

A Study on Critical Review of Drug Promotional Literature Using the WHO Guidelines

Archanabahen Chaudhari¹, Jitendra Zaveri²

¹Assistant Professor, Department of Pharmacology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India,

²Professor and Head, Department of Pharmacology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India

Abstract

Background: Drug promotion refers to all the informational and persuasive activities of the pharmaceuticals, which include the activities of medical representatives, drug package insert, provision of gift and samples, conducting or organize seminar, etc. However, promotion of drug by ethical way is important because it may influence the irrational drug prescriptions.

Objective: The objective of this study was to evaluate and analyze the drug promotional literature distributed by pharmaceutical companies to physicians using the World Health Organization (WHO) criteria for ethical medicinal drug promotion.

Materials and Methods: A total of 100 drug promotion literatures were evaluated collected from the various outpatient departments and evaluated according to the WHO criteria for drug promotion.

Results: Among 100 drug promotional literatures (DPLs), a total of 109 drugs were promoted. However, only 33% of DPLs gives side effect, precaution, contraindication, and warning and only 10% of DPLs gives drug interaction information. None of the DPLs fulfills all criteria of who drug promotion.

Conclusion: Information on the DPLs given only focus on the positive aspect of the drugs and not fulfill all the WHO criteria of drug promotion.

Key words: Drug promotional literature, Review, WHO

INTRODUCTION

According to the World Health Organization (WHO), 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” (WHO 1988).^[1] For the promotion of many new drugs, pharmaceutical companies are using drug promotional literatures (DPLs).^[2] Many studies conducted previously concluded that increased promotion is usually associated with increased sales.^[3]

All promotion making claims about drugs should be accurate, informative, up to date, and ethical.

They should not contain misleading, false and biased statements (WHO 1988). Pharmaceutical companies promote their products as best and better to existing to which physician are familiar. However, many times due to inadequate, inaccurate, and false information from DPLs lead to irrational drug prescription and for physicians, many times DPLs are only source for updating their knowledge about the existing and novel drugs.^[4,5]

MATERIALS AND METHODS

An observational cross-sectional study conducted by the Department of Pharmacology at Ananta Institute of Medical Sciences and Research Centre from January 2019 to March 2019. DPLs were collected from the outpatient department (OPD) of a tertiary care center attached Ananta institute of medical sciences and Research Centre from January 2019 to February 2019. Printed DPLs promoting allopathic drugs were collected from OPDs of medicine, pediatrics, skin, psychiatry, ophthalmology, obstetrics and gynecology, otorhinolaryngology, and orthopedics. 100 drug promotional literature included in the study according

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Corresponding Author: Jitendra Zaveri, Ananta Institute of Medical Sciences, Rajsamand, Rajasthan, India.

to exclusion criteria. DPLs were evaluated using the WHO criteria by the following parameters:

1. The names of the active ingredients using either international non-proprietary names or approved generic names of the drugs.
2. The brand names.
3. Amount of active ingredients per dose.
4. Other ingredients known to cause problems, i.e., adjuvant.
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. References to scientific literature appropriate.

Exclusion criteria: DPLs promoting:

- Drugs other than allopathic drugs,
- Medicinal devices.
- Equipment.

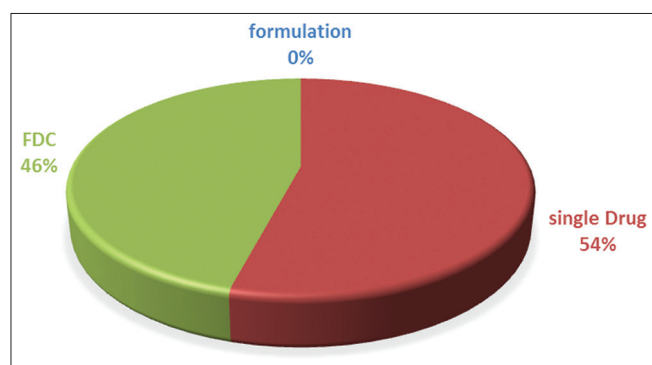


Figure 1: Distribution according to drug formulation

RESULTS

A total of 100 DPLs evaluated. A total of 109 drugs were promoted from 100 DPLs. Among them, 59 (54%) were prompted as single drug formulations and 50 (46%) promoted as fixed drug combinations [Figure 1].

