

Analysis of Drug Promotional Literature and its adherence to WHO guidelines.

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Abstract

Background: Drug Promotional literature (DPL) is an important tool for both pharmaceutical industry (marketing strategy) and physicians (up to date knowledge). The objective was to evaluate the accuracy, consistency, and validity of the information in accordance with the World Health Organization (WHO) ethical criteria for medicinal drug promotion.

Methods: A cross sectional observational study was performed in Department of Pharmacology, Medical college Jhalawar, a tertiary care teaching hospital in Rajasthan. Total 247 drug promotional Literatures were randomly collected from private clinics of Jhalawar out of which 47 were excluded. 200 drug promotional literatures were evaluated by using WHO guidelines framed in 1988.

Result: Out of 200 promotional literature 115 promotional literature advertise single drug formulation and 85 were for fixed dose combination. On assessing DPL using WHO criteria, all DPL mentioned brand names and generic names (100%). Most of them mentioned the content of active ingredients (90%), therapeutic uses (88.5%), dosage regimen (81.5%), contraindication (22%), drug interaction (13.5%), side effects (11%), reference to scientific literature (41%), name and address of manufacture and distributor (96%).

Conclusions: Our study point towards big lacuna in DPLs. None of the DPL's satisfied all the WHO criteria. Incomplete information may lead to irrational prescription of drugs. Therefore, more strict regulations need to be implemented and physicians must critically evaluate DPL's before considering the same for prescribing.

Keywords: Drug promotional literature, pharmaceutical industries, WHO guidelines, Drug advertisements.

INTRODUCTION

A "pharmaceutical product" means all pharmaceutical or biological products which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body. The word "promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet. One of the well-known promotional activities of pharmaceutical industries is to produce advertising brochures and leaflets¹.

According to World Health Organization (WHO), medicinal 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"². Hence, for the rational use of drugs, WHO has laid down ethical criteria for medicinal drug promotion and has recommended pharmaceutical industries to implement these guidelines³. Pharmaceutical companies spend large amount of money on drug promotions. In 2005, a pharmaceutical industry in the USA has spent more than 30 billion dollars in marketing and promoting to enlighten the clinicians about their products⁴. The main ethical criteria for medicinal drug promotion literature (DPL) is to support and encourage the improvement of health care through the rational use of medicinal drugs. They apply to prescription and non-prescription medicinal drugs also known as over-the-counter drugs

In private or public clinic set-up direct to physician (DTP) marketing is major method used by drug manufacture

companies and distributors⁵. Many a times, it is the only source on which treating physicians depend on for updating their knowledge about the existing and novel drugs⁶. Many of physicians currently get their information from commercial sources, usually through well set network of medical representatives⁷. In drug advertisements, pharmaceutical manufacturers have an opportunity to proclaim the existence of a drug, promote its advantages, and also provide useful information to help a clinician to decide whether and when to use the medicine. Three main types of printed drug advertisements such as; handouts/booklets that are given by medical representatives, advertisements in periodicals, and individual direct mail advertisements. It plays a crucial role in keeping the physicians updated about various aspects of pharmaceutical products and the newer therapeutic modalities, helping them provide the most appropriate solution for treating the patients.

Ethical criteria for medicinal drug promotion by World Health Organization, 1988; is thought to be the foundation of self-administrative code of International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) as well as Organization of Pharmaceutical Producers of India (OPPI), a self-regulatory code of pharmaceutical marketing practices, December 2012. The rationality of drug promotional literature can be assessed by considering World Health Organization criteria for ethical medicinal drug promotion, 1988^{8,9,10}.

Many studies have illustrated that information disseminated through DPLs is inconsistent with the code of ethics¹¹. However, not enough studies have been conducted in the Indian setup to gauge this issue and with this viewpoint the present study was taken up to critically review the DPL's and to evaluate the collected DPL's for accuracy, consistency, and validity of the information

presented in it, using World Health Organization (WHO) criteria for ethical medicinal drug promotion.

METHODS

This was a cross-sectional observational study carried out in department of Pharmacology, Jhalawar Medical College, Jhalawar, a tertiary care teaching hospital in Rajasthan. All available drug promotional literatures of different pharmaceutical companies were collected randomly from private clinics of Jhalawar. All DPL's were evaluated based on the following parameters of WHO Ethical criteria 1988 of medicinal drug promotion¹².

- The name of the active ingredient(s) using either international nonproprietary 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

Exclusion Criteria

Brochures promoting medicinal devices and equipments, orthopedic prosthesis, ayurvedic medicines, drug monographs and literature promoting more than two brands, DPLs promoting drugs other than allopathic drugs were excluded from the study.

Statistical Analysis

All the data collected were entered and compiled into a Microsoft excel worksheet. Descriptive statistics number and percentages were calculated. The data were analysed using statistical software's SPSS 20.

RESULTS

Out of 200 promotional literature 115 promotional drug literature were of single drug formulation and 85 were of fixed dose combination. Majority of DPL's were from antimicrobial class (25.5%) followed by GIT, Vitamins and minerals, CNS as shown in Table 1. On analysis of DPL using WHO criteria as shown in Table 2, all DPL mentioned brand names and generic names (100%). Most of them mentioned the content of active ingredients (90%), therapeutic uses (88.5%), dosage regimen (81.5%), contraindication (22%), drug interaction (13.5%), side effects (11%), name and address of manufacture and distributor (96%), reference to scientific literature (41%). Total number of references were 210, out of which 170 (80.9%) were from journal articles, 4.7% from websites. Among the journal article references 98 (46.7 %). Out of all the articles mentioned 160 (76%) were from indexed journals and 50 (23.8%) were from non-indexed journals as shown in Table 3.

