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## Evaluation of Rationality of Drug Promotional Literature in Malaysia Using Local and International Guidelines

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### ABSTRACT

The study was designed to assess drug promotional literature for rationality, accuracy and validity of the information provided, using World Health Organization (WHO) and PhAMA guidelines for ethical promotion of pharmaceutical products. The promotional brochures were evaluated for the essential drug information, nature of claims, pictures used and for the cited references. This observational, cross-sectional study was conducted in the tertiary care hospitals, private clinics and pharmacies in Klang Valley, Malaysia. The promotional literature were collected and evaluated in accordance with WHO and PhAMA guidelines for rationality, accuracy and validity. The data was collated and analyzed using descriptive statistics. A total of 301 promotional brochures were analyzed. Only few (19%) of the promotional literature fulfilled all the criteria as mentioned by the guidelines. In the analyzed promotional literature, multiple claims were commonly used. Eighty four percent of the brochures claimed about the efficacy of product, and a 38% about the safety. The most common missing information was on drug regimen (51%), safety (48%) and active ingredient (36%). The prescription behavior of the healthcare providers is largely influenced by promotional materials provided by the drug companies. Our observations suggest that few aspects of the information provided by the pharmaceutical companies in the promotional literature were not in accordance of the local and international guidelines on drug promotion. There is a perceived need for interventions to improve on the same.

**Keywords:** Drug promotional literature/ brochure, WHO guidelines, PhAMA guidelines.

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## INTRODUCTION

The communication between pharmaceutical companies and prescribers greatly influences rational prescribing by healthcare providers. In today's era, the availability, similarities and differences among similar therapeutic agents varies significantly. The prescribers need to keep themselves updated with the ever changing scientific knowledge of medicines from sources like CME programs, conferences, clinical trial summaries, scientific and promotional literature. The role of companies that research and develop medicines is to provide information that is scientifically fair and accurate, with the main aim of providing quality healthcare to the patients. Drug advertising and educational communications decipher information can be classified as promotional, non-promotional, or scientific. However a clear distinction between the promotional and non-promotional information is not be always possible<sup>1</sup>. Drug promotion using promotional literature is an integral part of pharmaceutical marketing. In this context, the World Health Organization (WHO) refers to "promotion" as 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. Similarly, according to the Pharmaceutical Association of Malaysia (PhAMA) CODE, 9th Edition, "promotion means any activity undertaken (or material prepared) by a member company or any third party acting on behalf of the company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet"<sup>2, 3</sup>. Different methods have been adopted by the pharmaceutical companies to facilitate direct to physician marketing e.g. interaction via medical representatives, distribution of free drug samples, sponsoring medical events, advertisement in journals, reminder articles, printed literature etc<sup>4,5</sup>. These promotional activities incur heavy costs to the company. Studies from different parts of the world have observed that these brochures are biased and the information contained may not be as per the required guidelines and of low educational value<sup>6, 7, 8</sup>. The quality of advertisements generates potential for inappropriate prescribing practices, increase healthcare costs and compromised patient care. World Health Organization (WHO) first published its Ethical Criteria for Medicinal Drug Promotion in 1988,<sup>2</sup> and medicinal drug promotion has been a matter of constant debate ever since. Pharmaceutical advertising practices have changed significantly over the past decade. In addition to laws and regulations, the industry has implemented various mechanisms to self-regulate communication and drug promotion. Contemporary guidelines and regulations that govern the pharmaceutical communications to healthcare providers are internal company procedures,

pharmaceutical industry code of practice and laws laid down by national and international bodies. The aim of these guidelines is to enable effective communication with high standards from the pharmaceutical companies for the benefit of healthcare professionals and their patients<sup>1</sup>. Many studies to date have shown that advertisements for drugs do not meet the local and international guidelines published in various countries. However, very few studies on evaluation of promotional material have been carried out in Malaysia. In this study, we analyzed the validity and rationality of the promotional drug literature as per ‘PhAMA’ (Pharmaceutical Association of Malaysia) and WHO’ (World Health Organization) guidelines for ethical promotion of drugs. In addition, the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) code is relevant to all the member countries, including Malaysia<sup>9</sup>.

