WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 10, Issue 01, 1090-1098. Research Article ISSN 2277– 7105

CRITICAL APPRAISAL OF DRUG PROMOTIONAL ADVERTISEMENTS OF DIFFERENT PHARMACEUTICAL COMPANIES AS PER WHO GUIDELINES

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Article Received on
21 October 2020,
Revised on 11 Nov. 2020,
Accepted on 01 Dec. 2020
DOI: 10.20959/wjpr202101-19388

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ABSTRACT

Objective: With the competition between pharmaceutical companies and a vast amount of increment in drug promotional spending, unethical practices are not uncommon. The objective of this study was to critically analyse the data that is presented to the practitioners on drug promotional advertisements (DPAs). **Methods:** An observational study to critically assess DPAs was carried out in the Department of Pharmacology & Therapeutics, GSVM Medical College, Kanpur, U.P. The DPAs were collected randomly from the websites of respective pharmaceutical companies. Each DPA was analysed as per the WHO established ethical criteria for medicinal drug promotional advertisements. **Results:** A total of 250 DPAs were collected and analysed. Most of the DPAs were for antimicrobial drugs (18%) and except for the brand name, none information was contained in all DPAs. Most of the DPAs contained information such as the name(s) and the content of the active ingredient(s), dosage form, and approved therapeutic uses but only a few of all DPAs (3.6%) had safety information such as the side-effects, major adverse drug reactions, precautions, contraindications, warnings, and major interaction and none had information regarding the name of other ingredients known to cause problems. The reference to scientific literature was written in only 14% of DPAs. DPAs provide only a maximum of 5 or 6 types of information out of 11 as per the WHO established ethical criteria. **Conclusions:** The pharmaceutical companies hide the safety information in most of the DPAs and do not

support their claims with appropriate references. For safe and rational prescribing practitioners should also consider gathering the information regarding the drug or the brand from medium other than the DPAs of the respective pharmaceutical companies.

KEYWORDS: WHO, Ethical drug promotion, drug advertisements, drug brochures, drug promotional literature.

INTRODUCTION

WHO established ethical criteria for drug promotion following the WHO Conference of Experts on the Rational Use of Drugs endorsed by the Thirty-ninth World Health Assembly in May 1986 which laid the foundation for proper promotion of medicinal drugs, consistent with the search for truthfulness and righteousness.[1] Often the only information that practitioners receive about medicinal drugs is provided by the pharmaceutical companies in the form of promotion of that medicinal drug[2] and there would be no concern if promotion leads to better prescribing, more rational use of medications or improved cost-effectiveness.[3] But as pharmaceutical companies worldwide are aggressively involved in the promotion of their drug,[4] they may engage in rather questionable tactics to push their drugs in the market.[5] There is an increment in most promotional spending from $15.6 billion to $20.3 billion from 1997 through 2016 in the United States by pharmaceutical companies[6] and this creates the possibility for an ethical dilemma because such a substantial increase in promotional spending may influence practitioner prescribing behaviour without necessarily benefiting the patient.[7] Even it is not uncommon that most drug promotional materials provide incomplete, inaccurate, misleading, or unethical information.[8-10]

The objective of this study was to critically analyse the data that is presented to the practitioners on drug promotional advertisements (DPAs) so that we shall make the practitioners aware of the hidden information and reliability of the claims made by pharmaceutical companies.

MATERIAL AND METHODS

An observational study to critically assess drug promotional advertisements was carried out in the Department of Pharmacology & Therapeutics, GSVM Medical College, Kanpur, U.P. during the COVID-19 pandemic. The DPAs were collected randomly from the websites of respective drug companies. Each DPA was critically analysed as per the following list, based on the WHO established ethical criteria for medicinal drug promotional advertisements,

which can serve as an illustration of the type of information that such advertisements should usually contain, among others:

- The name(s) 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.

The data was compiled and tabulated in the Microsoft Excel sheet and descriptive statistics was produced and expressed as percentage.

RESULTS

A total of 250 DPAs were collected and analysed. Figure 1 presents the category of drugs, as per therapeutic class, which were promoted by DPAs. Antimicrobial drugs lead the DPAs with 18%, followed by CNS (17.2%), GIT (12%), Vitamins & Minerals (11.2%), CVS (10%), Miscellaneous (7.2%), RS (6.8%), NSAIDs (4.8%), Hormonal (4.8%), Skin (3.6%), Antidiabetic (2.8%), Renal (2.4%), and Antiallergic (2.4%) drugs.

