

## A Critical Evaluation of Drug Promotional Literatures provided to Prescribers at a Tertiary Care Teaching Hospital in Gujarat

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### Original Research Article

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**Abstract:** Drug Promotional literatures (DPLs) form an important means of promotion of drugs. With a constant increase in number of brand drugs, an increased need of monitoring of DPLs is evident. In this single point observation study, new drug advertisement DPLs were collected from the desk of select prescribers in the institutes associated with a medical college according to convenient sampling. Collected DPLs were analyzed for appropriateness using WHO ethical criteria for medicinal drug promotion. A total of 53 new drug advertisement DPLs of drugs affecting various body systems were collected during the study period. Brand name (100%) and generic names (98.11%) were mentioned in most DPLs and were easily readable in majority DPLs. Very few DPLs (11.3%) mentioned details of inactive ingredient. Prescribing information such as therapeutic indications (94.3%), adverse reactions (86.7%), contraindications (90.5%), dosage form (100%), regimen (92.4%) and cautions (83%) were mentioned in majority of DPLs. Details of drug drug interactions were mentioned in 45.2% of DPLs. Details of manufacturer was provided in majority of DPLs, however, none mentioned details of distributors. Claims were present in majority of DPLs (94.3%) and majority (62.2%) were cited with a justifiable reference. Pictures used in DPLs were found to be inappropriate in significant number (41.5%) of DPLs. Supportive data, statistical data and data of post marketing surveillance were missing in majority of DPLs. While new drug advertisement DPLs provide good amount of prescribing information, improvement is required in provision of details regarding inactive ingredients, drug drug interactions, post marketing surveillance, statistical and supportive data.

**Keywords:** Drug Promotional literatures, contraindications, dosage form, therapeutic indications

### INTRODUCTION

Drug promotion is primarily carried out to increase the awareness about a particular drug/ brand among the prescribers. Various means of drug promotion are available including advertisements, information by medical representatives, free drug samples etc[1]. One of the popular means of drug promotion is provision of Drug Promotional Literatures (DPLs) to prescribers [2]. A DPL is considered as a new drug advertisement till four years from its introduction. After four years, the advertisement is considered to be a reminder and usually requires less information as compared to a new drug advertisement [3].

While guidelines for crafting a DPL has been devised by WHO [3], many DPLs do not effectively follow these guidelines. Lack of coherence with the guidelines while crafting a DPL can give inadequate and inaccurate information to prescribers and wrongly

influence the decision of a prescriber to select a particular drug/brand. Studies have indicated that DPLs provided to prescribers often contain information not congruent with the ethical standards [4]

With an ever growing number of brand drugs in the pharmaceutical market [5], there is an increased need to monitor and improve the quality of DPLs provided to prescribers. Hence, the present study was conducted to evaluate the quality of DPLs provided to prescribers in a tertiary care teaching hospital with an aim to monitor and quantify deficiencies.

### MATERIALS AND METHODS

Present was an observational, single centre, cross sectional study conducted at Department of Pharmacology of a medical college in Gujarat. The study was conducted over a period of 7 months i.e. March to September 2017. New drug promotional advertisements of past four years i.e. 2014 to 2017 were

collected from the personal desk of select prescribers in the hospitals affiliated with the medical college. DPLs were collected according to convenient sampling. Collected DPLs were analyzed for appropriateness using WHO criteria for medicinal drug promotion [3]. The criteria includes information set such as presence of brand name, generic name, indications, contraindications, warning and precautions, use of pictures or statistical data, appropriateness of references etc [3]. Collected DPLs were analyzed for appropriateness using these criteria. References given for the claims present in the DPL were considered appropriate if these were from scientific journals, guidelines, textbooks, official product information or other standard sources of information. Pictures used in DPLs were analyzed for appropriateness considering the relevance to the product or disease. In addition, brand name and generic names were checked for ease of readability. Data was recorded in MS Excel and analyzed for frequency and percentages.

## RESULTS

A total of 53 DPLs were collected from prescribers' desk from Departments of Medicine, TB and Chest disease of the hospitals affiliated with medical college according to convenient sampling. These included DPLs of endocrine drugs (16), cardiovascular drugs (14), drugs affecting hematological system (9), drugs affecting respiratory system (3), drugs used for psychiatric disorders (2), drugs used for GI disorders (2), drugs affecting peripheral nervous system (2), vaccines (2) and one DPL each of drugs affecting CNS, antimicrobial and antihistamine. Appropriateness and completeness of DPLs were analyzed according to WHO criteria for medicinal drug promotion. Results are presented as frequency and percentage (Table 1). Brand names in all the DPLs were found to be easily readable. Information was provided under appropriate headings in 51 (96.22%) DPLs.