## MATERIALS AND METHOD

This study was conducted to analyze the validity and rationality of promotional drug literature provided to healthcare providers by using local and relevant international guidelines like Pharmaceutical Association of Malaysia (PhAMA) Code, 9th Edition and WHO criteria for ethical medicinal drug promotion, 1988<sup>2,3</sup>. This observational, cross-sectional study was conducted in the tertiary care hospitals, private clinics and pharmacies in Klang Valley, Malaysia, after necessary ethical approvals. A total of 301 promotional brochures were collected randomly from various OPDs e.g. medicine, surgery, obstetrics and gynecology, pediatrics, and dermatology over the period from 1st July to 31st July 2013. The promotional literature was classified as LBL (Leave behind literature), Patient Information Booklet, Patient Education Booklet, Advertisement in journals, Newsletters, Case studies and Journal Reprints. Collected promotional brochures were divided into ‘drug’ and ‘non-drug’ promotional categories. A check-list was prepared for analyzing the brochures based on the local (PhAMA) and international (WHO) guidelines for ethical promotion of pharmaceutical products. Mandatory information that a promotional literature should contain, according to WHO and PhAMA criteria for ethical medicinal drug promotion include:

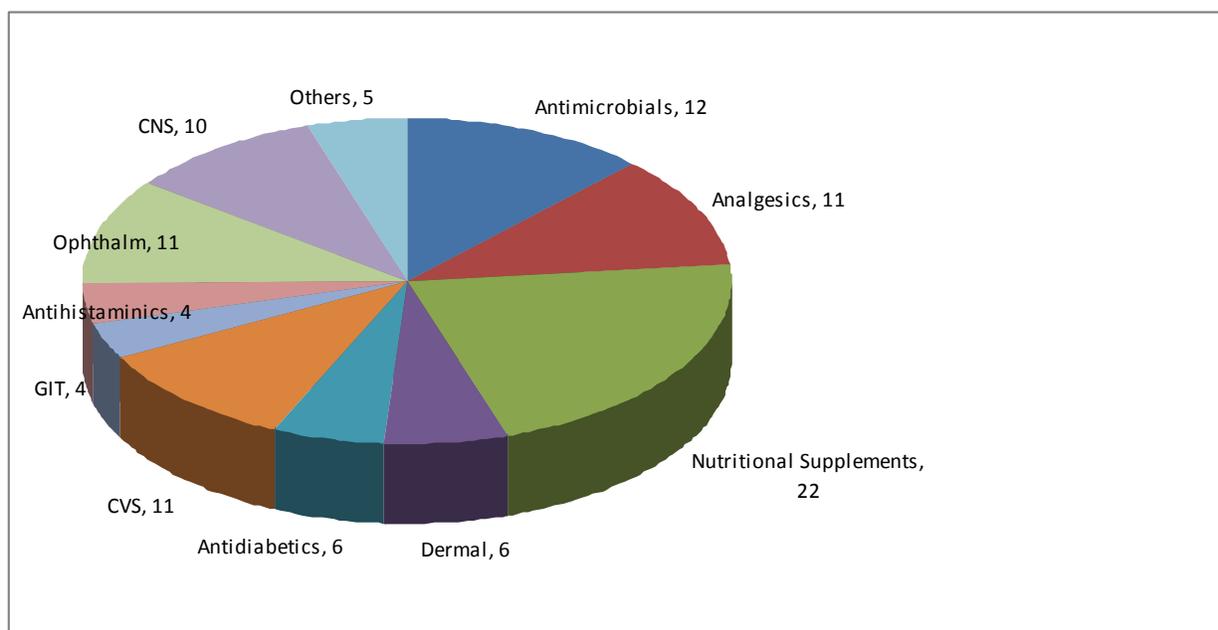
1. The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug.
2. The brand/ trade name
3. Content of active ingredient(s) per dosage form or regimen
4. Name of other ingredients known to cause problems, i.e. adjuvant
5. Approved therapeutic uses
6. Dosage form or regimen

