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Original Article

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Evaluation of Drug Promotional Materials using World Health Organization Guidelines in a Tertiary Care Hospital-Rural Setting

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ABSTRACT

Background: Drug promotional materials, supplied by medical representatives, are important sources of drug information for doctors. World Health Organisation (WHO) has prescribed appropriate guidelines both for drug promotional literature (DPL) and drug reminders in 1988. We aim to evaluate the drug promotional materials available at various outpatient departments using WHO criteria and assess the validity of the claims cited in them.

Methods: This observational, cross-sectional study was carried out in the OPD of all the departments in Bankura Sammilani Medical College, for one month starting from 1st November to 31st November, 2015. Drug promotional materials were collected randomly from different outpatient departments and evaluated after recording their claims in a database set up for this purpose. The percentage of literature fulfilling the criteria was calculated, and the validity of the references was checked.

Result: We collected a total of 193 DPLs and 132 drug reminders. All of them contained the names of the active ingredient (INN & Brand name), content and the dosage form. The majority (87.2%) mentioned the approved therapeutic uses. Most DPLs (84.6%) cited scientific references as support for their claims. The majority (87.4%) of references were from journals. On scrutiny, 69% of claims regarding efficacy were substantiated. Pictures given were mostly (82%) non-scientific. Among the drug reminders, 91% contained the INN, while only 19.4% mentioned the full name/address of the manufacturer/distributors.

Conclusion: The study concluded that the drug promotional literature showed compliance with WHO guidelines, with strong support of evidence, with inadequate information regarding safety profile.

Key-words: Drug Promotional Literature, WHO Ethical Criteria, Rational Drug Use, Evidence-Based Promotion, Pharmaceutical Marketing

INTRODUCTION

Several Pharmaceutical companies are in the business of developing and selling new drugs. These drugs are well accepted in the health care system by some of the health care professionals, and the availability is of little value; the prescriber is aware of the existence and has scientific data for using it effectively [1]. Pharmaceutical promotion is a communication and major technique for marketing by those companies, which is "direct-to-physician marketing. The medical representatives are encouraged to contact the physicians, and represent the sample drugs, token gifts, some articles and also specifically some medical education and advertisements in some of the reputed medical journals [2]. One of the famous promotional activities adopted by the pharmaceutical industries is the production of advertising brochures, which is inaccurate and of very low educational importance [3]. These promotional activities may invite some irrelevant prescribing practice, which not only

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impacts the treatment of the patient, but also enhances health care costs [4]. Organisation of Pharmaceutical Producers of India (OPPI) has formulated a self-regulatory code of pharmaceutical marketing practices, which governs the activities of promotion by some of the renowned pharmaceutical companies and also by the National legislation [5]. Adherence to the code of conduct is a membership requirement for the association of manufacturers. However, many studies have explained that the information spread through the drug advertisements is inconsistent with the code of ethics [6]. The advertisements that claim to promote should ensure reliability, accuracy, truthfulness, an informative, well-balanced nature and up-to-date information. They should be free from any misleading or unverifiable claims which induce unjustified drug usage, or provide risks [7]. WHO has raised some ethical concerns for the promotion of a significant number of medicinal drugs? WHO recommended some of the pharmaceutical industries for the implementation of the guidelines in case of the development of PDLs [8]. This study evaluated the quality, accuracy, completeness, and ethical standards of the promotional material drug which are distributed in the outpatient department of a tertiary care hospital. The study assessed the compliance of the promotional materials according to the WHO criteria, which identified the deficiencies of the information on the drug and analysed the drug promotion practices.

MATERIALS AND METHODS

Research design- The study was a hospital-based, observational, cross-sectional study to evaluate the drug promotional materials on the basis of the WHO guidelines. The study was conducted in all the departments' Outpatient Department (OPD) in Bankura Sammilani Medical College (BSMC), Bankura, and West Bengal. The study was conducted for a period of 1 month, from 1st September 2015 to 31st November 2015. Data collection was done from DPLs which were available in the OPD. WHO indicators were analysed for the usage of the drug and other promotional studies.

Inclusion criteria

- Drug Promotional Literatures (DPLs) available in OPD of all the departments.
- DPLs which promote a maximum of 4 drug brands of modern medicine only were included.

