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Original Research Article

Analysis of scientific and ethical status of drug promotional literatures using WHO guidelines

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Abstract: The prime objective is to evaluate the scientific and ethical status of the drug promotional literatures (DPLs) available in Indian market using World Health Organization (WHO) criteria for ethical medicinal drug promotion. An observational, cross-sectional study was carried out in Department of Pharmacology, Sardar Patel Medical College, Bikaner, Rajasthan(India) from 1st July to 31st August 2015 to evaluate '120'drug promotional literatures by WHO criteria. These randomly collected DPLs were also analysed for graphical presentation of data, pictorial content, types of claims and references cited in support of these claims. None of the drug promotional literatures fulfilled all the WHO criteria. Antimicrobial and cardiovascular agents were the most promoted drug groups. Majority of the literatures claimed about the efficacy, safety, pharmaceutical properties etc. and journal article references were most commonly used to support these claims. Literatures presenting irrelevant pictures were 30%, whereas only 9.8% of the DPLs mentioned about brief prescription information (BPI). The most neglected aspect of the drug promotion was the safety information i.e. information about adverse drug reactions, drug interactions, precautions and over dosage. This study highlights that WHO guidelines are not followed by the pharmaceutical industries while promoting their products. To make drug prescribing more effective, critical review of the drug promotional literatures is essential.
Keywords: drug promotional literature, WHO criteria for drug promotion, pharmaceutical industries, drug promotion.

INTRODUCTION

There has been a tremendous increase in the number of new drugs coming into the market. Thus it is almost impossible for a busy medical professional to study and compile the most current and detailed information. Drug manufacturers or distributors are interested in promoting the sale of new drugs and the primary goal of drug advertisements is to convince healthcare professionals to prescribe the particular product [1].

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" (WHO 1988) [2]. Pharmaceutical promotion is a persuasive communication and the major marketing technique of pharmaceutical companies is "direct to physician"(DTP) marketing. The reality at present is that most health professionals get their information from commercial sources, usually through an extensive network of medical representatives [3].

Promotional activities by pharmaceutical industries are governed by Organization of Pharmaceutical Producers of India (OPPI), Self-regulatory code of pharmaceutical marketing practices and by National legislation [4, 5]. One of the well-known promotional activities of pharmaceutical industries is to produce drug promotional literatures which at times are non- scientific, less accurate and of poor educational value [6].

In an attempt to support and encourage the improvement of health care through the rational use of drugs, WHO has published ethical criteria for medicinal drug promotion and has recommended their implementation to its member states. Since the promotional activities create the potential for inappropriate prescribing by influencing physicians' prescribing behaviour, it is of utmost importance to critically analyze the promotional material of the drugs in step with the growing popularity of evidence based medicine [7].

The accuracy and usefulness of drug advertisements has been the subject of debate for many

years. Therefore, we conducted this study with the aim of evaluating the scientific and ethical status of drug promotional literatures as per WHO criteria for ethical medicinal drug promotion.

MATERIALS AND METHODS

This cross-sectional, observational study was conducted in the department of Pharmacology of Sardar Patel Medical College, Bikaner, Rajasthan, India after its approval from Institutional Ethics Committee, to find out the scientific and ethical status of drug promotional literatures presented to prescribers by using "WHO Criteria for ethical medicinal drug promotion 1988".

A total of '120' drug promotional literatures were randomly collected from out- patient departments (OPDs) of practicing physicians of different regions of Bikaner. For collection of the literatures, OPDs of medicine, surgery, obstetrics & gynaecology, paediatrics, skin, orthopaedics, ophthalmology and psychiatry were visited for a period of two months, starting from 1st July 2015.

Following literatures were excluded from the analysis:

- Literatures promoting medicinal devices and equipments like blood glucometer, insulin pump etc.
- Orthopaedic prosthesis
- Ayurvedic medicines
- Drug monographs
- Reminder advertisements
- Drugs name list and
- Literatures promoting more than two brands

WHO criteria for ethical medicinal drug promotion dictate that promotional literature should contain following information

1. The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug
2. The brand name
3. Amount of the active ingredient(s) per dose
4. Other ingredient(s) known to cause problem 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. Reference to scientific literature as appropriate

All the DPLs were evaluated for fulfilment of each of the criteria mentioned above. In addition to this, the DPLs were also analysed for the references cited, types of claims, pictorial content and graphical presentation of the data.

