturer/importer	Y/N

Score: Y = 1 and N = 0 (zero) point. Irregularities on evaluation scale: 1–6 = Mild, 7–12 = Moderate and 12–18 = Severe

Table 2: Showing the distribution of DPL (n = 162) as per system

System wise distribution of DPL	*Number*	*Percentage (%)*
CVS	21	12.9
Antimicrobial	27	16.6
Endocrinology	12	7.4
GIT	16	9.8
Hepatology	8	4.1
CNS	14	8.6
Hematology	11	6.7
Multivitamins	24	14.8
Renal	6	3.7
Autacoids	5	3
ANS	6	3.7
Obstetrics and gynecology	12	7.4

(GIT), central nervous system (CNS), hematology, renal, autacoids, and autonomic nervous system (ANS) (Table 2). Of the 162 drugs promoted, 85 (52.4%) were single-drug formulation and 77 (47.5%) were fixed-dose combinations (FDC) interpreting that the pharmaceutical companies were promoting FDC in large number of cases. Out of 162 DPLs, 63 (38.8%) DPLs were graphically presented to show information in the form of columns, bar, and others patterns for data presentation. It was also observed that out of 162 DPL, the criteria followed as per WHO guidelines were: use of active ingredients' name or INN or approved generic name was 100%, brand name as 100%, and 69.1% with active drug per dosage form, 4.9% with adjuvant, 83.9% with approved therapeutic use, 87.6% with dosage form, 38.2% with dosage schedule, only 16% with side effects/major adverse drug reactions (ADRs), 11.7% with precautions and warnings, 4.9% with contraindications, 1.8% with major drug interactions, 100% having name of the drug marketing company, 28.3% had address of the manufacturer and 80.2% were having reference to scientific literature (Table 2). This showed that the main focus of DPL by the pharmaceutical companies was on providing information about the segment of the patients where the drug was to be used with emphasis on the company name so as to generate brand loyalty. Thus, the claims made in majority of the cases in DPLs were regarding product segment and pharmaceutical properties shoed the least importance to safety and pharmacokinetics. As is shown in Table 3, the safety information on side effects, precautions and warnings, contraindications was seen in only 56 (34.5%) out of 162 DPLs showing that the stress on information about ADRs was lesser. This indicated that the marketing strategy of the drug/product is on selling only and not on educating the doctors about the safety features (Table 3). Sources of various references were cited in 130 (80.2%) in all DPLs (Table 4). Out of these 130 references, 70% of references were from national/international journals (76.5% before 2017 and 23.4% after 2017), followed by websites 9.2%, books 1.2%, and from other nonspecific sources as 3.8% and data on file as 12.3%. It was also seen that out of 162 DPLs, more than one reference per DPLs was found in 82 (50.6%) and 80 (49.3%) had only one reference for the claims that had been made. Out of 130 DPLs, the number of complete reference was seen in 4 (3%), and 24 (18.4%) DPLs showed incomplete reference which mainly consisted of source with incomplete details of the source (Table 4). It was also seen that out of 130 references, 89 references (68.4%) could not be retrieved from the websites or from the internet and out of 130 references, 59 references (45.3%) had the claims by the

Table 3: Showing the WHO criteria followed in DPL ($n = 162$)

Sr. No.	*WHO criteria*	*No. of DPLs*	*Percentage*
1.	Active ingredients name or international non-proprietary name (INN) or approved generic name	162	100
2.	Brand name	162	100
3.	Active drug per dosage form or amount of active ingredient per dose	112	69.1
4.	Adjuvant	8	4.9
5.	Approved therapeutic use	136	83.9
6.	Dosage form	142	87.6
7.	Dosage schedule	62	
8.	Side effects and major adverse drug reactions	26	16
9.	Precautions and warnings	19	11.7
10.	Contraindications	8	4.9
11.	Major drug interactions	3	1.8
12.	Name of the manufacturer	162	100
13.	Address of the manufacturer	46	28.3
14.	Reference to scientific literature	130	80.2
15.	Other ingredients known to cause problems	0	NA
16.	Dosage regimen	12	74

Table 4: Showing the reference cited in DPL ($n = 162$)

Sr. No.	*References*	*No. of DPLs ($n = 162$)*	*Percentage*
1.	References cited out of total DPL	130	80.2
2.	Journals	64	49.2
	Before 2017	49	76.5
	After 2017	15	23.4
3.	Website	12	9.2
4.	Book	2	1.5
5.	Other sources	5	3.8
6.	Data on file	19	14.6
7.	References with name of the author, title and source	4	3
8.	Reference with only source	24	18.4
9.	No reference	32	19.7

pharmaceutical companies not matching with the claims been made in DPLs. The classification of the references in DPL showed that out of 64 journal articles the most common source of reference was research article 13 (20.3%) with 11 randomized control trial (17.1%), 8 randomized placebo control trial (12.5%), 17 review article (26.5%) and from other sources as 15 (23.4%). Out of 162 DPLs, 129 (79.6%) DPLs had the irrelevant pictures, 24 (14.8%) relevant as per the drug or disease-related pictures and 9 (5.5%) had mixed picture presentation.

Name of the drug in branded formulation and in generic formulation in all DPLs were different in pattern as per the font size and color with catchy terms/phrases like "most safe," "tried and trusted protector," "time tested," "Best in performance" "superpower in your hands," etc. were used in 159 (98%) DPLs. Based on the irregularities on evaluation scale as 1–6 = Mild, 7–12 = Moderate, and 12–18 = Severe, it was observed that out of 162 DPLs 74 (45.6%) DPLS had mild, 59 (36.4% had moderate, and 29 (17.9%) DPLs had severe irregularity in the information provided in the DPL (Table 1). This showed that the DPLs were not designed as the ethical standards laid by the Uniform code of Pharmaceuticals Marketing Practices (UCPMP), Government of India.[9] This showed that the pharmaceutical companies were mainly focused on branding of the product and paid little attention toward educating the prescribers in terms of efficacy, side effects, drug interactions, precautions. Thus, the most ignored part of DPLs was information on drug safety, such as serious ADR, major drug interactions, precautions, and information on over dosage. Thus, it can be concluded that the pharmaceutical companies make multiple irrelevant claims in DPLs by misguiding and manipulating therapeutic information. Claims about efficacy were extrapolated using support from scientific references. For attractive presentation of DPLs, companies use catchy pictures on DPLs. The majority of pictures were not relevant to disease and promoted drug.