Exclusion criteria

- Literatures with advertisements associated with medical devices.
- Advertisements related to herbal or Ayurvedic products
- Drug monographs

Procedure- The cross-sectional study was conducted to assess the quality of the drug promotional literature (DPL) which was distributed by some of the pharmaceutical companies. A total of 193 DPLs were obtained from different medical representatives. Each of the promotional literature items was screened to check if it contained the information associated with the pharmaceutical products for promotion. All duplicate materials or any irrelevant promotional content were excluded from the study. The collected DPLs were reviewed using the use of WHO Ethical guidelines for Medicinal Drug Promotion. The DPL was investigated for some of the information, which includes the names of the genera and brand, active composition, the use of therapeutics, dosage concentration and unfavourable impacts. It also includes the interaction with the dug, the details of the manufacturer and also some of the scientific references. The features include the class of the promoted drugs, the regimen type, which includes the monotherapy or combination therapy, the form of the doses, the nature of the claim for promotion, source and the validation of the references, which were also recorded by the use of an extraction form of the structured data. Data verification was done for completeness, and databases were entered.

Statistical Analysis- Microsoft Excel was used for the data entry, and SPSS version 27 was used for the data analysis. Descriptive statistical methods were used for the analysis of the data. The frequencies and percentages were used for the presentation of the categorical variables. Some of the tables, bar diagrams, and pie charts were used for the data findings presentation, to emphasise the analysis of the pattern of the distribution.

RESULTS

Fig. 1 showed that the most commonly prescribed regimen was the two-drug therapy, which accounted for about 46% of the prescriptions, which was followed by

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the monotherapy (28%) and some of the regimens that contain more than two drugs (26%). The findings also revealed that 72% of prescriptions consisted of multiple drugs.

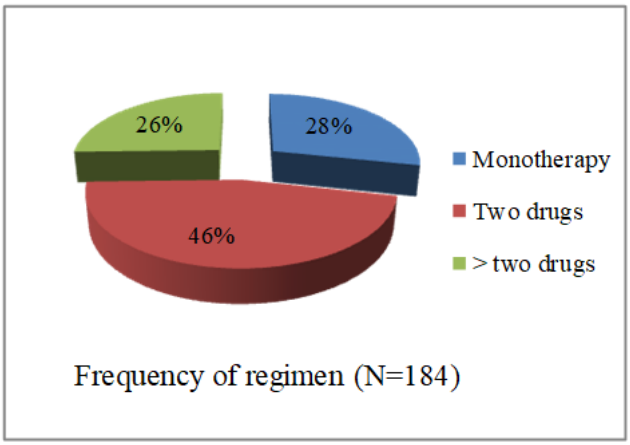

Fig. 1: Type of Frequency of regimen

Fig. 2 showed that the most frequent prescribed drug for all types of the treatment regimen was the cardiovascular system (CVS) drugs which were followed by the endocrine and gastrointestinal drugs. The most common CVS and GI drugs was the monotherapy. The mostly used was the antimicrobials. While very few prescriptions were provided by the respiratory, genitourinary, and other drug classes.

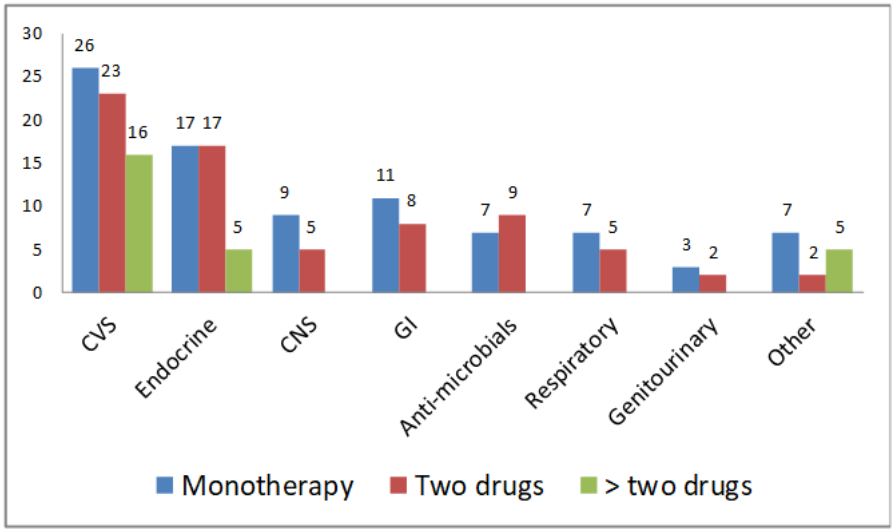

Fig. 2: Drug classification system-wise

Fig. 3 stated that the form of the oral dosage dominated the products, which accounted for about 92% of all formulations. 6% cases presented the parenteral preparations, while only 2% formed the topical formulation. These findings suggested strength on the oral administration of the medications for the promotional materials.

