Assessment of Knowledge of Phase II MBBS Students Regarding Drug Promotional Literature: A Questionnaire Based Study

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Abstract
Background: Drug Promotional Literature (DPL) is the most common source of information used by physicians to update their knowledge on existing and new drugs. These promotional materials can be highly informative if they are critically appraised, but when they are accepted without question, they may lead to irrational prescribing.

Aims & Objectives: So, the aim of this cross-sectional, observational questionnaire-based study was to sensitize the Phase II MBBS students regarding WHO & OPPI criteria for medicinal drug promotion. It was conducted on 112 Phase II MBBS students to evaluate their existing knowledge about DPL, based on WHO and OPPI criteria.

Results: In this study, 92% of the students were correct about the drug name, 99% regarding brand name and 96% about generic name of the drug. 91% of them were right about the presence of active ingredients, 93% about indications, 80% about the dose and 82% about the contraindications of the drug. But only 46% evaluated correctly about the method of use of the drug. While 81% estimated correctly about the side effects, only 64% were correct about the precautions and 67% about the mention of API. Only 31% students mentioned correctly regarding the date of production, 39% about the name & address of the pharmaceutical company and 35% regarding references.

Conclusion: Though the knowledge of the students regarding most of the points of DPL are considered good, but the significance of important information like the method of concerned drug use, name and address of the manufacturing company, date of production and the details of references, should also be stressed upon by the future medical practitioners.

Keywords- OPPI criteria, Printed DPL, WHO criteria.

INTRODUCTION
According to WHO, Drug Promotional Literature (DPL) is defined as “All informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.”(1) In our country, members of the Organisation of Pharmaceutical Producers of India (OPPI) are involved in the discovery of new medicines and vaccines for present and future generations and provide the latest scientific and educational content to benefit patients and support high quality patient care.(2,3)

Pharmaceutical companies develop, introduce, and sell many novel drugs on a regular basis. For them to be accepted and used in the healthcare system, the healthcare professionals need to be made aware of the correct scientific information about the drugs and their availability. To achieve this goal, the ethical promotion of prescription medicines is vital to the pharmaceutical industry’s mission of improving patient outcomes by discovering, developing, and promoting new medicines. It helps to ensure that healthcare professionals globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients. (2)

Drug promotion can be done by various methods such as audio visuals, drug reminders, and pamphlets. (4) Out of all the types of drug promotions, promotional literature seems to be the most common source of information used by physicians to update their knowledge on existing and new drugs. These promotional materials can be highly informative if they are critically appraised, but when they are accepted without question, they lead to irrational prescribing. (5) For these DPLs, currently, there are two main guidelines in existence. One is “Ethical criteria for medicinal drug promotion” recommended by WHO, 1988 (1) and the other one is the OPPI Code of Pharmaceutical Practices is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code. (2)
Like practising physicians, medical students are also exposed to drug promotion either during their medical course or during internship. Hence, to understand rational use of medicine and to prevent irrational prescribing, there is a need to educate our future practitioners regarding critical analysis of drug advertisements. This can be achieved by imparting knowledge regarding drug advertisements during the MBBS course and it is done during the phase II CBME curriculum when they are taught Pharmacology. Hence the aim of our study was to sensitize the students regarding WHO & OPPI criteria for medicinal drug promotion and to determine the impact of teaching critical appraisal of medicinal drug promotion to medical students. So, the present study has been conducted on phase II MBBS students to evaluate their existing knowledge about DPL and to educate them to deal with medical representatives and critically appraise any given Drug Promotional Literature properly.

**MATERIALS & METHODS**

This cross-sectional, observational questionnaire-based study was conducted in a tertiary care hospital. 200 phase II MBBS students were given a promotional drug literature and were asked to solve a 15 questioned validated questionnaire which was based on the WHO and OPPI criteria about a printed Drug Promotional Literature. This was conducted in the month of December 2022- January 2023. By circulating the questionnaire via google form, this was done to assess the knowledge of the students regarding Drug Promotional Literature.

**Questionnaire regarding a Printed Drug Promotional Literature**

- Is this Drug Promotional Literature legible?
- Is name of the product given?
- Is the brand name given?
- Is the generic name given?
- Are the active ingredients mentioned?
- Is there a statement about the indications of the product?
- Is the recommended dose mentioned?
- Is the method of use/administration given?
- Is there a statement about the contraindications of the product?
- Is there a statement about the precautions to be taken with the product?
- Is there a statement about the side effects of the product?
- Is the “abbreviated prescribing information” (API) mentioned?
- Is the date of production of the Drug Promotional Literature given?
- Is the name and address of the pharmaceutical company mentioned?
- Are the references about the studies related to the product given?

Data were collected, and knowledge of every point was analysed and evaluated in percentage.