7. Side-effects and major adverse drug reactions
8. Precautions, contra-indications, drug interactions and warnings
9. Abridged Prescribing Information (API)
10. Name and address of manufacturer or distributor
11. Reference to scientific literature as appropriate
12. Date of literature publication
13. Legibility of the literature

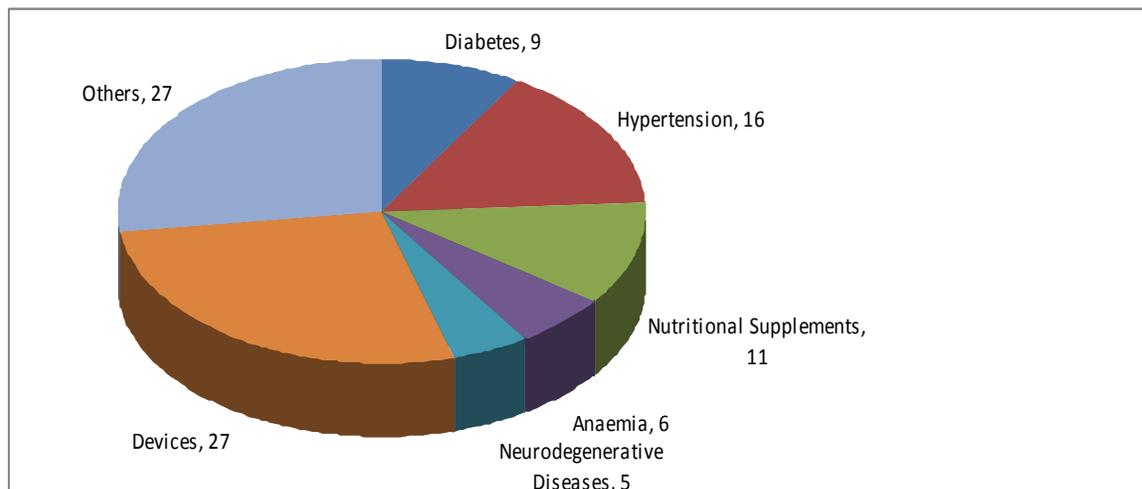
The data obtained were analyzed using descriptive statistics, according to the recommended local and international ethical criteria on medicinal drug promotion.

## RESULTS AND DISCUSSION

301 promotional brochures were evaluated, out of which 198 were drug promotional brochures and 103 were of non-drug nature (disease awareness, patient education etc.) The therapeutic classification of the drugs promoted in the promotional material is represented in Figure 1 and classification of the literature based on the disease is shown in Figure 2. The group of drug that were promoted the most were nutritional supplements, followed by chemotherapeutic agents, cardiovascular drugs, analgesics and ophthalmic drug preparations. Concerns arising with the promotion of these drugs include a tendency for self-medication, prescription refill and antimicrobial drug resistance.