Table 1 showed that the compliance along with the critical criteria of WHO, was variable with other 193 drug promotional literatures (DPLs). Some information regarding the International Nonproprietary Name (INN), brand name, content of active ingredients, and dosage regimen was noted for about 100% of the DPLs. The use of therapeutics was reported for about 87% of the materials, while the 68.9% were the references of the scientific literature. The most significant related information along with its side effects and the major adverse drug reactions noted to be as 15.5%. 8.8% of the cases noted for precautions and contraindications and 5.2% of the DPLs were the drug interactions. The findings revealed the promotional materials facilitated the identification of drug and the indications and it address the safety and the risk related information.

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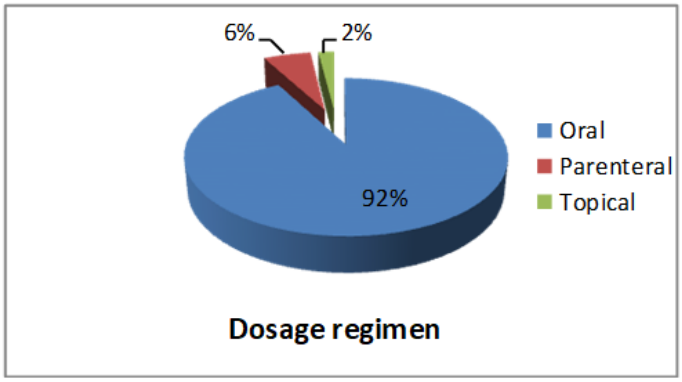

Fig. 3: Drug classification dosage form wise

Table 1: Fulfillment of WHO criteria by DPLs (n=193)

WHO criteria	Present in no. of DPLs (%)	Absent in no. of DPLs (%)	Total
INN of active ingredient(s)	193 (100%)	0 (0%)	193 (100%)
Brand name of active ingredient(s)	193 (100%)	0 (0%)	193 (100%)
Content of active ingredient(s) per dosage form	193 (100%)	0 (0%)	193 (100%)
Name of other ingredients known to cause problems	0 (0%)	193 (100%)	193 (100%)
Approved therapeutic uses	168 (87%)	25 (13%)	193 (100%)
Dosage form or regimen	193 (100%)	0 (0%)	193 (100%)
Side-effects and major ADRs	30 (15.5%)	163 (84.5%)	193 (100%)
Precautions, contra-indications and warnings	17 (8.8%)	176 (91.2%)	193 (100%)
Major interactions	10 (5.2%)	183 (94.8%)	193 (100%)
Name & address of manufacturer/distributor	34 (17.6%)	159 (82.4%)	193 (100%)
Reference to scientific literature as appropriate	133 (68.9%)	60 (31.1%)	193 (100%)

Fig. 4 showed that the efficiency claims were the most commonly noted among 26% of the promotional literature. Safety claims, pharmaceutical property claims, and other claims were noted to be as 23% and 13% were the cost-related claims. This indicated that the promotional materials were mainly focussed on the therapeutic efficacies and the safety compared to the economic importance.

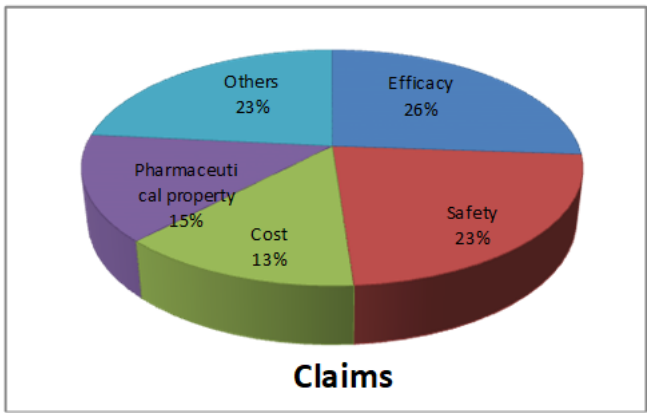

Fig. 4: Description of claims

Fig. 5 showed that journals were the most significant source for the references accounting for 74%, which was followed by 17% of websites. 7% was contributed by the books, and others accounted for 2%. This indicated that the drug promotional literature depends on the citation of the journals.

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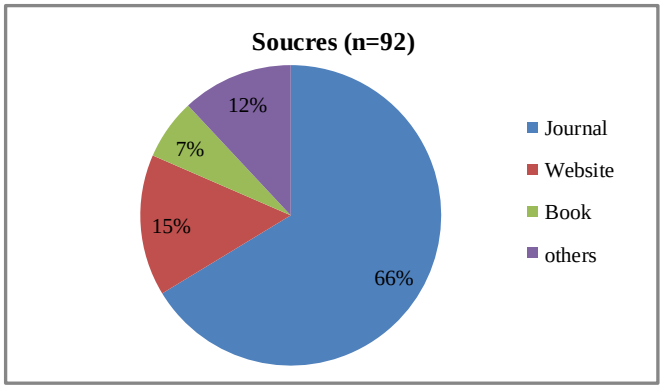

Fig. 5: Sources of references

Fig. 6 showed that the 193 claims were there for the efficacy claims, out of which valid claims were about 133 (68.9%) and 60 (31.1%) were the invalid claims. The safety claims indicated the highest validity; with the valid claims were about 143 of 168 claims (85.1%). Other category of claims showed lowest validity, with valid claims were about 7 of 173 claims (4.0%) and 166 (96.0%) were invalid.

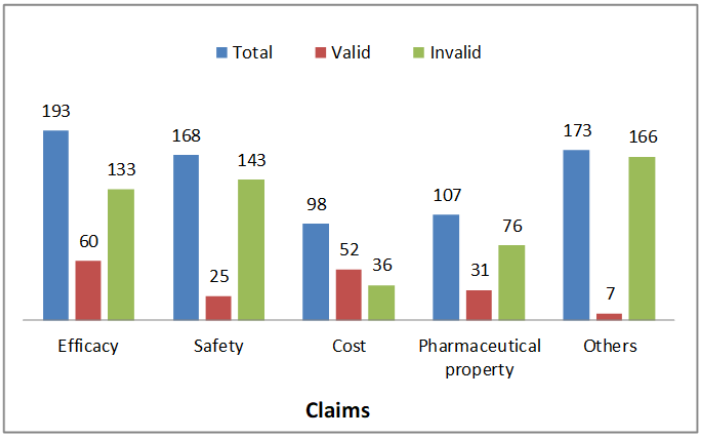

Fig. 6: Validity of claims

Fig. 7 shows that the healthy individuals (n = 141) and children (n = 127) were mostly observed among the drug promotional literature, which was followed by the by drugs (n = 107) and women (n = 85). 54 cases showed the scientific images, while 34 were the organ images, 26 were elders, 11 were doctors and patients were 7.

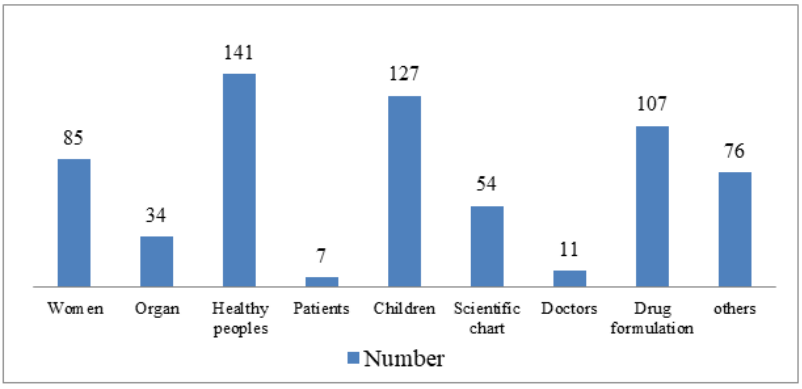

Fig. 7: Content of pictures

Table 2 stated that 92 references were cited in the promotional literature, with 31, 33.7% were double-blind randomized controlled trials (RCTs), which was followed by the open-label RCTs (29, 31.5%). Systematic reviews and international guidelines estimated for about 22 references (23.9%), which indicated the reliability of the

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high level evidence. Various observational studies were observed for 7 references (7.6%) and 2 references (2.2%) were limited to the meta-analysis. Only one reference (1.1%) was obtained from the case report. Only the cited evidence was extracted from the randomized controlled trials, which suggested that most of the claims were strengthen by the strong level of evidence.