RESULTS

Out of total '184' drug promotional literatures collected, '64' were excluded as per exclusion criteria. Rest '120' literatures were evaluated to determine their scientific and ethical status using WHO guidelines. The findings of the present study suggest that majority of the DPLs (>90%) had mentioned the international non-proprietary name (INN), brand name, active drug per dosage form and approved therapeutic uses. More than half (59%) of the literatures had given information about manufacturer's address.

However, most of the pharmaceutical industries were reluctant about treatment regimen and adjuvant, rather their main focus was on the promotion of the latest drug formulations. The information regarding adverse drug reactions, drug interactions, precautions and over dosage was missing in most of the literatures. Only 9% of them were found to contain this important safety information.

None of the '120' promotional literatures fulfilled all the WHO criteria. Detailed analysis of fulfilment of WHO criteria is given in table 1.

Table 1: Analysis of drug promotional literatures as per WHO criteria (n=120)

Sr. No.	WHO Criteria	No of DPLs (%)
1	International Non-proprietary Name (INN)	116 (96.7)
2	Brand name	120 (100)
3	Active drug per dosage form	115 (95.8)
4	Adjuvant	5 (4.2)
5	Approved therapeutic uses	115 (95.8)
6	Dosage form	105 (87.5)
7	Regimen	35 (29.2)
8	Safety information	11 (9.2)
9	Manufacturer's address	71 (59.2)
10	References	85 (70.8)

Most commonly promoted drug groups in the present study were antimicrobial and cardiovascular agents. Table 2 shows classification of the various drug groups promoted in the DPLs.

Table 2: Classification of the drug groups as per promotion in the literatures

Pharmacological group	Percentage
Antimicrobial agents	22
Cardiovascular agents	20
Gastrointestinal agents	14
Analgesic agents	14
Agents affecting respiratory system & antihistamines	09
Hormonal agents	08
Nutritional supplements	06
Agents acting on central nervous system	02
Miscellaneous agents*	05
Total	100

Miscellaneous agents* - local anaesthetics, antioxidants, muscle relaxants. Out of total '120' DPLs, 56% were designed to promote single drug formulations and rest 44% for fixed dose combinations (FDCs).

The pharmaceutical industries try to make the promotional materials attractive using various pictures and graphical presentations to persuade physicians for prescribing their product. In the present study, the pictorial content was analysed for the type of pictures (e.g. patients, organs, medicine etc.), number of scientific graphs/ tables and pseudo graphs. A pseudo graph is a graphical presentation without proper axis, labelling legend or just arrows to show increase or decrease.

Pictures unrelated to medicine, disease or treatment were presented in 30% of the literatures representing the tendency of the pharmaceutical industries of wasting money in printing eye catchy glossy paper promotional literatures deprived of important information. (Fig.1)

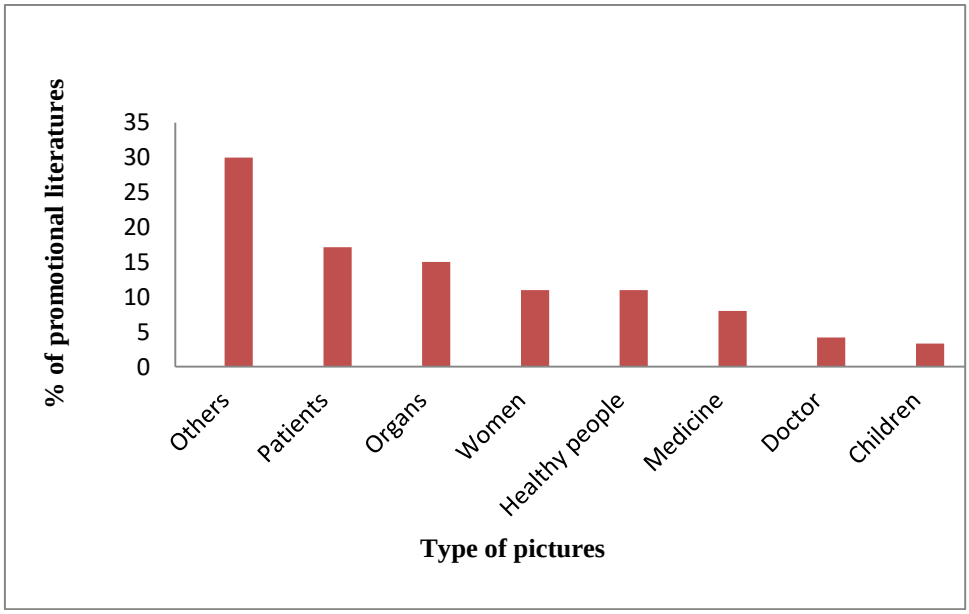

Fig.1: Categorization of pictures presented in promotional literatures (n=120)

The commercial and promotional attitude of the pharmaceutical industries is further proved by the fact that brief prescription information (BPI) of the promoted drug was given only by 9.8% of the literatures.