Discussion

There is huge expenditures of the pharmaceutical companies on marketing, branding, and research, and it is estimated that >11 billion dollars/year are spent in the United States of America (USA). Out of this expenditure, cost in dollars was 8,000–13,000/year on professional or promotional activities like making of visual aids, brochures, publications, conferences organization.[11] However, unfortunately, no such data on the expenses is available in India. This is a generalized fact that a large number of new drugs and old drugs with some newer information or indications enter every year in the Indian market. No doubt, drug promotional activities affects the prescribing behavior but the authenticity of the information has always been in question. Printed DPLs are an easily available, accessible, and less time-consuming source of drug information. Physicians all over agree on the point that their prescribing habits are affected by the information been provided by the information been given by the pharmaceutical sales representatives. Printed promotional literature, such as DPL, leave behind, abridged monograph, published complete articles, reminders, etc. are easily available, accessible, and important source of drug information.[12] Every drug marketing companies claim that their brands/products are much better than other brands/products in the same category. This questionnaire-based study was conducted to unravel the fact that the training/education in undergraduate period of the medical students is an important factor influencing the prescribing behavior of the doctors. Drug literature information of the marketed products is necessary to help prescribers to deliver rational drug therapy. Medical references are the integral part of DPLs as most of the claims in DPLs are taken from the medical information present in references. However, medical representatives (MRs) lack basic medical knowledge and try to extrapolate the information on pharmaceutical products to prescribers in an irresponsible and irrational manner. Unfortunately, forgetting the marketing ethics, these educative materials are often made misleading, confusing, and unethical and focus on physician-targeted biased promotion.[12] Some of the pharmaceutical companies provide training to MRs using brain wash techniques. In the study by Ziegler et al.[13] and Vencelik et al.[14] 37%, 61.2% of the physicians prescription was influenced by the pharmaceutical drug information as it was observed that the description of names, such as brand/generic names, dosage, formulations nature was available in literature but the information on safety was scanty. In an observational, cross-sectional study conducted by Mikhael[15] using the brochures collected from pharmaceutical drug exhibition, evaluated the brochures on the basis of WHO criteria of ethical drug promotion. It was observed in the same study that the 70% of drug information material had emotional pictures in all brochures, verification of the references for irretrievability, source, and authenticity of presentations showed that reference citation was present in 72% of brochures, and out of these, only 75% of references were correct. The same author also observed that there was a significant lack of information on drug interaction, mentioning of the drug side effects and contraindications. The information on adverse effects was written in a small font. In an observational study by Ganashree et al.,[16] 200 DPLs were collected from the various departments at R.L. Jalappa Hospital & Research Centre, Kolar, India. It was observed in the same study that 69% of the DPLs followed WHO criteria of drug promotion, the most common promoted drugs were from cardiovascular drugs (17%), followed by antidiabetic drugs (15.5%), antimicrobial agents (14.5%), and rest of the DPLs were from other categories. It was also observed that the single drug was promoted in 67%, fixed-drug combination (FDC) in 33% of the DPL. It was also observed that the name of the manufacturer was present in 97% cases but the address was only present in 54.5% DPLs only. The name of the ingredients with brand name and dosage form was seen in in 98% brochures with indication in 96.5% for claims on DPL. However, the adverse events, precautions, interactions, contraindications of the product was seen in 34.5, 32.5, 32.5, and 29% of DPLs and the percentage of the cited references was 66.5% in DPLs. In another cross-sectional observational study, 142 DPLs were evaluated by WHO criteria, by Khakhkhar et al.,[17] carried out in the Department of Pharmacology. It was observed in the same study that the majority of DPLs were having dosage schedule and therapeutic indications. But the importance on ADEs, precautions, contraindications, and drug interactions were not present. It was also concluded that the major drug prescription was present in cardiovascular, antidiabetic, and antimicrobials category of drugs. However, the above-said criteria are very important in patient care and also helps to avoid time wastage of the physicians by looking into other sources of medical information. In the present study, it was also observed that unsubstantiated/unauthentic claims were made in the brochures regarding efficacy and safety of their products. The addition of recent references are a necessary tool for updating the knowledge bank of the prescribers and hence the generation of the practice evidence-based medicine/rationale drug prescribing. Antimicrobials (16.6% followed by multivitamins (14.8%), cardiovascular drugs (12.9%) and in lower ranks were antidiabetic drugs, and others were the most commonly promoted drugs in DPL. Vitamins/nutritional supplements are the largest selling area of pharmaceutical industry of the nutraceuticals supplement and are often purchased online/over the counter,[18] without any specific indication in the patients. However, the use of vitamins should be only when they are prescribed for specific indications as excess of vitamins can cause harmful effects and so must be discouraged. Most of the DPLs in various studies[15–17] observed that there was no emphasis on the importance of dosage schedules, dosage, guidelines, and drug interactions. In fact, in 72% of the brochures there was no mention of the safety aspects of the drug promoted to the prescribers. All promotion about the different claims of the drugs should be rationale, appropriate, accurate, up-to-date, and ethical. This suggests that the pharmaceutical companies are mainly concerned with generating a commercialism with the treating doctors for enhanced sales, but ignoring the educational promotional aspects. In the present study, only 50 (29%) of the DPLs promoted FDC, more than one claim was present in 102 (62.9%), and 154 (95%) DPLs had catchy terms/phrases. However, none of the DPLs fulfilled all the WHO criteria of drug marketing in our study. In our study, none of the brochures had mentioned other ingredients, also called as excipients that are known to cause adverse effects in human. We also observed that majority of DPLs did not mention about dosage schedule, regimens, protocols guidelines but the stress on ADRs, precautions, CIs, and drug interactions was lesser in terms of percentage. Thus, it seems that the product/molecular information present in DPLs was more of a type of biased than to educate the physicians to make prescribe rationally on drug prescription. The claims presentation in the present study was found to be similar in study conducted by Rohra et al.