

Critical analysis of the drug promotional literatures advertised in a tertiary care hospital

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ABSTRACT

Background: The objective of the study was to critically analyse the drug promotional literatures (DPLs) advertised in a tertiary care hospital.

Methods: This observational study was conducted in department of pharmacology, grant government medical college. The data was collected over a period of 3 months after obtaining permission from Institutional Ethics Committee. Around 200 DPLs were collected from different specialty OPDs. Promotional literatures in the form of medical equipment's, ayurvedic medicine, drug monography, reminder advertisement, identical advertisement and drug name list were excluded from the study. Data compiled was compiled in an excel sheet. The complied data were analyzed with the help of tables and graphs.

Results: In our study, the name of the active ingredient, their brand name and the therapeutic uses were mentioned in all the DPLs (100%). The dosage form of the drug was addressed in 85%, whereas the schedule was present in 58% of the DPLs. Most of the DPLs had mentioned about the positive effects of the drug, while few of them described the negative effects of the drugs, namely, adverse drug reactions (39%), precautions to be taken (36%), contraindications (36%) and various drug interactions (33%).

Conclusions: A diverse set of results were obtained when a cohort of 200 promotional literatures were analyzed wherein the advantageous effects were highlighted covering the detrimental effects of the drug. DPLs were not in line and accordance with WHO guidelines, but where modified according to the company preferences.

Keywords: Drug promotional literature, Drug advertised, Sources

INTRODUCTION

Drug enquiry committee was constituted by Sir Ram Nath Chopra in India (1930) which scrutinized the drug pamphlets making spurious claims much before WHO awakened to this threat in 1988.¹ According to the "ethical criteria for medicinal drug promotion" by WHO, "drug promotion" refers to all informational and persuasive activities by manufacturers and distributors of the pharmaceutical industry, the effect of which is to

induce a favorable prescription, supply, purchase, and/or use of medicinal drugs.^{2,3}

Pharmaceutical companies spend around one third of all sales revenue on marketing their products which is twice that spent on research and development.⁴ Drug promotional literatures (DPLs) has been a shrewd strategy embraced by the pharmaceutical companies for the marketing of their drugs.

In an effort to regulate the promotional activities many national and international guidelines are being framed from time to time such as the WHO ethical guidelines, international federation of pharmaceutical manufacturers and associations code of pharmaceutical marketing practices, organization of pharmaceutical producers of India (OPPI) and uniform code of pharmaceutical marketing practices (UCPMP).⁵ Lately, OPPI has come into action as a self-regulated code for the pharmaceutical marketing practices, stating criteria's that has to be fulfilled in the DPLs.⁶ Powerful influence of drug promotional literature on physicians prescribing behavior, dissemination of deceptive information, unsubstantiated claims, and lapses in the field of ethics is a matter of enormous concern.⁷

Hence, this study was conducted to critically analyze fulfillment of WHO criteria in DPLs available in Indian market using WHO guidelines. This study aims to analysis the veracity of the drug promotional literature among the prescribers, which are tactically given to them by the medical representatives.

METHODS

The study was a prospective, observational and single centered study, conducted in the department of pharmacology, grant government medical college and Sir JJ Group of Hospitals, Mumbai, India. The data was collected over a period of 3 months (April to June 2019) after obtaining permission from Institutional Ethics Committee. Around 263 DPLs were collected from different specialty OPDs, namely medicine, surgery, psychiatry, obstetrics and gynecology, ophthalmology, skin, pediatrics, neurology, ENT and orthopedics, through convenience sampling. Out of which 200 DPLs were selected after excluding the promotional literatures in the form of medical equipment's, ayurvedic medicine, drug monography, reminder advertisement, identical advertisement and drug name list.

The following are the WHO criteria to be followed by pharmaceutical industries for the completeness of DPL.³ The names of the active ingredients using either international nonproprietary names or the approved generic names of the drug.

