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DRUG PROMOTIONAL LITERATURE: WHAT HAS CHANGED IN THE LAST TEN YEARS?

Pharmacology

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ABSTRACT

Introduction: Drug Promotional Literatures (DPLs) are major marketing tools to promote drugs by pharmaceutical companies. World Health Organization (WHO) guidelines for ethical medicinal drug promotion dictate that promotional literature should contain certain information. Many previous studies were conducted in India to evaluate the DPLs. These studies found that the information provided is not consistent with the code of ethical promotion.

Recent studies, however, have not evaluated the various claims presented in the DPLs. With this background, this study was undertaken to evaluate the rationality of DPLs as per WHO criteria, and also to analyze the claims in detail.

Objectives: The study was aimed to evaluate DPLs for accuracy of the information, and criteria for ethical medicinal drug promotion using WHO guidelines. Claims made in the literature along with their references were also evaluated in detail.

Material and Methods: This was an observational and cross-sectional study. It was conducted over a period of 4 months. DPLs were collected from various clinical departments at Vydehi Institute of Medical Sciences and Research Centre, Bangalore, India. Two independent researchers evaluated them. In addition to the fulfillment of "WHO criteria, 1988," the DPLs were also evaluated for the type of claims, and pictorial content presented and the references.

Results: A total of 155 DPLs were evaluated. Indications for use and safety information was mentioned in only 73.54% and 36.13% of the literature respectively. Only 26 (16.77%) of the DPLs had mentioned description of pharmacological effects, and 14 (9.03%) had mentioned about the pharmacokinetic parameters of the drugs. 769 claims were found from 155 DPLs, which were supported by 402 references. Only one DPL was without claims. Out of these references 91.62% were from Journal articles. The quality of all DPLs was good but font sizes in some were very small making it difficult to read. Overall, none of the DPLs fulfilled all WHO criteria.

Conclusion: It was concluded from this study that nothing has changed in the last the last ten years. Pharmaceutical industries did not follow WHO guidelines while promoting their drug products. Now days, companies promote and advertise products through innovative content in respective electronic devices. Awareness of prescribers on unethical promotion is important. Both company and stake holders should join hands, as patient benefit is the ultimate goal

KEYWORDS

Promotional drug literature, drug marketing, ethical drug promotion, WHO guidelines

Introduction

Drug Promotional Literatures (DPLs) are major marketing tools to promote drugs by pharmaceutical companies. They are designed to orient, aware, provide vital information, and promote drugs to prescribers. And are considered part of "direct to physician marketing"[1]. According to World Health Organization (WHO), promotion making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation, and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use, or to give rise to undue risks. The word "safe" should only be used if properly qualified. Comparison of products should be factual, fair and capable of substantiation. Promotional material should not be designed so as to disguise its real nature. WHO guidelines for ethical medicinal drug promotion dictate that promotional literature should contain certain information. The main objective of ethical criteria for DPLs is to support and encourage the improvement of health care through the rational use of medicinal drugs [1, 2].

In India, promotional activities standards are set by self-regulatory code of pharmaceutical marketing practices, January (2007), Organization of Pharmaceutical Producers of India (OPPI 2012), and by National legislation [1,3]. Many previous studies were conducted in India to evaluate the DPLs. The first such study was published way back in the year 2010 [1]. These studies found that the information provided is not consistent with the code of ethical promotion [1, 4, 5].

Recent studies, however, have not evaluated the various claims presented in the DPLs [4, 5]. With this background, this study was undertaken to evaluate the rationality of DPLs as per WHO criteria, and also to analyze the claims in detail.

Material and Methods

This was an observational and cross-sectional study. It was conducted over a period of 4 months from February 2017 to May 2017. A total of 196 printed DPLs were collected. These were collected on every Saturday on request from various clinical departments of Vydehi Institute of Medical Sciences and Research Centre, Bangalore, India, Bangalore. Each DPL was evaluated for compliance to ethical criteria for medicinal drug promotion laid by the WHO. Two independent researchers evaluated them. All the literatures were evaluated by WHO criteria for fulfillment of each of the following parameters: [6]

- The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug
- The brand name
- Content of active ingredient(s) per dosage form or regimen
- Name of other ingredients known to cause problems
- Approved therapeutic uses
- Dosage form or regimen
- Side-effects and major adverse drug reactions
- Precautions, contra-indications, and warnings
- Major interactions
- Name and address of manufacturer or distributor
- Reference to scientific literature as appropriate.

Data was entered in the excel sheet. Calculations were done and data was presented as percentage for each category and sub category. The claims in DPLs were evaluated based on previous studies. They were categorized into 4 types. Type A (unambiguous clinical outcome), B (vague clinical outcome), C (Emotive or immeasurable outcome) and D (non clinical outcome)[7] as shown in Table 1.