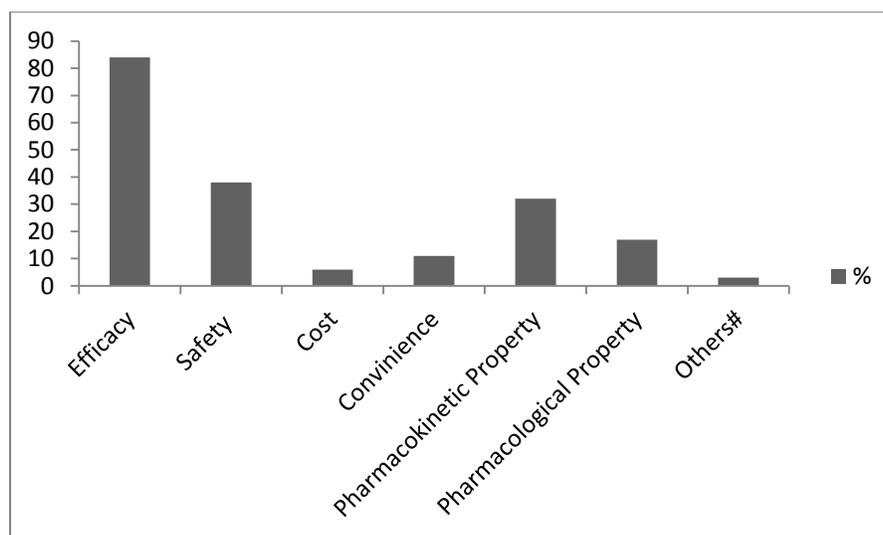


**Figure 1: Classification as per type of drug promoted in the drug promotional literature (in %, n=198)**



**Figure 2: Classification as per disease awareness/ information in the non-drug promotional literature (in %, n=103)**

Evaluation of the drug (n=198) and non-drug (n=103) promotional material is depicted in Table 2 and 3 respectively. We observed that, only 19% of the brochures fulfilled all the criteria laid down by the ethical guidelines for drug promotion. The information missed most commonly in the brochures was regarding the drug regimen, safety, adjuvants and references to scientific information. In addition to the desired therapeutic information, multiple claims regarding the product i.e. 2-6 per literature, was seen in majority of the brochures, the most common being on efficacy, safety and pharmacokinetic properties of the promotional drug, as seen in Figure 3.



# exaggerated, tall claims

**Figure 3: Type of claims**

The pictures depicted in promotional material were often found to be unrelated to medicine, disease or therapy. The pictures were also eye-catching and flashy. Stereotyping of images for

patients e.g. 'depressed female patients', 'at cardiovascular-risk male patient' was a common observation. A gender and racial bias was clearly evident in the pictorial depiction of healthcare providers and physicians. Our overall observation in this study is that the mandatory information in a printed promotional literature, according to the local and international guidelines for ethical drug promotion is not complied, which compromises on the ethical and educational aspect of a promotional literature. In addition, the therapeutic information provided in the promotional literature was not found to be sufficient for the prescriber to make a rational decision to use the promoted drug. Few studies<sup>6,7,8</sup> have reported that the advertising brochure created as a part of promotional activity for drugs by pharmaceutical companies, are at time inaccurate and with incomplete information, highlighting only on the strengths of the drug or formulation. In our evaluation, we found that the INN (International Non-Proprietary Name) was mentioned in 78% of the drug promotional literature and 70% in the non-drug promotional literature. The percentage of brochures having an active ingredient was found to be 87.87%<sup>4</sup> in a study conducted in Nepal and 88% in a Thailand-based study<sup>10</sup>. An Indian study has reported that INN was one of the nine WHO criteria that were fulfilled by 96.9% brochures<sup>5</sup>. Brand names were present in the entire set of promotional brochures that we analyzed, a finding similar to that of other studies done in the Asian subcontinent.<sup>4,5</sup> The information on the drug regimen (49%) and drug safety (52%) was reported to be low in our study in the drug promotional literature. Studies from India and Nepal also have reported similar observations on omission of certain important data in the drug promotional material<sup>4,5</sup>. Several claims in one brochure regarding efficacy, safety, pharmacokinetic properties, cost and convenience was observed to be quite common in our study, however brochures with tall, extravagant or unscientific claims was seen in only 2.3% brochures. The numbers reported by Mali et al were higher than our study, with regard to the extravagant emotional claims, claims regarding cost effectiveness and convenience<sup>5</sup>. Earlier studies have reported that multinational and national drug companies often grossly exaggerate the indications for the drugs and minimize or ignore the hazards. As a result, healthcare providers are given grossly exaggerated claims and the hazards of prescription drugs remain uncovered. However, considerable improvement in promotional practices of the multinational corporations has been found over the past few years<sup>11</sup>. A Brazilian study noted that approximately 75% of the advertisements failed to comply with regulations in Brazil.<sup>12</sup> Similarly in our study majority (81%) of the promotional materials did not provide all the necessary information as per WHO and PhAMA's Ethical Criteria for Medicinal Drug Promotion. Studies from India and Nepal also have reported that all the criteria were not fulfilled in their respective studies<sup>4,5</sup>. Another important aspect is appropriate referencing of the information