Out of total '120' DPLs, 24.5% of the literatures had used some type of graphical presentation. On further analysis, pseudo graphs were found in maximum number (34.3%) followed by bar diagram (28.2%) and tables (19.2%). In rest of the presentations,

line diagram (13.18%) and pie charts (5.12%) were used.

Apart from evaluating the therapeutic information, the promotional literatures were also analysed for making various types of claims. Most commonly presented claim was that of efficacy (40.50%) followed by safety and pharmaceutical properties. (Fig.2)

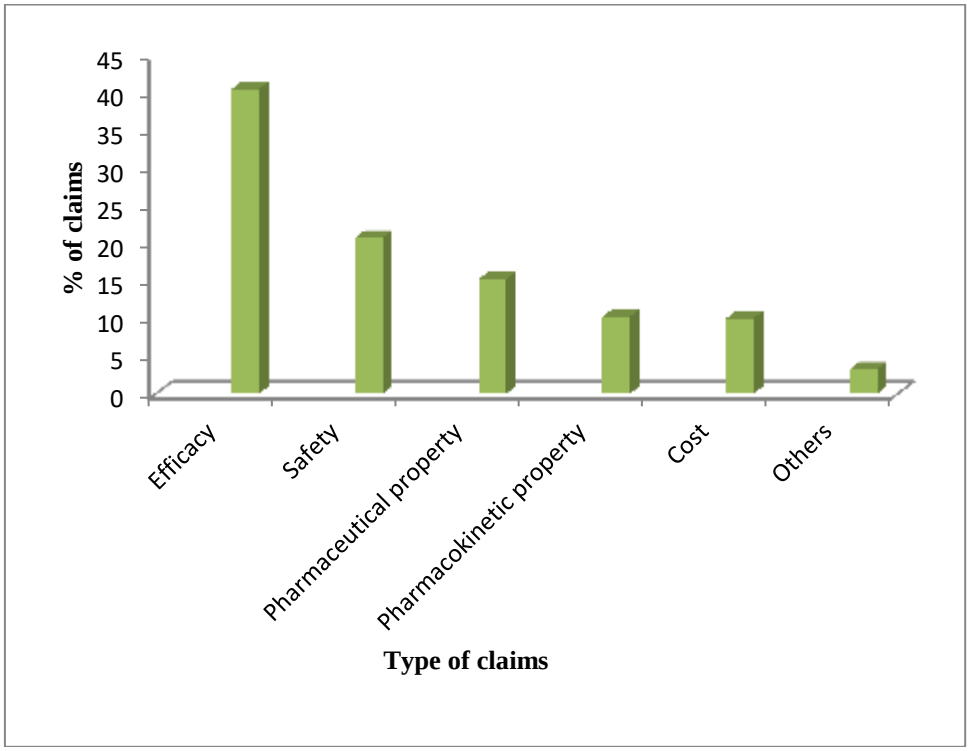

Fig.2: Classification of claims made in drug promotional literatures (n=120)

The references quoted in the literatures in support of various claims were examined to check their type, authenticity and irretrievability. References were mentioned in 71% of the literatures and the total number of references was 290. Major source of references was journal articles (92%) followed by data on file (5.33%) and websites (2.67%). No references were found to be given for books. (Fig. 3)

