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EVALUATION OF DRUG PROMOTIONAL LITERATURE FOR ABBREVIATED PRESCRIBING INFORMATION USING WHO AND OPPI GUIDELINES IN A TERTIARY CARE HOSPITAL: A CROSS SECTIONAL STUDY

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ABSTRACT **Background -** Pharmaceutical companies are competing for development and marketing of drugs and spend huge amount of money on drug promotions. WHO has laid down ethical criteria for medicinal drug promotion and pharmaceutical industries have to implement these guidelines. In India, promotional activities by pharmaceutical companies are governed by Organization of Pharmaceutical Producers of India(OPPI), a self-regulatory code of pharmaceutical marketing practices. It is essential to critically and scientifically evaluate the drug promotional literature as this may affect drug prescription and utilization. **Objective -** Evaluate the completeness of drug promotional literature using WHO guidelines and completeness of abbreviated prescribing information in drug promotional literature material using OPPI guidelines. **Methods -** 130 drug promotional literatures were randomly taken from different outpatient departments and were screened. **Results -** None of drug promotional literature fulfilled all WHO criteria. The name of the active ingredient and brand name, content of active ingredient per dosage were featured in 100% of literature, name and address of pharmaceutical company were mentioned in 64%, abbreviated prescribing information(API) was present in 42%, and references were mentioned in 76% of drug promotional literatures. Out of 46 drug promotional literatures in which API was present, indications were listed in 95.65%(44/46), dosage, method of use and contraindications featured in 100%, precautions and side-effects present in 4.34%(2/46). **Conclusion -** Most of the Pharmaceutical companies do not follow WHO and OPPI guidelines for promotion of their product in India. Therefore strict regulations should be made for proper promotion of information about drug product.

KEYWORDS : OPPI guidelines, promotional literature, abbreviated prescribed information.

INTRODUCTION

Almost each day in the market there is introduction of a large numbers of new drugs. Pharmaceutical companies are competing for the development and marketing of new drugs which are introduced into the health care system by channeling them through physicians, and making it available to patients. But unless the physician is aware of a new drug and has information of its scientific background to use it effectively, the drug cannot be marketed succesfully.[1,2] In private or public clinic set-up direct to physician (DTP) marketing is most common method used by Pharmaceutical companies and distributors for introducing their drug into the market. They use different modes of drug promotion which include visual aids, leave behinds, leaflets and audio visuals.[3] Most of the times, it is the main source on which the physician depend for updating their knowledge about the existing and novel drugs.[4] The huge number of products in the market make the selection of the right drug and its proper use an increasingly difficult task. Many of physicians get this necessary information through well set network of medical representatives.[5]

Pharmaceutical companies spend huge amount of money on drug promotions. In 2005, a pharmaceutical industry in the USA has spent more than 30 billion dollars in marketing and promotion to make the clinicians aware about their products.[6] Such kind of marketing practices influences clinician's prescribing behavior with or without benefitting the patient.

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”.[7] WHO has laid down ethical criteria for medicinal drug promotion and pharmaceutical industries have to implement these guidelines.[8]

There are universally applicable baseline standards coded by International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) for marketing practice, and these standards apply to all promotional communications from the pharmaceutical industry to the medical profession. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a non-profit, non-governmental organization (NGO) that represents the interests of national pharmaceutical associations and companies.[9]

In India, promotional activities by pharmaceutical companies are governed by Organization of Pharmaceutical Producers of India (OPPI), which is a self-regulatory code of pharmaceutical marketing practices.[9] This code is based on IFPMA code for drug promotional literature and has laid down criteria which are specific local guidelines for India.

It is essential to critically and scientifically evaluate the drug promotional literature because these promotional activities influence the prescribing behaviour of the physicians. Since last many years ethical promotion and authenticity of such drug promotion considered as the subject of debate.[10] Few studies have observed that information provided in drug promotional literatures are varying with the code of ethics.[8,11,12] So, this may affect the drug prescription, utilization, and sometimes can be irrational. Hence, this study was conducted to evaluate the completeness and appropriateness of the promotional drug literature using the WHO and OPPI guidelines.