**RESULTS & DISCUSSION**

Out of 200 students, 112 participated in our study. The evaluation of the Drug Promotional Literature by the students is shown in the following table-

<table>
<thead>
<tr>
<th>Questions (WHO &amp; OPPI based)</th>
<th>Number (%) of students answered correctly (n=112)</th>
<th>Correct answer according to the DPL given</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Legibility</td>
<td>70 (58.9%)</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Name given</td>
<td>103 (91.9%)</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Brand name</td>
<td>111 (99.1%)</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Generic name</td>
<td>108 (96.4%)</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Active ingredients</td>
<td>102 (91.1%)</td>
<td>Yes</td>
</tr>
<tr>
<td>6. Indications</td>
<td>104 (92.9%)</td>
<td>Yes</td>
</tr>
<tr>
<td>7. Dose</td>
<td>90 (80.4%)</td>
<td>Yes</td>
</tr>
<tr>
<td>8. Method of use</td>
<td>52 (46.4%)</td>
<td>Yes</td>
</tr>
<tr>
<td>9. Contraindications</td>
<td>92 (82.1%)</td>
<td>No</td>
</tr>
<tr>
<td>10. Precautions</td>
<td>72 (64.3%)</td>
<td>No</td>
</tr>
<tr>
<td>11. Side effects</td>
<td>91 (81.3%)</td>
<td>No</td>
</tr>
</tbody>
</table>
Drug Promotional Literature is a source of information about the novel drugs or newer implications of using the existing drugs. As drug companies are promoting the literature for their brand products, there is a possibility of partiality. (6) 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 brochures. These materials are often misleading and confusing. (7) The WHO and OPPI have set standards, globally and in India, respectively, to be followed regarding the ethical promotion of medicinal products. WHO’s ethical criteria for medicinal drug promotion includes the various details that a drug advertisement should contain. Accordingly, a drug advertisement should contain the name of the active ingredient(s) using either international nonproprietary name (INN) or the approved generic name of the drug. The generic name should be legible and should not be too small in comparison to the brand name. (5) So, it is very important for the future practitioners to know about the significance of legibility of a Drug Promotional Literature. In our study, about 59% students correctly answered about the legibility of Drug Promotional Literature. The indications, dosage regimens, contraindications, adverse effects, and precautions should be included in the drug advertisement. Such parameters need critical analysis. About 92% of the students were correct about the drug’s name, 99% regarding brand name and 96% about generic name of the drug. 91% of them were right about the presence of active ingredients, 93% about indications, 80% about the dose and 82% about the contraindications of the drug. But only 46% evaluated correctly about the method of use of the drug. This value is much higher than a similar study done in 2018 on medical undergraduates (8) & on medical postgraduate students (9). A study done on resident doctors in 2021 was in similar lines with our study. (10) Inappropriate usage of a drug in majority of people lead to various health problems because there are various side effects produced by drug. There is a tendency for drug companies not to highlight or lay emphasis on contraindications and adverse effects. (5) Hence, it is important that our future doctors should be aware regarding safety information in Drug Promotional Literature. While 81% estimated correctly about the side effects, only 64% were correct about the precautions to be taken and 67% about the mention of API. Only 31% students mentioned correctly regarding the date of production and 39% about the name & address of the pharmaceutical company. References are an integral part of drug advertisements because most of the claims should be substantiated by the references. Also, it is important to provide reference of scientific literature in Drug Promotional Literature because through these references physicians can get details of the drug regarding its mechanism of action, safety information, indications etc. and these will help them to take decision whether they want to prescribe that medicine or not. Only 35% students in the present study mentioned correctly about the presence of references. In a study done on resident doctors,
84% of participants understood that it is important to provide reference of scientific literature in a Drug Promotional Literature. (8)

The physician’s interaction with pharmaceutical companies begins early into their career, sometimes even in medical school, and it continues to take place throughout. (11) Thus, we need to encourage our future doctors to acquire knowledge of the art of critical appraisal of Drug Promotional Literature possibly during their undergraduate training. This would compel them to look up to the authentic medical literature for reference and to be cautious not to rely solely on these Drug Promotional Literatures. Furthermore, evidence supports the importance of physician mediated knowledge translation, as people report higher rates of intention to use medications when they have been informed of the benefits by their physician. (12) Incorporation of such less explored areas in the undergraduate teaching curriculum shall help to sensitize them. Furthermore, interventional educational research, workshops, and training programmes among the undergraduates about the ethical drug promotion are the highly suggested ways to improve the knowledge and awareness regarding the same. Awareness should be created among doctors to ensure a thorough assessment of DPLs before using them as a guide. (13)

Our study’s limitation is that it only assesses students’ knowledge towards one sort of pharmaceutical company's promotional activities, namely printed promotional literature. Assessment of knowledge of “Reminder advertisements” (2) & “Electronic materials of advertisement” (2) can also be done, not only in the students, but also in practicing physicians. Also, it can be done in the same batch of students when they get actual prescribing exposure during internship, to evaluate upgradation of the knowledge of Drug Promotional Literature in their minds.

CONCLUSION
In this study, though the knowledge of the students regarding most of the points of DPL are considered good, but the significance of important information like the method of concerned drug use, name and address of the manufacturing company, date of production and the details of references, should also be stressed upon by the future medical practitioners. DPL, if promoted rationally and analysed critically by the future healthcare professionals, may lead to better prescribing, more rational use of drugs and improved cost effectiveness. So, it is of utmost importance to appropriately train the future Indian Medical Graduates about the use of Drug Promotional Literature by incorporating a little change in their attitude towards it.

REFERENCES: