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Assessment of Promotional Drug Literature Using World Health organisation (Who) Guidelines.

KEYWORDS: Yoga, Perceived benefit ,Participant

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Introduction

Pharmaceutical promotion is a persuasive communication and the major marketing technique of pharmaceutical companies is "direct to physician marketing." Physicians are contacted by medical representatives, presented with sample drugs, token gifts, reminder articles and also targeted through sponsored continued medical education, advertisements in the medical journals, etc. [1]

The reality at present is that most health professionals get their information from commercial sources, usually through an extensive network of medical representatives.[2]

The pharmaceutical companies claim that their new formulations are superior to existing, effective, and inexpensive products, to which prescribers and consumers are familiar. They target prescribers through weekly or monthly visits, distributing samples and attractive, eyecatching brochures. These materials are often misleading and confusing. The intensive marketing motivates doctors to prescribe the new products, often without verifying whether the claims made are justified. [2,3] However, the information contained in promotional material may be inadequate or altogether inaccurate and when these are accepted without any question, can contribute to irrational prescribing. In an attempt to support and encourage the 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 promotional activities influence the prescribing behaviour of the health care providers, it is of utmost importance to critically analyze the promotional material of the drugs in step with the growing popularity of evidence-based medicine. [4,5]

Promotional activities by pharmaceutical companies are governed by Organization of Pharmaceutical Producers of India (OPPI), self-regulatory code of pharmaceutical marketing practices, January (2007) [6] and by National legislation.[7]Adherence to the code of conduct is a condition of membership for manufacturers' association.[6] However, many studies have illustrated that information disseminated through drug advertisements is inconsistent with the code of ethics. [8].[9],[10],[11] However, very few studies have been carried out in Indian setup.

We decided to evaluate the rationality of the promotional drug literature as per "World Health Organization criteria for ethical medicinal drug promotion, 1988"

Material Methods

The study was conducted as an observational, cross-sectional study in the outpatient department (OPD) of MGM Medical College & Tertiary care Hospital Kamothe Navi Mumbai ,India, after its approval by Institutional Ethics Committee, to find out the scientific and ethical status of drug promotional literatures presented to prescribers and its concurrence to 'WHO criteria for ethical medicinal drug promotion, 1988.' A total of 437 drug promotional literatures (brochures) were collected randomly from out-patient department (OPD) of Hospital for the period of one month starting from1st August to 31st August 2013. These literatures were collected from different OPDs of medicine, surgery, paediatrics, orthopaedics, and obstetrics and gynaecology departments. Collected brochures were then explored to exclude the following materials: Literature promoting medicinal devices and equipment's (insulin pump, blood glucometer, etc.), orthopaedic prosthesis and ayurvedic medicines, drug monographs, reminder advertisements (reminder advertisements do not present any therapeutic information and have different criteria for evaluation), [12] drugs name list, and literature promoting more than four brands.

All the literatures were evaluated by WHO criteria for fulfilment of each of the following parameters:[13]

- The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug
- The brand name
- FDC /Single drug
- Content of active ingredient(s) per dosage form or regimen
- 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 references mentioned in the literatures were evaluated for authenticity and retrievablity.

Out of total 437 drugs promotional literatures screened none of the promotional literature fulfilled all WHO criteria, A total of 437 drugs were presented drug promotional brochures.

Out of 437 literature, 40% (175) has mentioned dosage along with their regimen, 97% (418) included indications, 46% (201) were having false claims. 25% (108) has given references out of which 9% (40) were appropriate to scientific literature.

Manufacturer's name and addresses were mentioned in al-

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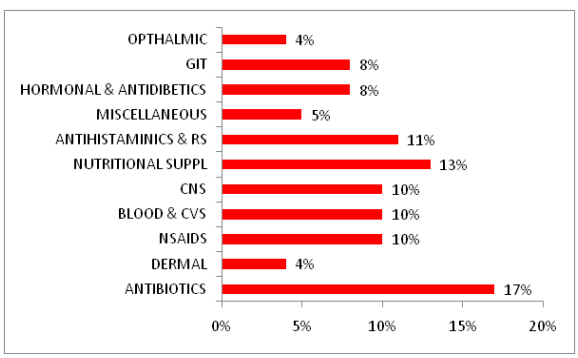
most all the literatures (100%). Out of all the literatures, Most neglected aspect of drug promotion was information about adverse drug reactions, drug interactions, precautions, and over dosage (>90%). 60% (262) of the literature lacking in the information on regimen & 95% (415) of them didn't mention about the safety aspect of the drug promoted.