[11] and the same author also observed that the claims were exaggerated (32%), ambiguous (21%), false (26%), and controversial (21%) in terms of percentage. Similar finding has been observed in various studies[5,6,9,12] showing that the DPLs were having unsubstantiated claims and irrational/unethical claims about the drug efficacy or pharmaceutical property. Product information on ADRs, drug–drug interactions, precautions, and overdosage was not covered while product detailing/drug marketing. These findings are similar to the observations drawn in other research work[5,6,12,17] done in other parts of India, where the observations that only <10% of the product information provide description about ADRs. based on the irregularities on the evaluation scale, it was observed that out of 162 DPLs, mild irregularities were observed in 45.6% DPLS, 36.4% had moderate, and 17.9% had severe irregularity in the matter present in DPLs. This showed that the target of DPLs was mainly focused on drug promotion in unethical, irresponsible, biased manner with a target to generate the sales without any consideration of any untoward effects to the patients. Rode et al.[19] in a prospective, OPD-based, observational study analyzed the DPL of different pharmaceutical companies. WHO criteria for “Ethical criteria for medicinal drug promotion, 1988” was used. It was observed that out of the 192 DPLs, the information on the generic and brand name, names and amount of active ingredients with name and address of the manufacturer was found in all the DPLs (100%). The mentioning of the therapeutic uses was seen in 91% of DPLs and dosage schedule (regimen) was present only in 60% of DPLs. The information about drug safety like side effects and solicited ADRs, contraindications, product precautions, and warnings, and major drug interactions was seen in 24, 36, and 20%, respectively. In a cross-sectional questionnaire-based study[20] on perceptions and exposure of DPL among 100 clinicians in a teaching hospital, it was observed that the majority (79%) of the clinicians had doubts about the accuracy of the claims made in DPL. It was also observed by 75% clinicians that the primary intention of DPL was on sales. More than 75% of clinicians felt that the training of the doctors in analyzing the DPLs should be done before interacting with MRs. In a Critical Review on DPL published in scientific medical journals,[21] a 370 DPLs were collected and out of these DPLs, 191 (51.6%) were obtained from scientific journals and 179 (48.4%) from OPDs. It was observed that in DPLs from journals, only 7.85% belonged to grade A (WHO guidelines). However, DPLs from non-scientific source followed the WHO guidelines with >90% from grade B. Only <5% of the DPLs belonged to grade C of both scientific journals and OPDs. This showed that none of the DPLs were designed to meet the primary objective of therapeutics. Most of the source of the DPLs was from grade B and did not provide information about adjuvants, ADRs, CIs, drug/product interaction, and also the references to scientific literature about the claims. The DPLs belonging to grade C even had no information about active ingredients and thus may lead to serious harm to patient due to the wrong drug prescription. So the prescribers may be easily misled by such irrational, unsubstantiated, and false claims with catchy terms/phrases, and thus this may affect the rational drug prescribing. Thus, conclusions can be drawn from the present study that study that WHO guidelines are not adhered by the pharmaceutical/drug companies while promoting their drug products in DPLs. The findings of our study concludes that unethical drug promotion is commonly misused by pharmaceutical companies for their selling motives and this is the major cause of unethical/irrational drug prescribing by the prescribers. The unsubstantiated claims noted in this study were present in majority of the cases in the brochures and were about the efficacy and safety. The presence of recent references were lesser and were present only in few DPLs making the prescribers unaware about the latest guidelines in their field and hence hampering the medical practice/expand the existing knowledge and practice of evidence-based medicine by the prescribers. Most of the pharmaceutical companies do not highlight or stress upon the product contraindications and serious adverse effects in fear of the creating panic among prescribers. The manufacturing product information, such as excipients name, product shelf life, source of outer shell packing, such as vegetarian/non-vegetarian and legal category in which the drug belongs are deliberately not covered in the literature and this makes the prescribers unaware of such vital information. The lack of such type of information can lead to unsolicited ADEs for which the prescribers are not prepared to handle and thus creating even legal problems. Thus, physicians should be made aware about the different unethical strategies adopted by the various pharmaceutical companies while promoting their products. The education of the prescribing doctors will help to enforce the pharmaceutical companies to regulate the ethical drug promotion, creating guidelines as per the standard operating procedures (SOPs), and help in correcting this problem. In addition, the indirect benefit will be that the physician will be able to evaluate critically the source of drug/product information forming the basis of material provided in DPLs.

Conclusion

It was observed in our study that none of the DPLs fulfilled all criteria of WHO for drug promotion and information present in DPLs had main focus on providing information on the positive features of drug while concealing or not providing information about the negative aspect of their products, for example, side effects, contraindications, and drug interaction. Thus, the pharmaceutical companies while making claims about theirs brands should make DPLs or any other informative materials as accurate, truthful, informative, unbiased, latest reference based in good taste. There should be no place for misleading or unreliable, non-verifiable statements that are likely to induce medically unjustifiable drug use claims. Education of the medical students in their primitive and formative years to become future doctors prescribing drugs is very important. This will enhance their skill about the critical evaluation of drug advertisements and will be very important in preparing practitioners to understand and analyze drug promotional activities ethically. The better understanding of drug promotional material henceforth will be improved while rationally prescribing inpatients.

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