Table 2: Nature of references

Grades of strength of evidence	Number	Percentage (%)
Meta-analysis	2	2.2
Systematic review/International guidelines	22	23.9
Double blind RCTs	31	33.7
Open label RCTs	29	31.5
Observational studies	7	7.6
Case report/Case series/ Expert opinion	1	1.1

DISCUSSION

The deficiencies in the drug quality were revealed along with several ethical standards for the promotional brochures. The evaluated composition does not fulfill the criteria by WHO for the promotion of an ethical medicinal drug. Data regarding safety profile, dosage concentration, adjuvants and the prescription pattern were removed, while the efficacy was dominated by the promotional elements. Various references were cited in support of the claims, which were invalid, partially valid, or irretrievable, raising concerns about the reliability of the information. Some of the brochures were used, which consisted of irrelevant content as well as some of the promotional graphics, along with the minimal space for significant therapeutic data, which reflected the strong focus compared to the educational content [9]. The study by Ganashree *et al*. 2016, showed the significance of the quality of the drug promotional literature when evaluated against the WHO criteria of ethical standard. Most of the brochures provide the data on the generic name, brand name, dosage form, and therapeutic indications; some of the information regarding the prescribing pattern like the contraindications, adverse effects, precautions, drug interactions, and drug cost, was removed. The most common category was the cardiovascular drugs, which were followed by the antidiabetic and antimicrobial agents. About 2/3rd of the brochures were cited with proper references, while the relevant and graphical presentation was constrained. About half of the standard was aligned with the standard prescribed, and no other promotional content were aligned with the WHO [10].

Maximum drug promotional literatures (DPLs) were unable to fulfill the WHO criteria, with only 5.8% had been aligned with the guidelines. The most commonly products which were promoted products were the nutritional supplements. Some of the crucial information, such as the contraindications, adverse effects, drug interactions, and adjuvants were removed, while the information, such as the name of the brand, name of the genera, form of the doses and the indication, was given. The promotional claims facilitated the efficacy, safety and absence of balance of the evidence [11]. All of the promotional contents contained the names of the brand, genus, and some of the active composition, data regarding the usage of the therapeutics (60.2%), 15.18% of references and 17.8% of unfavourable impacts. This was a survey study that showed the lack of awareness about the ethical guidelines of the WHO. Only 37.03% was aligned with the guidelines. All of the participants supported the incorporation of the DPLs into the medical academics of the undergraduate student. The study highlighted the lack of promotional materials and the requirement for improved training to evaluate the drug advertisements [12].

CONCLUSIONS

The study concluded that drug promotional literature (DPLs) provided a combination of therapies, with cardiovascular drugs as the most frequent class of therapeutics. The oral dosage form showed the wide majority of the promotional products. The assessment using WHO ethical criteria showed the consistency of the DPLs, which provide information on the brand and

generic names, active composition, and dosage regimen. Significant safety data, such as adverse drug reactions, contraindications, precautions, warnings, and drug interactions, were noted. Most of the references of the DPLs are originated from some of the scientific journals and was supported by some of the RCT studies and review studies, which reflected the usage of high-quality evidence. The findings indicated adherence to some of the ethical guidelines of the WHO and also facilitated the requirement for more strict regulation for the promotion of rational, balanced, and evidence-based drug promotion practices.

CONTRIBUTION OF AUTHORS

Research concept– Sourav Chakrabarty, Purnendu Mandal
Research design– Sourav Chakrabarty, Ayan Pal
Supervision– Purnendu Mandal
Materials– Sourav Chakrabarty, Ayan Pal
Data collection– Sourav Chakrabarty, Purnendu Mandal, Ayan Pal
Data analysis and interpretation– Purnendu Mandal, Ayan Pal
Literature search– Sourav Chakrabarty, Ayan Pal
Writing article– Sourav Chakrabarty
Critical review– Purnendu Mandal
Article editing– Sourav Chakrabarty, Ayan Pal
Final approval– Sourav Chakrabarty, Purnendu Mandal, Ayan Pal

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