**Table-1: Analysis of drug promotional literatures (DPLs) according to WHO ethical criteria for medicinal drug promotion.**

Sr. No.	Parameter	Yes (%)	No (%)	Remarks
1	Presence of brand name	53 (100.00%)	0 (0.00%)	-
2	Presence of generic name	52 (98.11%)	1 (1.88%)	-
3	Ease of readability of generic name	36 (67.92%)	16 (30.18%)	No generic name in one DPL (1.88%)
4	Other inactive ingredients mentioned	6 (11.32%)	45 (84.90%)	Partial information (2, 3.77%)
5	Name and address of manufacturer mentioned	37 (69.81%)	1 (1.88%)	Name only (15, 28.3%)
6	Name and address of distributor mentioned	0 (0.00%)	53 (100.00%)	-
7	Amount of active ingredient per dose mentioned	51 (96.22%)	2 (3.77%)	-
8	Name of other ingredients known to cause problems mentioned	0 (0.00%)	53 (100%)	-
9	Therapeutic uses mentioned	50 (94.33%)	3 (5.66%)	-
10	Dosage formulation mentioned	53 (100.00%)	0 (0.00%)	-
11	Dosage regimen mentioned	49 (92.45%)	4 (7.54%)	-
12	Adverse reactions mentioned	46 (86.79%)	7 (13.20%)	-
13	Drug drug interactions mentioned	24 (45.28%)	29 (54.71%)	-
14	Contraindications mentioned	48 (90.56%)	5 (9.43%)	-
15	Cautions/ warnings mentioned	44 (83.01%)	9 (16.98%)	-
16	Claim (s) present	50 (94.33%)	3 (5.66%)	-
17	Appropriate reference for the claim (s) provided	33 (62.26%)	3 (5.66%)	No claims present (3, 5.66%)

				Some claim(s) in the DPL not justified (14, 26.41%)
18	Catchy term(s) used	40 (75.47%)	13 (24.52%)	-
19	Picture used in the DPL	48 (90.56%)	5 (9.43%)	-
20	Appropriateness of picture	21 (39.62%)	22 (41.50%)	No pictures used (5, 9.43%) Some picture (s) in the DPL inappropriate (5, 9.43%)
21	Supportive data e.g. bar diagram, pie chart etc. included in the DPL	22 (41.50%)	31 (58.49%)	-
22	Statistical data included in the DPL	11 (20.75%)	42 (79.24%)	-
23	Fixed dose combination promoted	20 (37.73%)	33 (62.26%)	-
24	Data of post marketing surveillance provided	3 (5.66%)	50 (94.33%)	-

## DISCUSSION

The present study was conducted to evaluate the appropriateness of DPLs provided to the prescribers at a leading tertiary care hospital in Gujarat. A sample of 53 DPLs (new advertisements) were collected according to convenient sampling from the prescribers in the hospitals affiliated with the medical college and analyzed for appropriateness using WHO criteria for medicinal drug promotion.

DPLs collected and analyzed for the present study more commonly included DPLs of cardiovascular and endocrine drugs. However, convenient sampling was used for collection of DPLs, which could have influenced this pattern. A larger sample size is thus desirable to determine the proportionate use of DPLs for promotion of various groups of drugs.

As one can expect, all DPLs included brand names, which is a primary requirement for promoting the brand and improving the awareness regarding the product among the prescribers. Also, most DPLs (98.11%) mentioned generic names and indicated good coherence to WHO guidelines for medicinal drug promotion. Presence of generic name is important to avoid confusion regarding different brands among the prescribers and can be particularly useful in cases of sound alike/ look alike brand drugs. Khakhkhar *et al.* in a study to evaluate DPLs collected from various parts of Gujarat also reported that 98% of DPLs mentioned the generic name of the product[6]. Brand names in all DPLs were easily readable, while generic name was also easily readable in majority (67.9%), the latter, however can be improved.

While name and strength of active ingredient per formulation was mentioned in all DPLs similar to findings of Nath *et al.*[7], lack of information regarding inactive ingredient (84.9%) was conspicuous. Similar findings were reported by Jadav *et al.* in a study conducted in 2013 and indicates a continuing trend in this regard[8]. Inactive ingredients can sometimes be associated with variation in bioavailability of drug or adverse reactions. It is advisable to include this information in the DPL as a source of additional information for the prescribers to promote safe and effective use of drugs.

While majority of DPLs mentioned name and address of manufacturer (69.8%), few mentioned only name (28.3%). Name and address of manufacturers and other contact details are required in case the prescriber needs to seek additional information for doubts/ queries regarding the product. Our findings are different from those reported by Khakhkhar *et al.* and Jadav *et al.*, who reported a higher frequency of incomplete/ missing information in their study[6,8]. Mali *et al.* reported a similar number of DPLs (70.6%, n=513) mentioning address of manufacture in a study conducted at Nagpur, however, the study was conducted almost a decade ago and may not indicate recent trends [9]. Further, contact details of distributors were not present in any of the DPLs analyzed. While this may be unsubstantial in case of widely available brands, it is particularly important in case of drugs which are not available easily such as plasma derived products. Availability is an important criterion for selection of a particular drug/brand and is taken into consideration by all the prescribers.

