

A cross sectional study of drug promotional literatures in a tertiary care hospital

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ABSTRACT

Background: Arrival of 100s of new drugs into the market every year makes the rational use of drugs a challenge to the practitioners. The product promotion by pharmaceutical companies disseminates ambiguous drug information through medical representatives using drug promotion literatures (DPLs) which influence the physicians' prescribing pattern. Objective of the study was to evaluate DPLs for accuracy, consistency, and validity using WHO criteria for ethical medicinal drug promotion.

Methods: DPLs collected from different OPDs were analyzed and evaluated as per WHO criteria. References of DPLs in support of the claims were critically analyzed for their retrievability and validity.

Results: 50 DPLs of 76 drugs were collected and analyzed. Of which 49 were FDCs and 27 single drug formulations. None of the DPLs fulfilled all the WHO criteria. Only 26% (13) fulfilled a maximum of 8 WHO criteria. Out of 88 references given in support of claims, 17% (15) of the references were irretrievable, 62 were from journals, 4 from textbooks and 7 from website. Almost all the DPLs had pictures of which only 50% (49) were relevant.

Conclusions: Information provided is incomplete and biased. Hence, health care professionals must evaluate DPLs critically before considering the same for prescribing.

Keywords: Drug promotion literatures, Ethical drug promotions, Rational drug prescribing, WHO guidelines

INTRODUCTION

WHO definition of Medical drug promotion is "All information and persuasive activities by manufactures and distributors, the effect of which is to induce the prescription, supply, purchase, and /or use of medicinal drugs" (WHO 1988).¹ The rational use of drugs is a challenge to the practitioners due to steep competition among the pharmaceutical companies to promote their products.² The different methods of drug promotion are visual aids, flip cards, leave-behinds, advertisements, gifts and audio-visuals.³ The universally employed technique is "Direct to physician" marketing through the huge network of medical representatives by means of drug promotional Literatures (DPLs).⁴ The ultimate aim of the manufacturer is to persuade the practitioners to

prescribe the particular product. Critically appraised and reviewed DPLs can be highly informative by providing accurate information in a nutshell. Studies have proved that Medicinal promotion has a huge impact on the physicians' prescribing pattern.^{5,6} Though Pharmaceutical industries have the right to promote their products it should be done ethically. The promotions should be informative, reliable, truthful and up to date. However, to make the promotion effective and convincing pharmaceutical industries do not adhere to ethical principles which can lead to irrational use of drugs. Hence, there are a set of standards laid by the WHO, "International federation of pharmaceutical manufacturers and associations (IFPMA) and the Organization of pharmaceutical producers of India (OPPI), where the objective is to support and encourage

the improvement in healthcare through the rational use of drugs.⁷

Many studies have illustrated that information disseminated through DPLs is inconsistent with the code of ethics.⁸ However, very few studies have been carried out in the Indian setup. This study is an effort to critically review the DPLs.

Objective of the study was to evaluate the collected DPLs for accuracy, consistency, and validity of the information presented in it, using World Health Organization (WHO) criteria for ethical medicinal drug promotion.

METHODS

This is a cross sectional study, conducted at a tertiary teaching hospital in Bangalore. The DPLs were collected from all the OPDs of the Hospital over a period of 3 months. The DPLs of medical devices, equipment, orthopedic prosthesis, Ayurvedic medicines, reminder advertisements, drug name lists and literatures promoting more than 4 brands were excluded. The included DPLs were critically viewed on the basis of WHO criteria for ethical medicinal drug promotion. WHO criteria are:

1. The names of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug.
2. The brand name.
3. Amount of active ingredient(s) per dose.
4. Other ingredients known to cause problems
5. Approved therapeutic uses.
6. Dosage form or dosage schedule.
7. Safety information including side effects and major adverse drug reactions, precautions, contraindications and warnings, and major drug interactions.
8. Name and address of manufacturer or distributor.
9. Reference to scientific literature as appropriate.

These advertisements were critically analyzed for the credibility of claims, the validity of pictures, the retrievability of references and the traceability of the manufacturer.

RESULTS

Of the 97 DPLs which were collected 50 DPLs promoting 76 drugs were included in the study and analyzed. Of which 49 were FDCs and 27 single drug formulations. None of the DPLs fulfilled all the nine WHO criteria. Only 26% (13) fulfilled a maximum of eight, 30% (15) fulfilled seven, 40% (20) fulfilled six and 4% (2) fulfilled five criteria. All the DPLs mentioned about the active ingredients, brand name and amount of active ingredient per dose, dosage form or dosage schedule and name of manufacturer or distributor. Of the 212 claims, 69% were regarding efficacy, 13.2% regarding convenience and only a meager about the

safety. Out of 88 references given in support of claims, (15) 17% of references were irretrievable, (62)70% were from journals, (4) 5% from textbooks and (7)8% from website. Almost all the DPLs had pictures of which only (49) 50% were relevant.