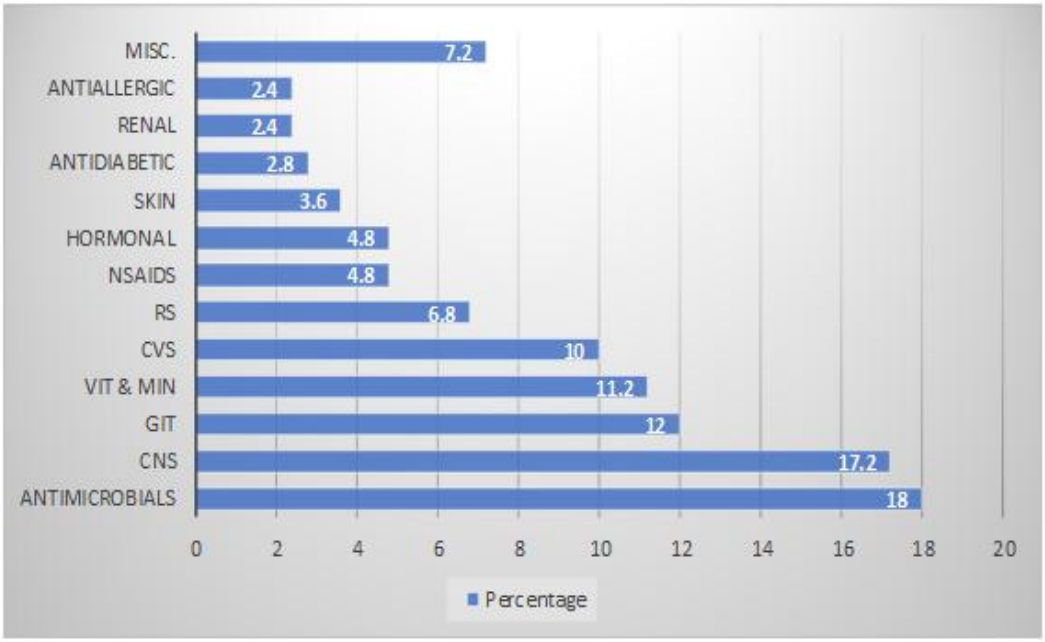

Figure 1: Category of drugs (as per therapeutic class) presented in drug promotional advertisements (n=250).

Abbreviations: NSAIDs, non-steroidal anti-inflammatory drugs; RS, respiratory system; CVS, cardiovascular system; Vit and Min, vitamins and minerals; GIT, gastrointestinal system; CNS, central nervous system.

Table I presents the analysis of DPAs as per WHO criteria and none of the DPAs provided the whole information that medicinal drug promotional advertisements should usually contain based on the WHO established ethical criteria. Except for the brand name, none information was contained in all DPAs. The name of the active ingredient or the approved generic name of the drug and its approved therapeutic uses were written in 99.6% of DPAs. The content of active ingredient per dosage form or regimen was written in 90.4% of DPAs. The dosage form was written in 98.4% of DPAs while only 4% of DPAs had information on the dosage regimen.

Only a few of all DPAs had safety information. The information regarding the side-effects and major adverse drug reactions (0.8%), precautions, contraindications and warnings (2.4%), and major interactions (0.4%) were provided sparsely. None of the studied DPAs had information regarding the name of other ingredients known to cause problems. The name of the manufacturer or distributor was written in 26% of DPAs while only 1.6 % of DPAs had their addresses. The reference to scientific literature was written in only 14% of DPAs.

Table I: Analysis of drug promotional advertisements as per WHO criteria (n=250).

S. No.	Information that advertisements should usually contain	Information contains (No. of DPAs)	Information contains (Percentage of DPAs)
1	The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug	249	99.6
2	The brand name	250	100
3	Content of active ingredient(s) per dosage form or regimen	226	90.4
4	Name of other ingredients known to cause problems	0	0
5	Approved therapeutic uses	249	99.6
6 (i)	Dosage form	246	98.4
6 (ii)	Dosage regimen	10	4
7	Side-effects and major adverse drug reactions	2	0.8
8	Precautions, contraindications and warnings	6	2.4
9	Major interactions	1	0.4
10 (i)	Name of manufacturer or distributor	65	26
10 (ii)	Address of manufacturer or distributor	4	1.6
11	Reference to scientific literature as appropriate	35	14

In our study, we found that out of 11 types of information as per the WHO established ethical criteria most DPAs (56%) usually contain only 5 types of information (Figure 2), followed by 6 types of information in DPAs (32.4%). Only 0.4% of DPAs contain a maximum of 9 types of information. Even some DPAs contain only 3 or 4 types of information and none DPA contains 10 or all 11 types of information.

