



TEACHING CRITICAL APPRAISAL OF DRUG PROMOTIONAL BROCHURES USING WHO GUIDELINES TO MEDICAL STUDENTS

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ABSTRACT

The primary goal of pharmaceutical advertisements was to influence physician's prescribing behaviour for company benefits. However, the skills for evaluating the promotional literature are not taught in the traditional medical school curriculum. 100 Promotional brochures were evaluated for accuracy, consistency and validity of the information using WHO criteria. A pre and post knowledge of 130 student's ability to identify violations of existing guidelines were assessed by giving 5 promotional literatures. The brand name, active constituents, therapeutic indications were mentioned in 100% of brochures. The information on side effects (36%), drug interactions (56%), special precaution (27%) and used in pregnancy and lactation (55%) was lacking. In medical students post-intervention scores were significantly higher. Pharmaceutical companies did not strictly follow WHO guidelines while preparing these promotional brochures. Physicians should be critical while referring to such promotional literatures. There is a need to educate medical students about these for future practice.

KEYWORDS: Drug Promotional Brochures, promotional literatures, medicine promotion, World Health Organization criteria, Critical appraisal



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INTRODUCTION

Pharmaceutical companies invest lot of money on new drug research processes. After the approval of new drugs, Pharmaceutical manufacturers also invest on promotion and marketing of those drugs.¹ History of promotional drug brochure goes back to 1930s, when a Drug Enquiry Committee was formed under Sir Ram Nath Chopra, which critically scrutinized various drug pamphlets available at that time.² World Health Organization (WHO), defines 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 drug.'³ The Pharmaceutical industry has tremendous influence on the practice of medicine through its considerable marketing efforts, both to patients through direct to consumer advertisement, and to physicians through providing samples, continuing medical education (CME) and other efforts.⁴ Different modes of drug promotions include visual aids, flip charts, leave-behinds, advertisements, gifts, and audio-visuals for promotion of drugs. Advertising brochures and leaflets were widely used method of promotion to influence the physicians.⁵ The information given by pharmaceutical companies is concerned more for the promotion of their product rather than education. Eleven per cent of the verbal statements about drugs made by medical representatives to the clinicians have been found to be inaccurate. Surprisingly only 25% physicians are aware that the information provided is wrong. A majority of journal advertisements have been found to be based on studies of poor methodological quality. Though the objective of the promotional literature is to promote a product, an active approach by doctors can transform it into a useful and accurate source of information.⁵ When there is a new drug in the market, this might be the only source of information to the physicians. Hence it is important to critically appraise these promotional brochures which can influence the prescribing behaviour of the physicians.^{6, 7} WHO has published ethical criteria for medicinal drug promotion in the year 1988 to evaluate the appropriateness of promotional drug literatures.⁸ In India, promotional activities by pharmaceutical

companies are governed by Organization of Pharmaceutical Producers of India (OPPI), self-regulatory code of pharmaceutical marketing practices, January (2007) and by National legislation. Furthermore there is no proper education and training program among medical faculty and undergraduate medical students except in their second year curriculum by a single part of practical session, therefore it is necessary to evaluate their knowledge about promotional brochures. Keeping in mind these backgrounds this study had been planned which combined the evaluation of drug promotional brochures using WHO guidelines and teaching critical appraisal of it in medical students.

MATERIALS AND METHODS

This observational study was conducted in the outpatient department of B.J. Government Medical College and Sassoon General Hospital Pune, after getting approval from Institutional Ethics Committee. The study was conducted to find out the scientific and ethical status of drug promotional literatures presented to the prescribers and its concurrence to WHO criteria for ethical medicinal drug promotion, 1988. Objectives of the study were to evaluate drug promotional brochures for accuracy, consistency, and validity of the information presented in it, using World Health Organization (WHO) criteria for ethical medicinal drug promotion and to determine the effect of training critical appraisal of drug promotional brochures on the ability of undergraduate medical students to identify violations of existing guidelines on drug promotion. In addition to these the study also focused on to sensitize undergraduate medical students regarding World Health Organization (WHO) criteria for medicinal drug promotion. A total of 128 drug promotional literatures were collected randomly from the out-patient department (OPD) of Sassoon General Hospital and B.J. Government Medical College Pune for the period starting from 1st January 2014 to 31st June 2015. These literatures were collected from different OPDs of medicine, surgery, paediatrics, orthopaedics, skin, psychiatry, ENT and obstetrics and gynaecology departments. Literatures promoting medicinal devices and equipments (e.g. insulin pump, blood

glucometer etc.), orthopaedic prostheses, Ayurvedic medicines, drug monographs, reminder advertisements, drug lists, and literature promoting more than two brands were excluded from the analysis. All collected

drug promotional literatures were classified according to Pharmacological class of drug and evaluated by WHO criteria for fulfilment of each of the following parameters