Table 1: Type of claim terminology with examples

Type	Terminology	Example
A	Unambiguous clinical outcome	Comparison with another drug: When compared with drug X, drug Y delivers faster symptomatic relief
B	Vague clinical outcome	Without comparison: Drug X is the new effective 20mg pill with low incidence of discontinuation due to skin problem

C	Emotive or immeasurable outcome	Catchy terminology Drug X : One of a kind Drug X: a source of healing power Only recommended by the US FDA
D	Non-clinical outcome	Drug plasma half lives or bioavailability in a 30% increase in arterial luminal diameter in postmortem dissection

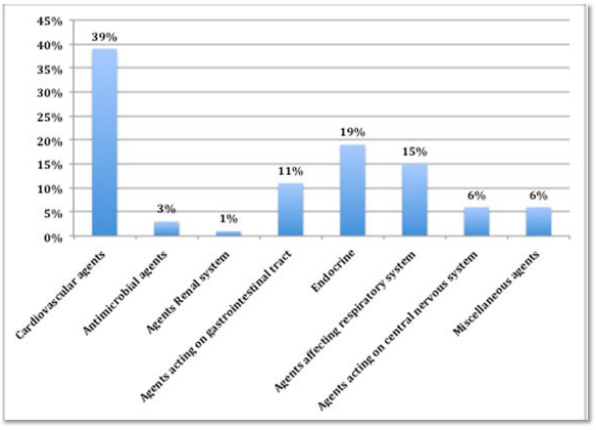
Results

A total of 196 DPLs were screened. Out of 196, only 155 were included in the study. DPLs promoting medical devices, ayurvedic medicines, drug monographs, reminder advertisements, and identical advertisements were excluded from the present study. Prescribing information leaflets were also excluded as they were considered to be non-promotional in nature. Out of these, 130 (83.88%) literatures belonged to Indian pharmaceutical companies, and 25 (16.12%) belonged to Non-Indian companies. Paper quality, print, and color were excellent in all 155 literatures. The font sizes in some DPLs were very small making it difficult to read. The results were further divided into the following categories.

1.) Type of drug

Out of the literatures, 14 (26.46%) were for promotion of single drug formulations, and rests 114 (73.45%) were for fixed dose drug combinations (FDC). Cardiovascular agents were the most promoted group (39%), followed by drugs acting on the endocrine system (19%). These are the medicines once started, are taken for lifelong, providing long-term financial benefit to the pharmaceutical companies. Categorization of drug literatures according to pharmacological groups is presented in Figure 1.

Figure 1: Therapeutic category of drugs promoted in promotional literatures (n = 155)



2.) Fulfillment of WHO criteria

None of the drug promotional literature fulfilled all the WHO criteria. [Table 2]. Around 149 (96.13%) of the literatures had mentioned International Nonproprietary name (INN) of each active ingredient. Recommended dosage form or dosage schedule was mentioned in only 77(49.67%) literatures. Only 26 (16.77%) of them had mentioned description of pharmacological effects, and 14 (9.03%) had mentioned about the pharmacokinetic parameters of the drug Safety information was missing from 99 (63.87%) DPLs. Manufacturer's name was not mentioned in 1(0.64%) literature. 79 (50.94%) literatures had both the name and addresses of the manufacturer. The address was missing in the remaining 75 (48.42%) literatures. The cost of the drug was mentioned in only 5 (3.22%) literatures.

All the literatures were specifically evaluated for the references cited. References were mentioned in 120 (77.41%) of the collected literatures. In these 120 literatures, total numbers of references cited were 440. Out of these, 403 were from journal articles, 16 were from textbooks, 7 were from websites, and rests 14 were from other sources of information. [Table 3]

Table 2: Evaluation of promotional literature as per WHO criteria (n = 155)

Pharmacological Information	Mentioned	Not mentioned
INN of each active ingredient	149 (96.13%)	6 (3.87%)
Brand name	142 (91.61%)	13 (8.39%)
Active drug per dose	136 (87.75%)	19 (12.25%)
Adjuvant	21 (13.54%)	134 (86.46%)
Recommended dosage form	77 (49.67%)	78 (50.33%)
Indications	114 (73.54%)	41 (26.46%)
Dosage schedule	42 (27.10%)	113 (72.90%)
Safety information	56 (36.13%)	99 (63.87%)
Manufacturer's name & address	79 (50.96%)	76 (49.04%)
References	120 (77.42%)	35 (22.58%)

Table 3: Classification of references given in the drug promotional literature

References	Percentage
Journal articles	91.62%
Textbooks	3.63%
Website	1.59%
Meta-analysis	0.45%
Review article	1.13%
Data on file	0.45%
Abstract in conference	1.13%
Animal studies	0%

3.) Claims and their references

769 claims were found from 155 DPLs, which were supported by 402 references. Only one DPL was without claims. The minimum and maximum claims per literature was 1 and 16 respectively. Table 4 represents the distribution of number of claims per drug literature.