mentioned in the literature and also accessing the same. Several studies have reported that as high as 40% of information in the promotional material was not referenced and approximately 22% references were irrevocable.<sup>5, 13</sup> It has been reported that promotional literature are at times racial and gender biased, by dissipating human pictures and mentioning names of the physicians or patients in their advertisements, which, according to the WHO or PhAMA guidelines, are not appropriate, unless approved otherwise<sup>14</sup>. It is well known that, drug promotion by pharmaceutical industries is a convincing communication and the major marketing method of pharmaceutical companies marketing via printed promotional literature.<sup>15</sup> Since promotional activities are a big influence on the prescribing behavior of the healthcare providers, it is important to critically analyze promotional materials used by pharmaceutical companies with reference to applicable guidelines. Besides, education, research and publication on the research on drug promotional materials are urgently needed to improve the prescribing behavior of the physicians therefore improving the healthcare delivery. Effective drug regulation has been suggested as a solution to the problem of unethical drug promotion by Alam *et al.*<sup>4</sup>The observations from this study highlight that health care professionals need to analyze the information provided in the promotional literature for its authenticity, before accepting it. One of the strategies to overcome the unethical drug promotion suggested by the same researchers is to sensitize the medical students, budding doctors and future prescribers regarding ethics and guidelines for promotion of prescription drugs. Incorporation of such less explored areas in the Pharmacology curriculum shall definitely help to sensitize this population. Adopting pro-active measures like mandatory pre-launch reviews for effective and compliant communication regarding new drugs is a measure that involves active participation of the drug companies.

**Table 1: Evaluation of Drug Promotional Literature (n=198)**

Sr. No.	Evaluation Criteria	Mentioned Number (%)
1	INN*	154 (78)
2	Brand Name	198 (100)
3	Active ingredient	126 (64)
4	Adjuvant	4 (2)
6	Approved Therapeutic Use(s)^	178 (90)
7	Dosage Form	198 (100)
8	Regimen~	97 (49)
9	Safety Information	102 (52)
10	API**	163 (82)
11	Manufacturer's Name & Address	198 (100)
12	Reference to Scientific Information	163 (82)

\*International nonproprietary name, ^Approved by the FDA, Summary of Product Characteristics,  
~Dose, frequency, duration of therapy, \*\*Abridged Prescribing Information

**Table 2: Evaluation of Non-Drug Promotional literature (n=103)**

Sr. No.	Evaluation Criteria	Mentioned Number (%)
1	INN*	72 (70)
2	Brand Name	103 (100)
3	Active Ingredient	64 (62)
4	Major Therapeutic Indication(s)	80 (78)
6	Precautions/ Warnings, C/I	41 (40)
7	Manufacturer's Name & Address	103 (100)
8	Legible	103 (100)

\*International nonproprietary name

## CONCLUSION

Majority of promotional literature in our study did not completely comply with the local and international guidelines calling for ethical regulation & legislative control with government oversight. It is also worthwhile to mention that the fine line between ethics and law must be balanced while promoting prescription drugs. Adopting just the “tick-box approach” to comply guidelines” highlighting the importance of preserving sensitivity to the local ethical concerns and guidelines.

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