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 active ingredient(s) per dose
4. Other ingredients known to cause problems, i.e. adjuvant
5. Approved therapeutic uses
6. Dosage form or dosage schedule
7. Side effects and major adverse drug reactions,
8. Precautions, contraindications and warnings, (elderly, liver disease, renal disease lactation. pregnancy and children).
9. Major drug interactions
10. Name and address of manufacturer or distributor
11. Reference to scientific literature as appropriate Further, promotional brochures were also evaluated for the following additional parameters also
 1. Analysis of literature for references cited in promotional literature
 2. Storage conditions
 3. Toxicity
 4. Font size for generic and brand name
 5. Commonly exaggerated words
 6. Paper quality, print and colour
 7. Literatures presented with pictures

The study had also been aimed to evaluate the knowledge of II year MBBS students in B.J. Government Medical College, Pune. Total 148 students were participated for a training session out of which 130 students completed both pre and post-tests. 5 separate promotional brochures were given to each student and asked them to comment. After that a training session on critical appraisal of medicinal drug promotion that consisted of 2 hour session where conducted. In the first

session, lectures on critical appraisal methodology and the existing guidelines on medicinal drug promotion were given followed by small group discussions. In the second session same brochures were given to all students again and conducted post session evaluations. The scores obtained serving as the pre- and post-intervention measurements. All the students were not aware of the design and purpose of the measurements.

Evaluation of medical students was based on the following parameters

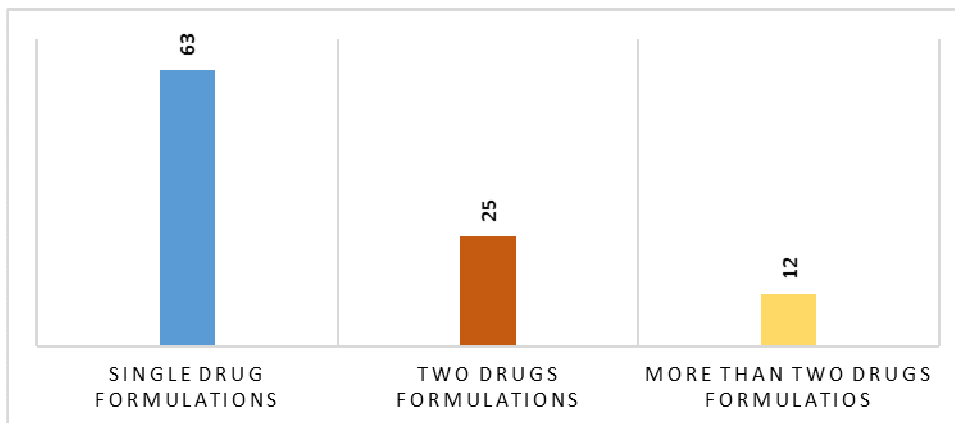
1. Students comments
2. Relevance of photos appeared on promotional literature
3. Graph evaluation
4. Exaggerated word used in promotional literature

RESULTS

A total of 128 promotional brochures were collected from different OPDs running at Sassoon General Hospital, Pune; Out of which 100 brochures were selected on the basis of inclusion criteria. They were evaluated for

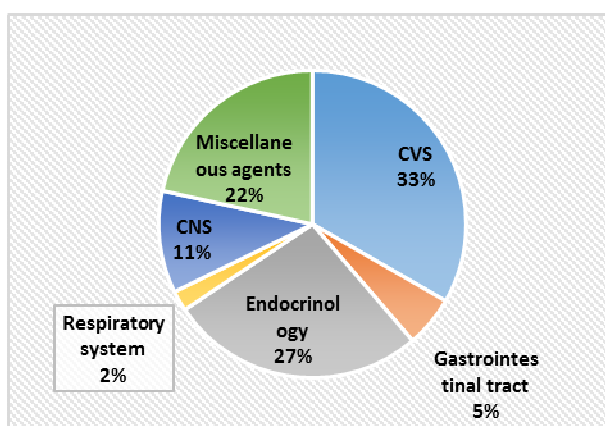
their concurrence with WHO criteria. Out of 100 promotional literatures their, 63% were of single drug formulation, 25% were of two drugs formulations and remaining 12% brochures were of more than 2 or more than 3 drugs combinations as shown in Graph I