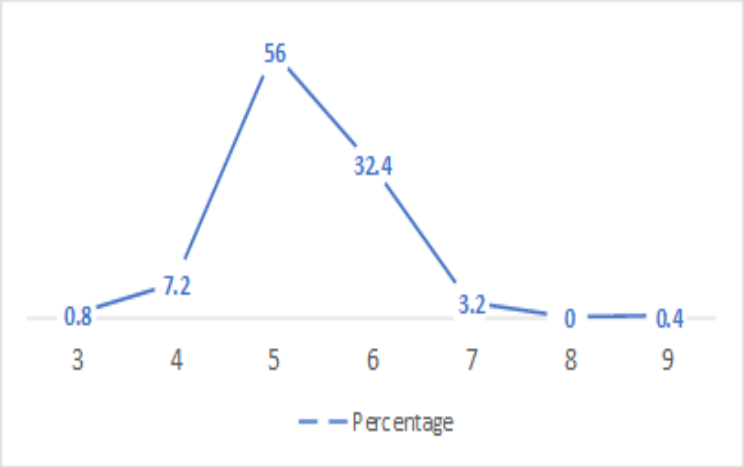

Figure 2: The types of information presented in the drug promotional advertisements (n=250).

DISCUSSION

The information provided by pharmaceutical companies through the DPAs must be scientifically accurate and fair. DPA is an important component of interaction between practitioners and the companies and it should always be appropriate and support good patient care.[11] This current study was an attempt to analyse DPAs from various pharmaceutical companies and in this study, we found that none of the drug companies followed the WHO established ethical criteria in promoting their drug products via advertisement brochures. This finding is similar to many studies such as by Hailu HG *et al.*,[8] Mali SN *et al.*,[9] Ganashree P *et al.*,[12] and Jha N *et al.*[13]

The finding that most of the DPAs highlighted the information regarding the name(s) and content of the active ingredient(s) and their therapeutic uses are similar to another study by Al-aqeel SA *et al.*[14] The information regarding the side-effects, major adverse drug reactions, precautions, contraindications, warnings, and major interaction was provided only in 3.6% of DPAs. So, it was observed that efficacy was highly emphasized while safety was inconsiderably highlighted which is similar to studies by Hailu HG *et al.*[8] and Randhawa GK *et al.*[15] A finding similar to Alam K *et al.*,[16] none of the DPAs provided information regarding the name of other ingredients known to cause problems and although they are mostly well tolerated but some adverse events and idiosyncratic reactions are well known for a variety of inactive ingredients. These excipients play a critical role, especially in liquid and chewable drug preparations that are mostly prescribed to infants and children.[17] Pharmaceutical companies deliberately highlight the efficacy of the drug while hiding the safety issues which may lead to the irrational prescribing behaviour of the practitioners[12] and it could be a reason behind a substantial proportion of ADR-related hospitalisations.[18]

In our study, we found that most of the DPAs had information regarding the dosage form of the drug while only a few had information about the dosage regimen to be followed by the patients. This finding is similar to another study by Jadav SS *et al.*[19] Only a few of all DPAs contained information regarding the references to support their claims which is similar to studies by Charan J *et al.*[20] and Islam MS *et al.*[21] A system of integrated international and national codes of practice on promoting their drug products via advertisement applies to many multinational companies. International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) apply the IFPMA Code of Practice while in India, the Organisation of Pharmaceutical Producers of India (OPPI) apply the OPPI Code of

Pharmaceutical Marketing Practices[11] and it seems that companies have paucity in code-based compliance.

In the present study, we found that the maximum number of drug advertisements promoted antimicrobial drugs while the least number of DPAs were of antiallergic drugs. This finding is similar to another study by Jha N *et al.*[13]

CONCLUSIONS

Practitioners need to be cautious of DPAs as our findings suggest that they can't be fully relied upon. The pharmaceutical companies hide the safety information in most of the DPAs and do not support their claims with appropriate references and provide only a maximum of 5 or 6 types of information out of 11 as per the WHO established ethical criteria for medicinal drug promotional advertisements. For safe and rational prescribing practitioners should also consider gathering the information regarding the drug or the brand from medium other than the DPAs of the respective pharmaceutical companies.

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