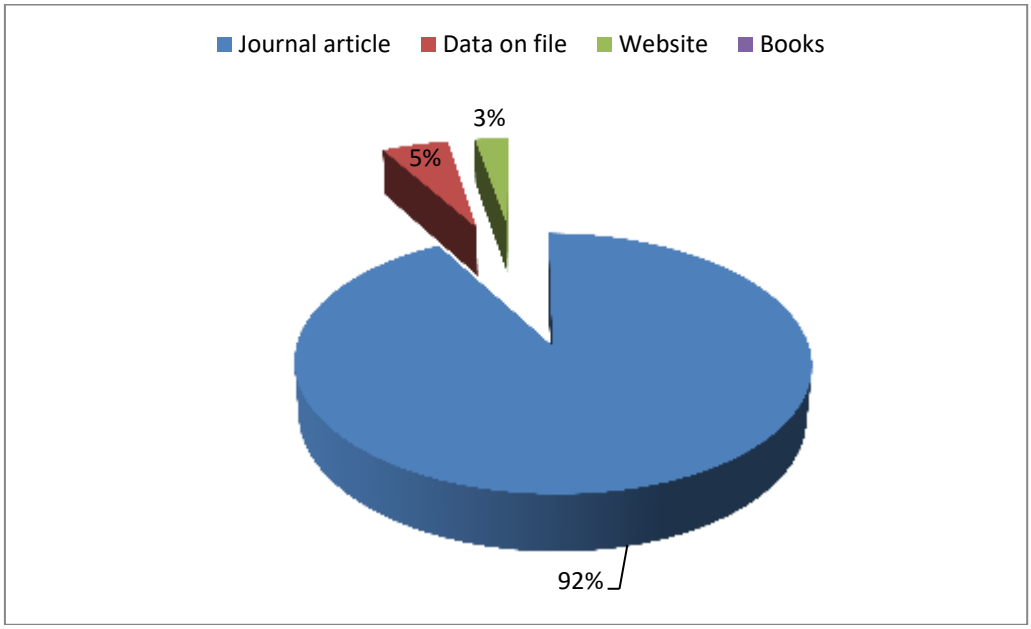

Fig.3: Classification of references quoted in promotional literatures

Major share of journal articles was contributed by research articles followed by review articles. More than half (52%) references were presented validly and were retrievable. Rest were either irretrievable or invalidly presented. The behaviour of the pharmaceutical companies was found to be very surprising that on one hand 38% of the literatures had mentioned six to eighteen references per DPL and on other side 29% of it did not bother to give any to support their claims.

DISCUSSION

The number of new drugs entering the market is growing at an alarming rate. Very few among them are genuine innovations and rests are with altered formulation which joins more than 20,000 drug formulations already in the market [3].

The availability of different types of sources of information helps to answer drug-related questions. Most health professionals are dependent on commercial sources of drug information from medical representatives, drug advertisement brochures etc. which influences prescribing practices also. Around $8000 to $ 13000 per year is spent on each healthcare professional for drug promotional activities [6, 8].

Our study depicted that WHO guidelines are not followed by pharmaceutical industries while promoting their drug products. Studies conducted in India and Nepal also observed the similar findings [9, 10].

The findings of the present study reveal that the INN, brand name, active drug per dosage form and approved therapeutic uses were mentioned in almost all the literatures. However, information about ADRs, drug interactions, precautions and over dosage was missing in most of the DPLs.

These findings coincide with the observations of a Russian study reporting less than 5% of literatures mentioning ADRs and also coincide with a similar study conducted in India.(10)(11)(12) The promotional literatures were found to contain many unsubstantiated claims regarding efficacy and safety which were therapeutically irrelevant also. This aspect of drug promotion in present study is in agreement with findings of other similar studies [6, 10, 13].

In present study, references were quoted in 71% of DPLs, showing that 29% of DPLs not even bothered that references should support their claims. Likewise, two other Indian studies reported the similar results [10, 14].

Irrelevant pictures were presented in 30% of the DPLs which is in agreement with the studies done by Stimson and Cooper. In another study by Mali *et al.;* irrelevant pictures were observed in higher proportion [1, 10].

Many literatures were found to present their data in the form of graphs and tables. Non scientific and less accurate information given in these literatures suggested the commercial rather than educational purpose of the pharmaceutical industries which is in concurrence with the study by Cooper and Schriger.

In countries like UK and Canada, it is a signatory condition for membership of the association to observe a code of practice in marketing activities. In India also, regional ethics committees have been set up to collect complaints against unethical drug promotion advertisements which forward these complaints to drug controller authority to take necessary legal steps [3, 11].

CONCLUSION

Printed promotional material is an important source of information. Although the promotional literature made available by the pharmaceutical companies is based on good evidence, this may not be the case always. Findings of the present study suggest that physicians need to be aware of the flaws in promotional literatures before accepting it as valid information. By following the general points of assessing the literature and applying the Safety, Tolerability, Efficacy and Price i.e. STEP criteria, the physicians can quickly judge the quality of the promotional literature. Moreover, forwarding complaints about irrational promotion to regulatory authority by cautious physicians might lead pharmaceutical industries to incline toward self-regulation.

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