The brand name, content of active ingredient per dosage form or regimen. Name of other ingredients known to cause problems, i.e., adjuvant, approved therapeutic uses, dosage form or regimen, side effects and major adverse drug reaction, precautions, contraindications, and warnings, major interactions. Name and address of the manufacturer or distributor. Reference to scientific literature as appropriate.

Data compiled was compiled in an excel sheet. The complied data were analyzed with the help of tables and graphs.

RESULTS

A total of 200 DPLs were collected for the study. The name of the active ingredient, their brand name and the therapeutic uses were mentioned in all the DPLs (100%). None of the DPLs had mentioned anything about the other adjuvants used (0%). The dosage form of the drug to be given was addressed in 85%, whereas the schedule of the drugs to be taken was present in 58% of the DPLs. Most of the DPLs had mentioned about the positive effects of the drug, while few of them described the negative effects of the drugs, namely, adverse drug reactions (39%), precautions to be taken (36%), contraindications (36%) and various drug interactions (33%). Name of the manufacturing company was acknowledged in 88% and their address was cited in 60.5% of the DPLs.

Table 1: Analysis of DPLs as per who criteria.

Criteria	Total no. of DPLs fulfilling the criteria	Percentage (%)
Active ingredient	200	100
Brand name	200	100
Amount/dose	200	100
Other adjuvant	0	0
Indication	200	100
Dosage form	170	85
Schedule	116	58
Adverse drug reactions	78	39
Precautions	72	36
Contraindications	72	36
Drug interaction	66	33
Manufacturer name	176	88
Manufacturer date	61	30.5
Manufacturer address	121	60.5
References	163	81.5

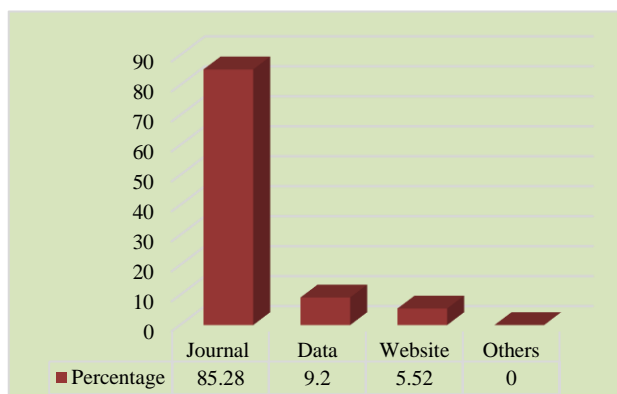


Figure 1: Source of references.

Out of the 81.5% references notified in the DPLs, 85.27% of them were cited from various journals, 9.2% were mentioned from the data available and 5.5% were quoted from the various websites.

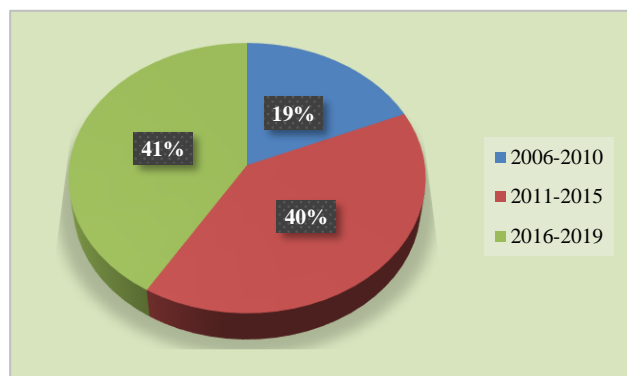


Figure 2: Year of publication.

Majority of the references were cited from journals, of which references published from a period of 2016-19 were 42%, 2011-15 were 40% and before 2010 were 18%.