Table:1 Analysis of literature according to WHO criteria n=437

Criteria	fulfilled (%)
INN	428 (98)
Brand Name	437 (100)
Content	358 (82)
Adjuvant	9 (2)
Approved therapeutic use	423 (97)
Dosage form	437 (100)
Regimen	175 (40)
Safety Information	22 (5)
Manufacturers Address	437 (100)
Reference to scientific information	109 (25)

Figure 1 : Classification as per the type of the drug promoted in the literature



As shown in figure 1. chemotherapeutic (Antibiotics) (17%) & nutritional supplements (13%) were commonly promoted drug group followed by drug used in CNS ,blood & CVS(10%), GI(8%), Hormonal & Antidiabetic (8%), Dermal were (4%).

Discussion

The pharmaceutical industry, in general and large international companies in particular, has kept abreast of developments in the evidence-based medicine movement and have tried to incorporate the movement's tenets into their promotional strategies.[14] The information provided for drug promotion should be accurate, scientific, and evidence-based to keep the doctors informed about the company's products and all related information. The drug promotional practices carried out by the pharmaceutical industry are more of a commercial relationship between prescriber and pharmaceutical company. Although assessment of the truthfulness of the drug promotional claims is very complex, we tried to analyse this keeping in mind the objectives of the evidence-based medicine. Each claim was analysed objectively with the help of available evidences in the medical literature for its concurrence with WHO guidelines. [15] on the basis of observations it was found that majority of promotional literature had mentioned INN(98%), brand name(100%) & approved thearaputic use(97%)out of 437 literature studied 46% were having false claims which is in agreement with the similar studies a similar other Indian study.[16] This aspect of the drug promotion was also highlighted in other similar studies.[16,15,17]

The promotional brochures were full of unsubstantiated claims regarding safety or efficacy, and those claims were therapeutically irrelevant also. Important information regarding adverse drug reactions, contraindications, or drug interactions was missing. Moreover, the information was given in fine print and hard to read as shown in other study.[7]

60% of the brochure lacking in the information on regimen & 95% of them didn't mention about the safety aspect of the drug promoted. In this study reference related with the scientific information was mentioned in 15% of the brochure.

Most neglected aspect of drug promotion was information about adverse drug reactions, drug interactions, precautions, and over dosage these findings coincides with that of a Russian study[19] reporting less than 5% of literatures mentioning adverse drug reactions and also coincides with a similar study carried out in other parts of India.[16] This suggests that unethical drug promotion is widespread in India as well as over the world, which needs concern of all health authorities.

It has been estimated that $ 8000 to $ 13000 is spent per year on each physician for drug promotion. The huge amount spent by pharmaceutical industry for drug promotion escalates the health care cost. [3]

It is suggested that physicians need to aware of the flaws in promotional literature before accepting it as valid information. Such marketing may influence physicians prescribing behaviour without necessary benefiting the patient. Such marketing may lead to inappropriate prescribing practices.

In developed countries like UK, Australia, and Canada, it is required to observe a code of practice in marketing as a signatory condition for membership of the association.[11] India has also set up regional ethics committee to collect complaints against unethical drug promotion advertisements at Mumbai, New Delhi, Chennai, and Chandigarh which forward these complaints to drug controller authority to take necessary legal steps to discipline guilty companies.[20,19] Forwarding more complaints about irrational promotion to regulatory authority by cautious doctors might lead pharmaceutical industry to incline toward self-regulation. Therefore, it is a responsibility of a practicing physician to critically evaluate the information given in a drug promotional literature before taking it as a scientific source of information, and any flaws, if identified, should be reported to appropriate authority.

This study evaluates one type of promotional activity of pharmaceutical company, i.e. printed promotional literature; however, interventional research to assess the awareness of the physicians about these facts and alerting them about the same will help gain accurate and ethical information from promotional literature. Some remedial measures to this issue are prescriber's education, reinforcement of existing laws, and development of guidelines and their implementation by pharmaceutical companies for drug promotion.

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