Table 1. Drug Promotional Literature (DPL) based on Pharmacological drug class.

System wise distribution of DPL	Number (n)	Percentage (%)
CVS	18	9
Antimicrobials	51	25.5
GIT	25	12.5
CNS	23	11.5
Autocoids	18	9
Blood	14	7
Endocrinology	20	10
Vitamins & Minerals	24	12
Miscellaneous	7	3.5

Table 2. Analysis of drug promotional Literature (DPL) according to WHO criteria (n=200).

WHO Criteria	DPL fulfilling criteria (n)	Percentage (%)
International non-proprietary names	200	100
Brand name	200	100
Content of active ingredient(s) per dosage form or regimen	180	90
Name of other ingredient known to cause problem	05	2.5
Approved therapeutic uses	177	88.5
Dosage form or regimen	163	81.5
Side-effects and major adverse drug reactions	22	11
Precautions, contra-indications and warnings	44	22
Major interactions	27	13.5
Name and address of manufacturer or distributor	192	96
Reference to scientific literature as appropriate	82	41

Table 3. Classification of reference as per its source (n=210)

References	Number (n)	Percentage(%)
Total number of reference cited	210	100
Journal article references, categorized by publication dates	170	80.9
After 2010	98	46.7
Before 2010	112	53.3
Indexed Journal	160	76
Non-indexed Journal	50	23.8
Website	10	4.7
Textbook	8	3.8

DISCUSSION

Companies spend nearly 35% of sales on marketing of drugs and spend only one third on research and development¹³. Promotion is nothing but one of the tactful ways to push the drugs into the market. Drug marketing does affect prescription habits of doctors and hence increases the sale. Physicians agree to the fact that meeting with the medical representatives affect their prescribing behavior.

In this study 100% of drug promotional brochures mentioned INN or generic name. Similar results also have been reported by Phoolgen et al, in Nepal found that

97.32% of drug promotion brochures mentioned INN name¹⁴.

Brand name was mentioned in 100% of brochures which was the same observation as in Mali et al study conducted in Nagpur, Phoolgen et al, study conducted in Nepal and Kasyap et al, study conducted in Bangalore¹⁵.

Name of other ingredients known to cause problems was mentioned in 2.5% of drug promotional brochures in this study while other authors (Kasyap et al, study observed 12%, Mali et al observed 1.9%) have observed less percentage of brochures mentioned this criteria. Phoolgen et al observed none of the drug promotional brochures mentioned other ingredients known to cause problem in their literature¹⁶.

Regimen or drug dosage was mentioned in 81.5% of brochures in this study. This finding was bit lower when compared with the study of Phoolgen et al¹⁶, Chirac et al, Khakhkhar et al where it was 83.10%, 87%, 84% respectively. But in the study by Mali et al only 32.2% of brochures mentioned drug dosage¹⁵.

Approved therapeutic use was mentioned in 88.5% of drug promotional brochures. The findings from other studies revealed that it was slightly more than other results. The study conducted by Mali et al in Nagpur government hospital observed that out of 513 total brochures collected only 86.3% of brochures had mentioned approved therapeutic use of the drugs¹⁵. Similarly, in the study conducted by Phoolgen et al, in Nepal, out of 100 brochures collected from psychiatric outpatient department, 83.10% of brochures mentioned approved therapeutic usage¹⁶.

Side effects and major adverse drug reactions were mentioned in 11% of total drug promotional drug brochures collected in this study. Phoolgen et al, study showed that only 11.27%, Mali et al, and by Khakhkhar et al, in Gujarat, showed 8% of drug promotional brochures had mentioned side effects and adverse effects in both the studies¹⁷.

Major drug interactions were mentioned in 13.5% of the drug promotional brochures, which was more when compared to other studies. In the study by Phoolgen et al, and Vlassov et al, it was observed that only 8.45% of brochures mentioned major interactions¹⁸. In our study 96% of the drug brochures mentioned name and address of the manufacturer. But in the study by Mali et al, Phoolgen et al, and Khakhkhar et al, it was observed that 70.6%, 84.50% and 100% respectively mentioned the name and address of the manufacturer respectively^{14,16,17}. Total number of references were 210, out of which majority (80.9%) were from journal articles similar to studies conducted by Gautam et al¹⁹.

LIMITATIONS

This study has several limitations, firstly the relatively small sample size. Secondly, the study was conducted only in a single centre. Multicentric studies with a larger sample size will yield better results. Lastly, out of all the promotional material only DPL's were analysed. Other promotional materials were not analysed and if done so will give deeper knowledge regarding the drug promotional activities.

CONCLUSION

None of the DPL's satisfied all the criteria laid down by the WHO. The pharmaceutical companies should comply with the guidelines more meticulously. Incomplete information may lead to irrational prescription of drugs. Therefore, stricter regulations need to be implemented by the concerned authorities for promotional activities and physicians must also carefully evaluate DPL's before considering the same for prescribing.

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