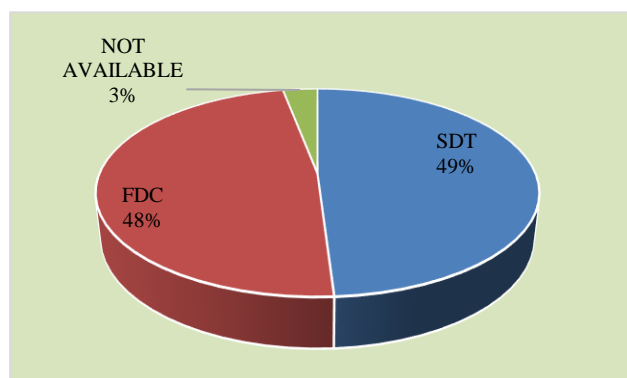


Figure 3: Nature of dosage form.

Out of 200 DPLs collected, 48% of them promoted single drug therapy while 49% of them encouraged fixed dose combinations.

DISCUSSION

DPLs or the pharmaceutical advertisements play an important role to disseminate the information among the prescribers, regarding the availability of new drugs in the market. In busy lives of today where it becomes difficult to go through every journal, articles or any other source of information, most of the prescribers rely on DPLs for the information of neoteric drugs being launched in the market. Hence, it becomes important for the prescribers to rule out the risk-benefit ratio before prescribing these drugs. In order to maintain the reliability of these DPLs, the world health organization has laid down certain criteria that need to be followed by every pharmaceutical company. Hence, this study was conducted to critically analyze the DPLs available in Indian market using WHO

guidelines. For the fulfillment of the same purpose, 200 DPLs were collected from various departments in a tertiary care hospital and were analyzed critically and had the following denouement -

In our study it was found that the active ingredients, brand name and therapeutic uses of the drugs were mentioned in all the DPLs, occupying a substantial amount of its area, which correlated with the study conducted by Jadav et al (100%) and Priyanka et al (100%).^{8,9} This suggests that the companies highlight the approbative effects of the drugs trying to have a striking impact on the physicians.

The percentage of the dosage form mentioned in the DPLs collected (85%) evened with the study conducted by Gautam et al (92.3%) while the percentage of schedule for the drug intake cited (58%), equated with the study conducted by Shagupta et al (59.25%).^{10,11} This indicates that the pharmaceutical companies overlook the need to mention about the schedule (dose frequency and duration) which has to followed obtain the salutary effect of the drug.

Majority of the DPLs highlighted the therapeutic effects of the drug while not specifying the unfavorable effects of it. The same results were resonated in the study done by Puttaswamy et al, revealing the percentage of unfavorable side effects, namely, adverse drug reaction (32.5%), precautions to be taken (32.5%), contraindications (34.1%) and drug interactions (29%).¹² This advocates that the companies are being reluctant on providing essential information regarding the safety profile of the drug.

The name and address of the manufacturer revealed in our study (80%) was found to be equivalent with the study managed by Salma et al and Puttaswamy et al.^{12,13}

As it is evident from the (Figure 1), majority of the references were cited from journals, of which references published from a period of 2016-19 were 42%, 2011-15 were 40% and before 2010 were 18%. The same kind of results were seen in co-relation with Priyanka et al study. Recent references are necessary to cope up with the burgeoned knowledge and practice of evidence-based medicine.

Figure 2 revealed that out of 200 DPLs collected, 48% of them promoted single drug therapy while 49% of them encouraged fixed dose combinations, commensurating with the study conducted by Jadav et al. Hence the physicians should consider the rationality of the drug combination before prescribing the fixed drug combinations.

Hence, our study reveals that it's very essential for the treating physician to develop the adroitness of critically analyzing the DPLs according to the WHO guidelines,

before accepting them as a piece of conscientious information.

CONCLUSION

A diverse set of results were obtained when a cohort of 200 promotional literatures were analyzed wherein the advantageous effects were highlighted covering the detrimental effects of the drug. DPLs were not in line and accordance with WHO guidelines, but were modified according to the company preferences.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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