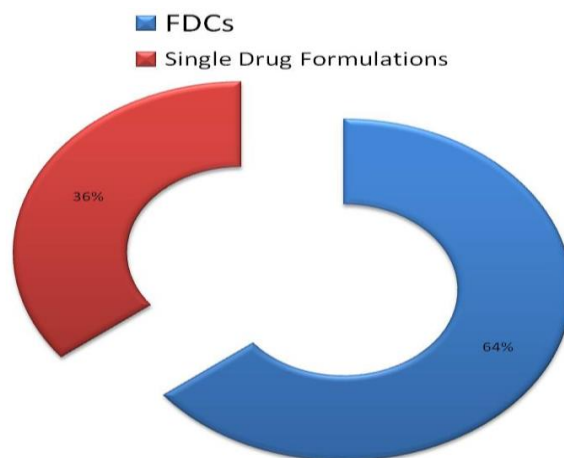


Figure 1: Types of drug formulations.

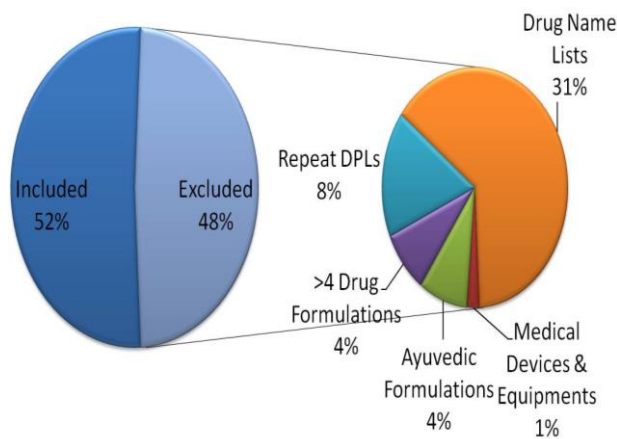


Figure 2: Drug promotion literatures.

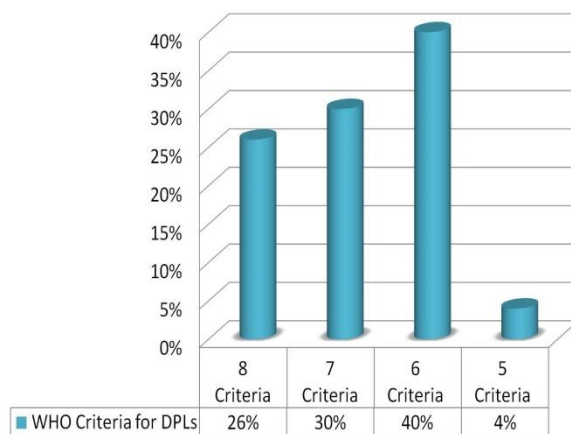


Figure 3: WHO criteria for DPLs.

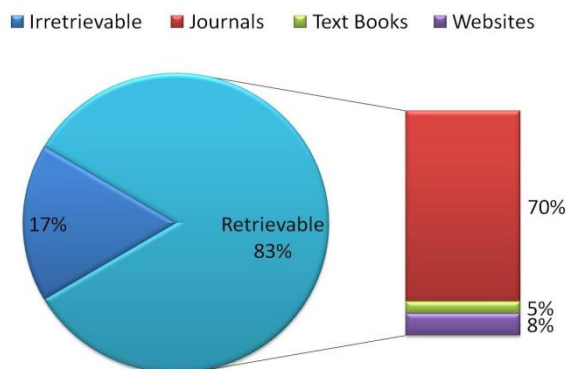


Figure 4: Types of references.

DISCUSSION

Majority of the DPLs were of fixed drug combinations as observed in a study by Saibhavana D et al.⁹ The rationality of the FDCs has always been a question mark. Moreover, a huge bulk of the FDCs was found to be irrational combinations leading to the possibility of ADRs. In our study none of the DPLs fulfilled all the WHO criteria as seen in a study by Khakkar et al, thereby depriving the physicians of the knowledge of many important properties/features of the marketed drug.¹⁰ With regard to the claims more emphasis was laid on the efficacy of the drugs rather than the safety or the cost effectiveness. This can be the reason for the wrong choices made by the physicians and the needless financial burden to the patient. Most neglected criteria were ADRs, drug interactions, contraindications, warning and precautions same as in the study by Jadav SS et al.¹¹ This information is very important in prescribing to the geriatric population having many co morbid conditions. Few DPLs did mention about these but it was in a very small font that could be read with difficulty which is unethical. The ratio of number of references to number of claims was not appropriate, similar observations were made in the study by Randhawa, et al.¹² Only 46% of the DPLs had a complete address, same as quoted in the study by Nath S et al, which makes the traceability of the manufacturer a difficult task.¹³ None of them mentioned about over dosage and other ingredients known to cause problems. This incomplete information can lead to irrational prescribing. Also, the DPLs used different catchy phrases like “Best Choice”, “Endorsed by the world”, “Best in Class”, “World’s no.1 prescription brand” which can lure the practitioners.

During our survey we noted that the knowledge of many physicians’ about ethical drug promotion is poor which warrants the urgent need to update the same. In the aftermath of which reporting of unethical DPLs to the concerned authorities can be expected. These measures would ensure ethical drug promotion and rational drug prescribing.

CONCLUSION

Information provided is incomplete and biased. Hence, critical evaluation of DPLs by the practitioners before considering the product for prescription would force the pharmaceutical companies to come up with ethically compliant DPLs there by leading to rational drug prescribing.

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

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