Number of DPLs (32, 20.64%) made extravagant emotional claims regarding effectiveness, pharmacokinetic properties and convenience of the drug. As shown in table 5 the claims where further divided into four types. The presence or absence of references for each type was also recorded. Maximum references were supported for type A claims (80%) followed by type B (61.85%) and C (8.9%) claims.

Table 4: Distribution of number of claims in the drug promotional literature

0	1 (0.64)
1	24 (15.48)
2	18 (11.61)
3	21 (13.54)
4	22 (14.19)
>5	69 (44.54)

Table 5: Claim distribution tables in relation with references

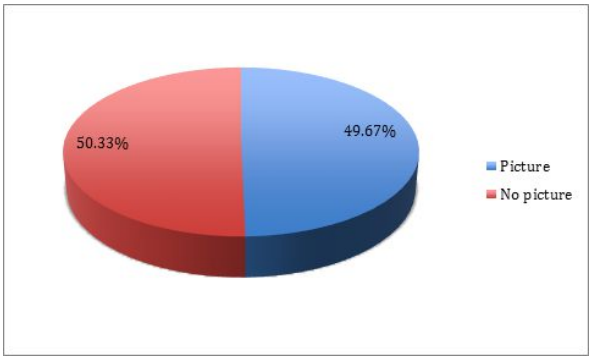
Type of claims	Total claims	Claims with reference	Claims without reference
Unambiguous clinical outcome	**45**	**36 (80%)**	**9 (20%)**
Vague clinical outcome	**561**	**347 (61.85%)**	**214 (38.15%)**
Emotive or immeasurable outcome	**146**	**13 (8.9%)**	**133 (91.1)**
Non clinical	**17**	**6 (35.29%)**	**11 (64.71%)**
Total	**769**	**402 (52.27%)**	**367 (47.73%)**

4.) Pictures

The DPLs were made more attractive and convincing by using various types of picture. The type of picture used in each DPL was evaluated. [Figure 2]. 78 (50.33%) DPLs were without pictures. Among the DPLs that had pictures (49.67%), maximum DPLs (16.88%) had picture of a single happy looking man. Second highest pictures were of a family 8 (10.38%). Followed by pictures of organ and limbs, which were 7(9.09%) and 6(7.79%) respectively. Other pictures were of a clock, butterfly, flight, pilot, vehicle, stadiums, globe, pollution, and rainbow, hope etc.

Most pictures were irrelevant and had no correlation to the drug being used. DPLs presenting pictures unrelated to medicine, disease or therapy were representing the tendency of the pharmaceutical industry of wasting money in printing eye catching glossy paper promotional brochures deprived of important therapeutic information. [1]

Figure 2: Pictorial content in the DPL (n=155)



Discussion

It was concluded from this study that pharmaceutical industries did not follow WHO guidelines while promoting their drug products. The DPLs lacked authenticity. Nothing has changed in the last ten years. Important information regarding safety, dosage adjustment, contraindication and drug interactions were still missing from the DPLs. None of the DPLs contained all of the information as per WHO guidelines for medicinal drug promotion. These finding are very consistent with other study results. [8]

Our study emphasizes on use of emotive, immeasurable and nonclinical outcomes by the pharmaceutical companies to promote the product. Only few studies have been reported from India in this aspect. Our literature search revealed only four published articles over the last 10 years. All the articles reported false claims about efficacy, and clinical outcomes of the drugs. In most cases, the claims were not supported by valid literature [6,7,9,10]. In studies that had cited literature, 32 (20.64%) had one or more false/tall claims. This aspect of the drug promotion was also highlighted in other similar studies. These false/tall claims may misguide the prescribers. [1,11,12,13]

Another aspect was that in this study evidence was missing for a lot of claims. Many DPLs contained information and pictures just to make the DPL look attractive. Such information was nowhere related to the drug. Moreover, the information was given in fine print and hard to read as shown in other study also [3].

In this study, references were cited in 52.27% of the collected literatures. The other 47.73% did not even think that references should support their claims. This is in concurrence with other Indian studies. Since the DPLs target a major population of prescribers and are considered useful source of knowledge about drugs, irrational information in DPLs may lead to wrong prescribing by the clinicians.

More studies are needed on DPLs. It is important to make physicians aware about these facts. Also, initiatives should be taken to alert them about the same. [14] Now days, companies promote and advertise products through innovative content in respective electronic devices. Awareness of prescribers on unethical promotion is important. Both company and stake holders should join hands, as patient benefit is the ultimate goal. 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. Forwarding 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. [3,6,9]

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