Majority of drug promoted in collected DPLs were from drug act on endocrine system 36 (33%) followed by cardiovascular system 20 (18%). There were only 3% DPLs of drugs acting on kidney and 4% of respiratory system [Figure 2].

Of 100 DPLs, 63 (63%) DPLs promoted one active compound formulation and 37 (37%) DPLs promoted >1 active compound formulation [Figure 3].

None of the DPLs fulfilled all the WHO criteria. Active ingredient generic name, brand name, and dosage detail were presented in all DPLs (100%). Only 33 (33%) DPLs showed side effect and 33 (33%) showed precaution, contraindication, and warning. Few of total collected DPLs showed drug interactions 11 (11%) [Table 1].

Of 100 DPLs, 30 DPLs had not shown any references for their claim and 70 DPLs showed their references. Among 70 DPLs which provide references for their claim where consider from various National and International Journals. Some of the DPLs also had given more than 1 references. Journal references about 40% were before 2010 [Figure 4].

For attractive presentation of DPLs, companies are using picture on drug promotional literature. Of 100 DPLs, 23 (23%) DPLs not given any picture, but majority of 77 (77%) were given the picture on DPL. Among these

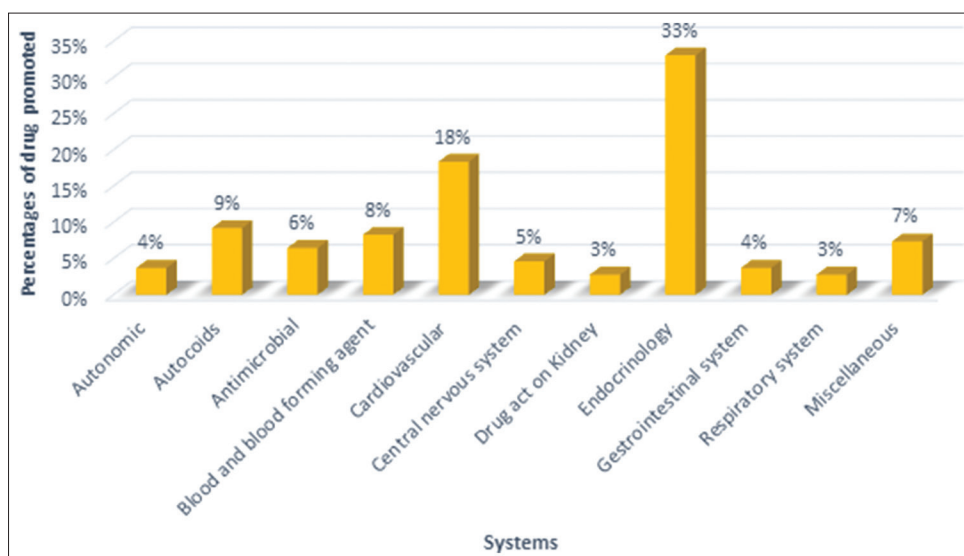


Figure 2: System-wise classification of drugs promoted in drug promotional literatures

77 literature, majority of picture were not relevant to disease and promoted drug 59 (77%). Only 18 (23%) DPLs presented with disease or drug-related picture.

DISCUSSION

The pharmaceutical industries have the right to promote its products, but it should do in ethical manner and promotional

claims need to be reliable, truthful, informative, balanced, and up to date. However, while promoting their products, pharmaceutical industries do not adhere to these ethical principles it may influence irrational use of drugs.^[6]

In the present study, 100 DPLs evaluated. A total of 109 drugs were promoted from 100 DPLs. Of 109 drugs, 59 (54%) were prompted as single drug formulations and 50 (46%) promoted as fixed drug combinations which are similar finding as the study conducted by Jadav *et al.*, of 224 drug promoted, 54% were single component and 46% FDCs.^[4]

In the present study, drug promoted from collected DPLs, majority of drug promoted in from drug act on endocrine system 36 (33%). In other studies, chemotherapy agents and cardiovascular drugs are promoted more which was different from the present study.^[2,7]