Graph I
Number of drug in promotional brochures (in percentage)



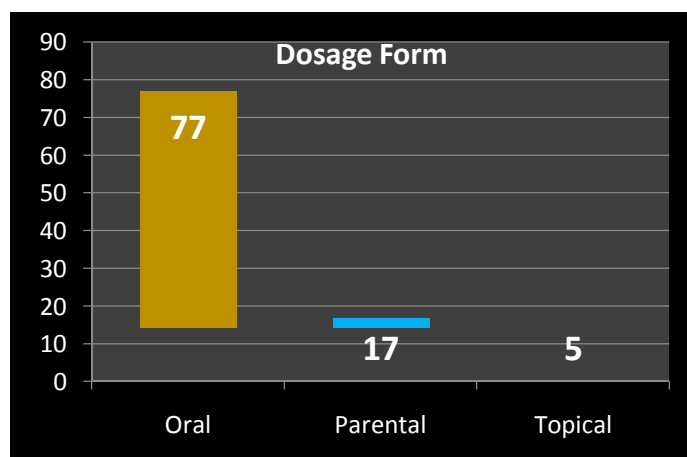
Selected literatures were classified system wise as shown in Graph II. The most common promoted drugs were of cardiovascular system (33%) followed by endocrine system (27%), miscellaneous drugs (22%), Gastrointestinal system (5%) and Respiratory system (2%).

Graph II
System wise classification of drug promotional literature



As far as dosage form is concerned, oral drugs were most commonly promoted (77%) followed by parenteral drugs (17%) and topical preparations (5%) as depicted in Graph III.

Graph III
Dosage forms frequencies in promotional brochures



None of the drug promotional literature fulfilled all WHO criteria as shown in Table 1. Generic name, Brand name, Content of active ingredient, Therapeutic uses, Dosage form was mentioned in 100% of promotional literatures.

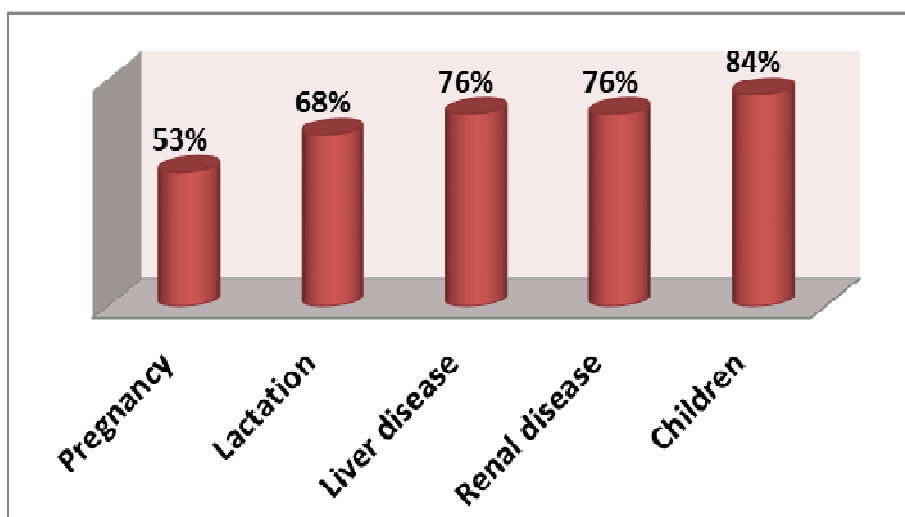
Table 1
Evaluation of promotional brochures as per WHO criteria

No	Criteria	Mention
1	Generic name	100 %
2	Brand name	100 %
3	Content of active ingredient	100 %
4	Therapeutic use	100 %
5	Dosage form	100 %
6	Adjuvant causes problem	35 %
7	Side effect / ADR	64 %
8	Precautions	73%
9	Major drug interactions	44%
10	Name and address of manufacturer	88 %
11	References to scientific information	89%

It was noted that a majority of brochures (73%) did not mention about various precautions supposed to be taken while prescribing drugs in special population like pregnancy (53%), lactation (68%), liver