Therefore, inclusion of distributor details in the DPL should be considered by pharmaceutical manufacturers. Most studies analyze name and address of manufacturer or distributor as a single criterion, hence, the later finding could not be adequately compared.

Prescribing information of the product such as therapeutic indications (94.3%), adverse reactions (86.7%), contraindications (90.5%), dosage form (100%), regimen (92.4%) and cautions (83%) were included in majority of DPLs and suggested a good practice. Our findings differ from those of Jadav *et al.*, Nath *et al.* and Vlassov *et al.* [7,8,10]. Jadav *et al.* reported that >93% of DPL lack the information regarding ADRs, drug interactions and precautions, while Vlassov *et al.* reported in a study conducted in Russia that majority of DPLs (89%) do not provide information about safety warnings and contraindications. Similarly, Nath *et al.* reported very few DPLs containing safety information. Drug- drug interactions, however, were not mentioned in more than 50% DPLs in the current study, similar to findings of above mentioned studies. The Information can be particularly important in case of drugs prone to interactions and those which are likely to be used in patients suffering from multiple ailments. Inclusion of this information is recommended to promote the safe and effective use of drugs.

Claims were present in most (94.3%) DPLs. Claims are included in the DPL to highlight the characteristics and/or advantages of the product such as efficacy or safety of the drug, cost effectiveness etc. Claims are required to be presented in the DPL along with a reliable scientific reference. A positive observation from the current study was presence of reference from scientific journals or other standard sources such as product information sheet in majority (62.2%) of DPLs. Relatively few DPLs presented claims without a justifiable reference such as that from commercial websites or data on file and suggested a good practice overall. These findings also differ from those reported by Jadav *et al.* in [8] and Khakhar *et al.* in [6], who reported inadequate practice in this regard. However, a limitation of the present study would be that qualitative aspect of claims was not analyzed as carried out by few authors[2,6,9,11]. Othman *et al.* reported in a systemic review that only 28% of claims in DPLs were unambiguous clinical claim[12]. Catchy terms were also found to be present in majority (75.4%) of DPLs. Catchy terms are used to grab the attention of the prescribers. While this can help improve the prescription of product, such practice is usually not recommended.

Nearly 90% DPLs exhibited presence of pictures for promotion of products. Pictures form an important part of drug promotional literature and are

found to occupy variable amount of space in DPLs[13]. These can be used to demonstrate advantage of product and add to the scientific content. However in the current study, a significant number of pictures (41.5%) were found not appropriate when judged for relevance to product and/or therapeutic indication. Inclusion of pictures which enhance the scientific value of the DPL is recommended.

A good number of FDCs of drugs (37.7%), primarily those acting on CVS and endocrine system were promoted using DPLs in the present study. This hinted that multidrug therapy is often required in patients suffering from CVS and endocrine disorders. While use of FDCs can improve patient compliance[14], prescribers need to be extra vigilant to determine the rationality and need of FDCs in patients. Unnecessary promotion and prescription of fixed drug combination can increase the cost of treatment as well as the risk of adverse reactions.

A negative finding from the current study was lack of inclusion of supportive data (such as bar diagrams) (58.4%) and statistical data (79.2%) in majority of DPLs. Supportive data such as diagrams can facilitate the understanding of effects of drugs especially with regards to comparison with other drugs. Further, statistical data demonstrating the level of significance with regards to parameters studied can help the prescriber select an appropriate drug for the given condition. Inclusion of these parameters is strongly recommended to improve the scientific validity of DPLs.

Another negative finding of the current study was lack of Post marketing surveillance (PMS) data in most (94.3%) DPLs. Post marketing surveillance data provides an additional estimate of safety and tolerability of drugs in a wide population in addition to that generated during clinical trials[15]. Such data provide a real world picture of safety of drugs in varied populations and can be extremely useful to prescribers in selection of drugs particularly in vulnerable populations such as elderly, pregnant patients, patients with renal or hepatic diseases, patients receiving multiple medications etc. Inclusion of such information in the DPL can be extremely useful to the prescribers and can help gain their confidence in the product as well.

Information in DPLs in the present study was included under appropriate headings, which was a positive finding and can help the prescriber to search for the desired information in the DPL in a quick manner.

#### **Limitation of the study**

The study included a relatively lesser number of DPLs (53) collected according to convenient sampling.

### Strength of the study

DPLs analyzed in the present study were collected directly from the personal desk of prescribers at a tertiary care teaching hospital. These DPLs, being present at the prescriber's personal desk, are likely to have a greater effect on drug promotion as compared to those provided during OPD hours only.

### CONCLUSION

While new DPLs provided to medical practitioners adhere well to the WHO guidelines with respect to prescribing information, improvements are required in certain sections such as information regarding inactive drug interactions, ingredients, post marketing surveillance and statistical and supportive data.

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