Original Research Article

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

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Received: 21 January 2020
Revised: 13 March 2020
Accepted: 22 April 2020

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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 compiled 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). 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. 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.

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 analyze the veracity of the drug promotional literature among the prescribers, which are tactically given to them by the medical representatives.

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.

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%.

**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%). 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%). 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%). 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. 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.

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 where modified according to the company preferences.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Thawani V. Drug promotion: can self-regulation work. Indian J Pharmacol. 2002;34(4):227-8.
2. Şahne BS, Yegenoglu S, Uner MM, Werheimer AI. Adherence of drug advertisements to the international marketing codes. Hacettepe University J Faculty Pharmacy. 2012;32(1):53-66.
3. Ethical criteria for medicinal drug promotion. World Health Organization. 13 May 1988. Available at: http://www.who.int/medicinedocs/collect/ednweb/pdf/whozip08e/whozip08e.pdf. Accessed on 12 September 2019.
4. WHO, Trade, foreign policy, diplomacy and health? Available at: http://www.who.int/trade/glossary/story 073/en/#main. Accessed on 12 September 2019.
5. Jacob NT. Drug promotion practices: A review. Br J Clin Pharmacol. 2018;84(8):1659-67.
6. Organization of Pharmaceutical Producers of India (OPPI) code of pharmaceutical practices 2019. Printed promotional material. Available at: http://www.indiaoppi.com/OPPI%20%Code%20of%20Marketing%20.pdf. Accessed on 3rd August 2019.
7. Randhawa GK, Singh NR, Rai J, Kaur G, Kashyap R. A critical analysis of claims and their authenticity in Indian drug promotional advertisements. Advances Med. 2015.
8. Jadav SS, Dumatar CB, Dikshit RK. Drug promotional literatures (DPLs) evaluation as per World Health Organization (WHO) criteria. J Applied Pharmaceutical Sci. 2014;4(6):84-8.
9. Sonwane PG, Karve AV. Drug promotional literature: Does pharmaceutical industry follow WHO guidelines. Int J Basic Clin Pharmacol. 2017;6(7):1790-3.
10. Sandhya RG, Preeta KC, Ravinder KS, Tripathi CD. Critical appraisal of drug promotional literature using World Health Organisation guidelines. Int J Basic Clin Pharmacol. 2017;6(8):2014-9.
11. Naikwadi SA, Jadhav RB, Patil AP. Critical Analysis of Indian Drug Promotional Literature (DPL) Using World Health Organization Criteria for Ethical Medicinal Drug Promotion. J Dental Med Sci. 2017;16(9):49-54.
12. Ganashree P, Bhuvana K, Sarala N. Critical review of drug promotional literature using the World Health Organization guidelines. J Res Pharma Pract. 2016;5(3):162-5.
13. Salma M, Tejus, Salmani MF, Sapna P, Mathur AG. An analysis of adherence to the World Health Organisation guidelines pertaining to drug promotional literature by pharmaceutical firms. Int J Basic Clin Pharmacol. 2018;7(12):2429.

Cite this article as: Dhodi DK, Chavan MS, Dawner F, Desai SA, Bhoir AR. Critical analysis of the drug promotional literatures advertised in a tertiary care hospital. Int J Basic Clin Pharmacol 2020;9:870-3.