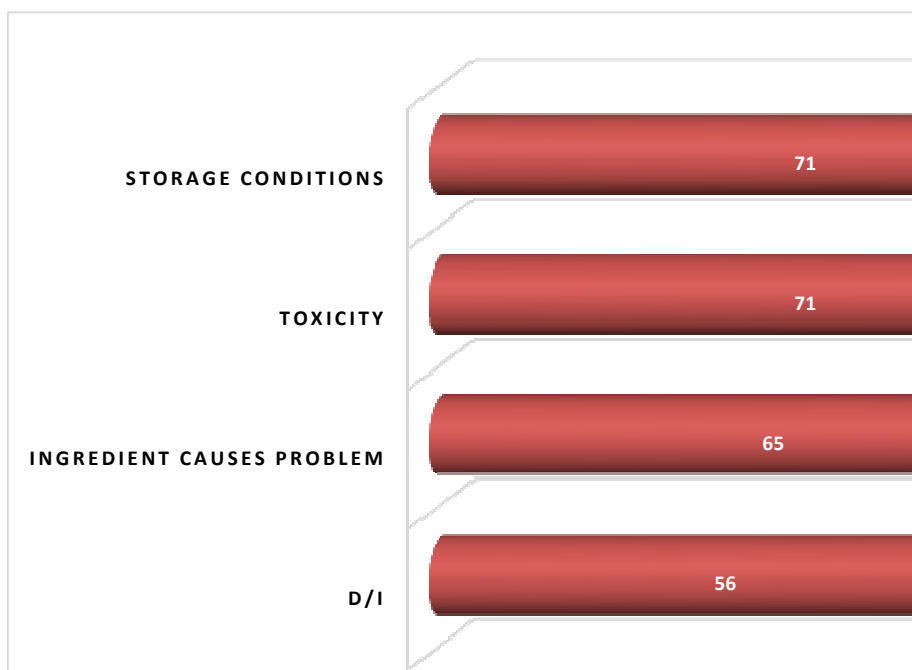
disease (76%), renal disease (76%). 84% of brochures did not mention about special precaution to be taken in paediatric population as given in Graph IV.

Graph IV
Precautions – In specific & special situations that were lacking



The promotional brochures were further evaluated for information regarding safety (Refer Graph V).

Graph V
Percentage of promotional brochure lacking in safety information about drugs



The information about adverse drug reactions (ADRs) and drug interactions were missing in 64% and 46% of brochures respectively. 51% literature did not give information regarding contraindications of medicines. Information regarding storage conditions, toxicity and

ingredient causing problems were not mentioned in 71%, 71% and 65% respectively. Information about references cited in promotional brochures were also evaluated [Table 2]

Table 2
Analysis of promotional brochures for reference cited

References cited	89%
Total no. of references	275
Sources of references	
Journal article	224
Text book	02
Web site	06
Others	27
References more than 5 yrs. old	66%
References less than 5 yrs. old	34%

It was revealed that 89% of brochures contain one or more references in it. In these 89 literatures total number of references cited were 275. Out of these 224 were cited from medical journals, 6 were from websites, 2 were from textbooks and 27 were from other sources of information like drug bulletins, magazines, data on files etc. All literatures were further evaluated for text and found that font size for generic names was small and brand names were written in bold font with

larger size. Paper quality and print and colour of literature were excellent in all the promotional literatures. 63% of literature consisted of one or more pictures in them.

Students Evaluation of promotional brochures as per WHO criteria

Results of pre and post-test evaluation among II year MBBS students are mentioned in Table 3 and Graph VI. Results from post intervention assessment showed that there is higher score

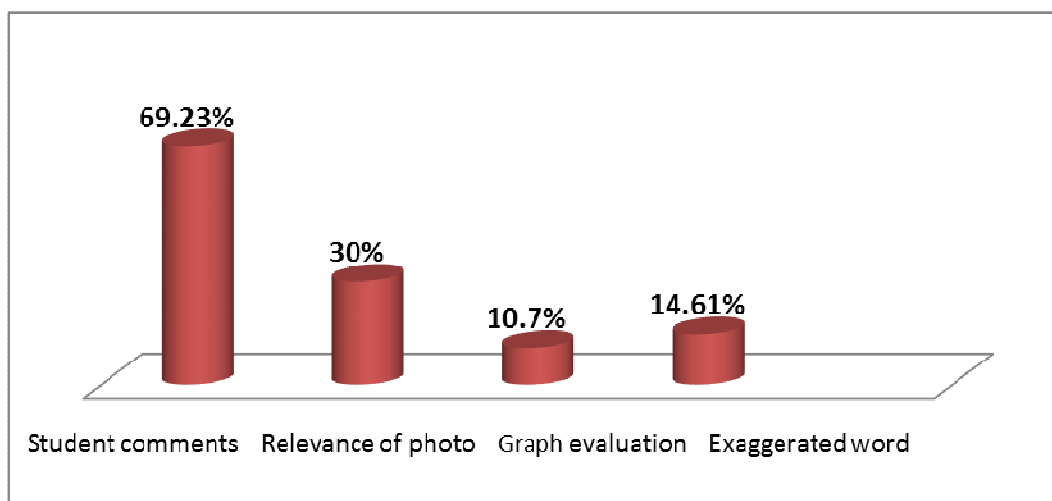
as compared to pre intervention score. This indicates that the intervention was successful in improving the student's ability to identify violation of existing guideline on medical drug promotion materials. There was statistically

significant improvement observed in student's performance in criticising promotional brochures according to WHO criteria except in criticising on therapeutic uses mentioned in brochures.