Materials and methods

A cross sectional observational and single centered study was carried out in the Department of Pharmacology of Tertiary Care Teaching Hospital of Mumbai for period of 1 month in November 2018.

The primary objective was to evaluate the completeness of drug promotional literature using WHO guidelines and completeness of abbreviated prescribing information in drug promotional literature material using OPPI guidelines and secondary objective was to study appropriateness of abbreviated prescribing information in drug promotional literature of Indian and International pharmaceutical companies.

Total 130 drug promotional literatures were randomly taken from different outpatient departments and were screened. Literatures promoting medicinal devices and equipment (Insulin pump, blood glucometer, etc.), orthopedic prosthesis and ayurvedic medicines, drug monographs, reminder advertisements, drug lists, and literature promoting more than two brands and also leaflets and leave behinds were excluded from the analysis.

Therefore out of 130 drug promotional literatures 110 were selected. The following WHO criteria were followed to check for the

completeness of drug promotional literature: [7]

The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic names of the drug The brand name Content of active ingredient per dosage form or regime Name of other ingredients known to cause problems, i.e., adjuvant Approved therapeutic uses Dosage form or regime Side effects and major adverse drug reaction Precautions, contraindications and warnings Major interactions Name and address of the manufacturer or distributo Reference to scientific literature as appropriate.

All the literatures were evaluated for completeness of the above mentioned information. Descriptive statistics were used to analyses the data. The data were expressed as percentage.

Results

Promotional literatures for fixed drug combinations were 47%(52/110) and single drugs were 53%(58/110).

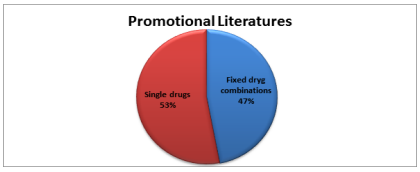

Figure 1: Classification as per drug combination (n=110).

None of drug promotional literature fulfilled all WHO criteria. Though name of the active ingredient and brand name featured in 100% of the literature, content of active ingredient per dosage form was mentioned in 100%, name and address of pharmaceutical company were mentioned in 64% of literatures, abbreviated prescribing information was present in 42% drug promotional literatures, references were mentioned in 76% of drug promotional literatures as shown in Figure 2.

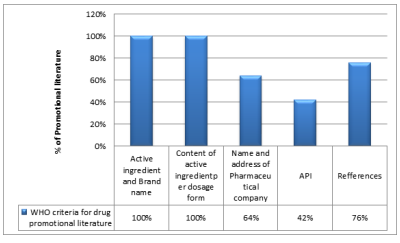

Figure 2: Analysis of promotional literature according to the WHO criteria.

Out of 110 drug promotional literatures selected, abbreviated prescribing information was present in(41.81%) 46 drug promotional literatures and which was analysed by OPPI criteria.

Out of 46 drug promotional literatures in which abbreviated prescribing information was present, indications were listed in 95.65%(44/46). Though dosage, method of use and contraindications featured in 100% of these literatures, 4.34%(2/46) of them had information related to precautions and side-effects. (Figure 3)

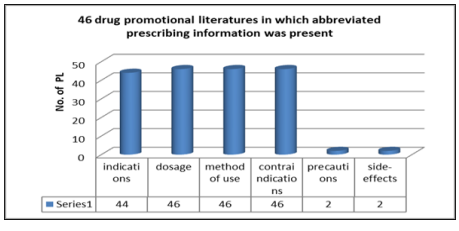

Figure 3: Analysis of abbreviated prescribing information.

Out of 110 drug promotional literature selected 80(72.72%) were of Indian pharmaceutical companies and 30(27.27%) were of International pharmaceutical companies. We found that out of these 20%(16/80) of abbreviated prescribing information mentioned by Indian companies were appropriate, whereas 86.66%(26/30) of abbreviated prescribing information mentioned by International companies were appropriate. (Figure 4)

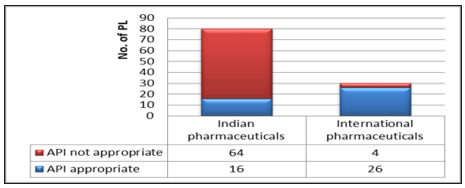

Figure 4: Analysis of appropriateness of API in drug promotional literature.

DISCUSSION

Many new drugs enter the Indian market every year, out of which many are "me too" products which are not genuine innovations. They are then included in more than 20,000 drug formulations which already exist in the market.[5,8,15] Pharmaceutical companiesuse various strategies for marketing their new drugs to physicians. Direct to physician(DTP) marketing is one of these strategies which is a very important tool of the promotion.[10] Most of the time promotional literatures are the only source by which the physician get to know about new drugs or new indications for old drugs. This has great impact on their prescribing behaviour of physician. Most physician depend on commercial sources of drug information from medical representatives, drug advertisement brochures etc.[8] Therefore promotional literatures should have all the information needed by the prescribing physician and at the same time should be accurate. This would help to minimise irrational prescriptions, incidence of drug resistance, adverse effects, and also reduce the cost incurred by patients.[10]

In our study, it was observed that none of the drug promotional literatures fulfilled all the criteria laid down by the WHO guidelines. A similar finding was reported in other studies[2,8,11,13]. Out of all the drug promotional literatures half were single drug and the other half were multidrug combinations as seen in other studies.[15] On the basis of the observations of this study, it was seen that majority of the literatures had mentioned name of each active ingredient (100%) but the recommended dosage form was mentioned in only 46%. Out of all the literatures, 60-70% lacked information related to duration of therapy, and dose adjustments in special situations like pregnancy, lactation, liver or kidney diseases etc. Out of all the promotional literature in API was mentioned, dosage, method of use and contraindications featured in 100% of these literatures, while 4.34% (2/46) of them lacked information related to precautions and side-effects. Thus most neglected aspect of drug promotion was information about adverse drug reactions, drug interactions, precautions, and over dosage (>90%). Similar findings were observed in study carried out by khakhkhar et all.[8] Only 20% of the promotional literature had mentioned other ingredients that are known to cause problems.

When we compared between the promotional literature of Indian and International pharmaceutical companies we found that only out of these 20% of abbreviated prescribing information mentioned in promotional literature by Indian companies were complete and appropriate, whereas 87% of abbreviated prescribing information mentioned in promotional literature by International companies were complete and appropriate.

References were mentioned in 80% of drug promotional literature. Most of drug promotional literature were published recently i.e. within 2 years, but large number of journal article references were before 2010. This finding was in accordance to the findings in study carried out by Sonwane et al.[16] It is highly possible that new data about the concerned drugs has been published in the recent years which have been missed by not providing recent references. Thus pharmaceutical industry should provide physicians the most recent evidence published about their drugs. This would help the physicians to prescribe the drugs rationally.

The association of pharmaceutical companies in developed countries, e.g. UK, Australia, and Canada are required to observe a code of practice in marketing as a signatory condition.[14] In India, there are regional Ethics Committees for complaints against unethical drug promotion advertisements. Drug controller authority takes necessary legal steps in response to such complaints to against drug manufacturers and distributors.[2,5,8] DTP method of marketing definitely influences prescribing behaviour of the physicians. Development of necessary laws and their implementation by drug manufacturers,

practitioner's awareness and strengthening of existing guidelines can be useful measures in this matter. It requires group efforts of physicians, pharmaceutical companies and regulatory body which can ultimately led to ethical drug promotional activities and rational prescribing.

Limitations of the study were that it was conducted in government hospital and it was single centred study. We could not include the promotional literatures available to the private physicians. There is need to assess the awareness of the physicians by interventional study and provide guidance about accurate and ethical information from drug promotional literatures.

CONCLUSION

Most of the Pharmaceutical companies do not follow WHO and OPPI guidelines for promotion of their product in India, out of which Indian companies lacked more information as compared to International industries. Therefore more strict regulations should be made for proper promotion of information about drug product.

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