In our studies show that none of the DPLs fulfill the WHO criteria which is similar finding as other studies.^[2,7,8,9] Active ingredient that is generic name, brand name, and dosage detail were presented in all DPLs (100%), but other prescription information such as side effect precaution, contraindication, and warning were presented only on 33% of DPLs, drug interaction presented only in 11% of DPLs. This information is very important for rational use of drug but not available in majority of the DPLs. The study conducted by Sonwane *et al.* same shows that side effect, major drug interaction, precaution, contraindication, and warning were mentioned in only 31% which is also match with other studies.^[8]

Of 100 DPLs, among 70 DPLs, majority of reference are from journal articles (93%), but among them 40% of references from before 2010. Hence, recent data about product are not given. Moreover, catchy words such as “best one” and “the only” are not available in given references. DPLs are colorful and attractive, but the picture provided on it majority were not related with disease and promoted drug.

Table 1: WHO criteria for drug promotional literature

WHO criteria for drug promotional literature	Information available in DPL n=100 (%)
Active ingredient-generic name of drug	100 (100)
The brand names	100 (100)
Amount of active ingredients per dose	100 (100)
Other ingredients known to cause problems, i.e., adjuvant	5 (5)
Approved therapeutic uses	89 (89)
Dosage form or dosage schedule	100 (100)
Side effects	33 (33)
Drug interaction	11 (11)
Precautions, contraindications, and warnings	33 (33)
Name of manufacturer or distributor	93 (93)
Address of manufacturer or distributor	42 (42)
References to scientific literature appropriate	70 (70)

WHO: World Health Organization, DPLs: Drug promotional literatures

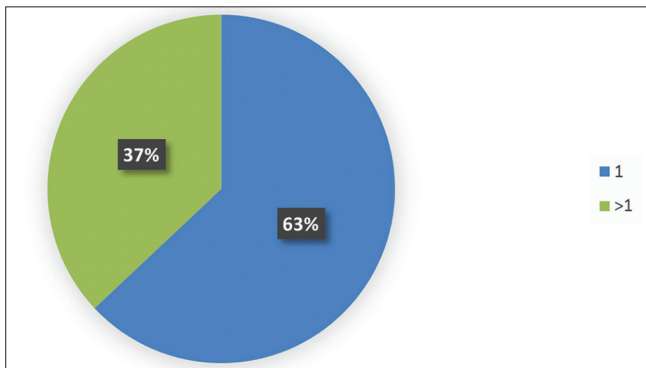


Figure 3: Distribution according to the number of drugs promoted in drug promotional literatures

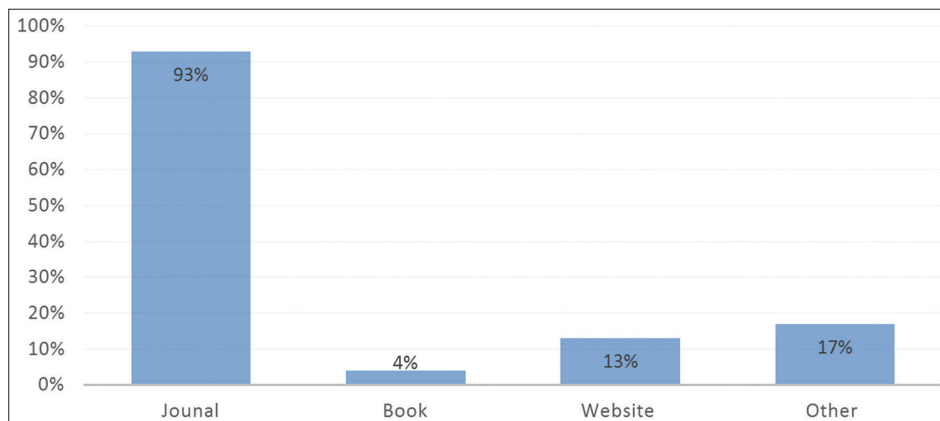


Figure 4: References given in drug promotional literatures

CONCLUSION

None of the Drug promotional literatures fulfilled all criteria of WHO for drug promotion. Promotion mainly focuses on the positive aspect of drug not the negative aspect such as side effects, contraindications, and drug interaction.

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