Table 3
Pre Test vs. Post Test data of Student's Evaluation of promotional brochures as per WHO criteria

No.	WHO criteria	Pre Test- score	Post Test -score	P value
1	Generic Name	3.75	4.92	<0.0001
2	Brand Name	4.71	5.00	<0.0001
3	Dosage form	3.00	4.75	<0.0001
4	Other ingredients known to cause problems	0.11	3.02	<0.0001
5	Therapeutic use	4.49	4.62	>0.05
6	Side effect / ADR	2.29	4.92	<0.0001
7	Precautions	1.33	4.71	<0.0001
8	Major drug interactions	0.44	3.89	<0.0001
9	Name and address of manufacturer	0.86	4.65	<0.0001
10	References to scientific information	0.49	4.43	<0.0001

Graph VI
Student's Response after teaching Session



DISCUSSION

The study shows that pharmaceutical companies do not strictly follow the WHO criteria while making their promotional literatures. Most of the promotional literature were of single drug formulations type and of oral dosage form. This may be because of oral dosage form was the most convenient and widely prescribed route of administration. Among the most promoted drugs, cardiovascular drugs followed by endocrinological drugs were on the top list. This may be because of increased prevalence and incidence of cardiovascular risk factors as

a result of lifestyle changes. Furthermore as India is known to be capital of diabetes therefore, more and more pharmaceutical companies were focussing on such medications. In a similar study by Preeti Narendra Bhatt et al ⁶ also found that cardiovascular drugs were most promoted drugs followed by antimicrobial agents and nutritional products. Studies conducted by Ehab Mudher Mikhael ⁹ found that majority of medical brochures were promoting antibiotics. Generic name, brand name, content of active ingredients, therapeutic uses, dosage form were mentioned in all promotional brochures that reflect basic information about drugs. Study by Smita N Mali et al ¹⁰ shows similar

findings as per our study. A similar finding was obtained through evaluation of brochures in Nepal and Saudi Arab.^{11, 12} Persons with pre-existing liver or renal diseases are at a special risk of developing untoward effects of drugs as there are changes in metabolism and excretion of some drugs by these situations. Most of the brochure in our study did not mention any information about such scenarios. Results from another study¹³ shows that very few brochure mentioned about precautions to be taken for liver and renal diseases. Precautionary measures should also be mentioned in case of special populations like in pregnant and lactating women and children. This information was lacking in more than half of the promotional brochures similar to a study conducted by Satyendra Kasyap et al.¹³ Information regarding ADRs, contraindications and drug interaction is an important tool to decide and to overcome safety issues related with drugs. About half of the brochures did not mention anything about these safety parameters. Similar findings were obtained in a study conducted in Nepal.¹¹ Though most of the promotional brochures did quote the references for their information, about two third of all references were from older articles of more than five years back. As medical science is rapidly changing from time to time, promotional brochures should cite recent references preferably of less than five years. In a similar study¹⁴, it was found that about 80% of references were from older articles or

books. This study is a unique as it simultaneously focused on evaluation of drug promotional literature and the role of training about the same in undergraduate medical students. There was statistically significant improvement in knowledge about promotional brochures and commenting and criticising abilities of undergraduate students after training program. In a study conducted by Alvero RGY et al¹⁵ on teaching critical appraisal of promotional brochures in a medical school in Philippines found that post intervention scores were significantly higher in those who underwent the teaching module on critical appraisal of medicinal drug promotion. So such training programs should be a part of syllabus in all years of undergraduate medical education including their internship year.

CONCLUSION

Pharmaceutical companies did not strictly follow WHO guidelines while preparing promotional brochures. The main thrust is apparently on brand names. Crucial information from a safety point of view i.e. adverse events and precautions is predominantly lacking. There is a need to teach medical practitioners as well as undergraduate medical students, the art of critical appraisal of medicinal drug promotion, so that they would be able to write rational prescriptions.

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