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RESEARCH ARTICLE

Knowledge and opinions of postgraduate resident doctors regarding promotional drug literature: A cross-sectional study

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ABSTRACT

Background: Pharmaceutical companies develop, introduce, and sell many novel drugs on a regular basis. For the manufacturers and distributors of these drugs, the sole important focus remains promoting them to prescribers, who are their target audience. It has been observed in a number of studies that a large number of drug promotional literatures (DPLs) do not follow the code of ethics. Hence, we undertook this study to assess resident doctors' knowledge and opinions with regard to pharmaceutical promotional material. **Aim and Objective:** The objective of this study was to determine the knowledge and make an objective assessment about the opinion of postgraduate residents on DPL. **Materials and Methods:** The study design followed was a cross-sectional, observational, questionnaire-based descriptive study to assess knowledge, attitude, and practices of DPL. **Results:** Out of the 100 residents, 65 were female and 35 were male. About 92% of the students were unaware of any guidelines applicable for ethical DPL. Only 17% read the text cited fully and 53% felt that the generic name is not given enough prominence in the DPLs. About 63% preferred pictures, 26% preferred scientific tables, and 11% preferred scientific graphs. About 41% do not check the original article(s) and 46% claimed to not observe for any conflict of interest in the references mentioned for the claim(s) made in the DPLs. About 32% claimed that DPLs affected their prescribing habits. **Conclusion:** There is a need to educate physicians early into their careers about the ethical guidelines set for assessing DPLs. This will enable them to understand and assimilate the information in a more critical manner.

KEY WORDS: Drug Promotional Literature; Questionnaire; Knowledge; Resident

INTRODUCTION

Pharmaceutical companies develop, introduce, and sell many novel drugs on a regular basis. For them to be accepted and used in the health-care system, the health-care professionals need to be made aware of the correct scientific information about the drugs and their availability.^[1] For the manufacturers and distributors of these drugs, the sole important focus

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remains promoting them to prescribers, who are their target audience.^[2] Drug promotion can be done by various methods such as audiovisuals, drug reminders, and pamphlets.[1] Out of all the types of drug promotions, promotional literature seems to be the source of information most commonly used by physicians to update their knowledge on existing and new drugs. Hence, drug promotional literature (DPL) should contain information that is most important and accurate.[3] Drug companies are well within their rights to promote their drugs and there are a number of ways to do it. However, since it influences physicians' prescribing habits to a large extent, drug promotion must be done ethically. Despite best efforts on behalf of the pharmaceutical companies, DPLs do not always give out the most updated, precise, and reliable information in their drug promotions.[1] Keeping this in mind, the "WHO, International Federation of Pharmaceutical

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Manufacturers and Associations, and the Organization of Pharmaceutical Producers of India (OPPI)" have laid down guidelines and criteria to ensure drug promotion which leads to more rational prescribing of drugs. [4] It has been observed in a number of studies that a large number of DPLs do not follow the code of ethics. [5]

We undertook this study to assess physicians' perspective with regard to pharmaceutical promotional material. We conducted the study to assess the opinions and knowledge, attitude, and practices of postgraduate residents regarding DPL and whether it affects their prescribing practices.

MATERIALS AND METHODS

The study design followed was a cross-sectional, observational, questionnaire-based descriptive study. It was conducted amongst 100 PG residents at MGM Medical College, Navi Mumbai. The Institutional Ethics Committee permission was taken before commencement of the study. Before taking part in the study, an informed written consent was taken from each participant. A validated and modified questionnaire^[6-8] was distributed among the residents and data were collected. The questionnaire assessed participants on their knowledge, attitude, and the practices in relation to DPL. Individual questionnaires were analyzed and results formulated.

RESULTS

Results of analyzed questionnaires filled by PG students to assess the knowledge, attitude, and practices toward DPL are given here:

Out of the 100 residents, 65 were female and 35 were male. The mean \pm SD and median age were 26.57 ± 1.47 and 27 years, respectively. About 56% of the residents were in the 2nd year, 29% in the 1st year, and 15% in the 3rd year of residency. The residents were from different areas of specialties which are shown in Figure 1. About 92% of the students were unaware of any guidelines applicable for ethical DPL. Out of the 8% that claimed to be aware of the guidelines, none of them knew the name of the guidelines correctly.

We assessed their knowledge of the WHO guidelines for ethical DPL using questionnaire about which nomenclature of drug to be used, how much general information and the safety information it should contain and it is reflected in Figures 2-4.

Attitude of the residents toward DPL was assessed on their opinion regarding importance given to text cited, relevance of pictures, and proportional space occupied by them and importance given to various nomenclatures of drugs. On assessment of residents' attitude toward DPL, it was observed

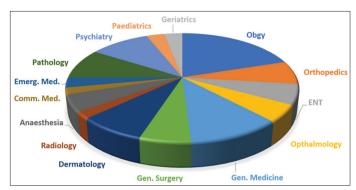


Figure 1: Area of specialization

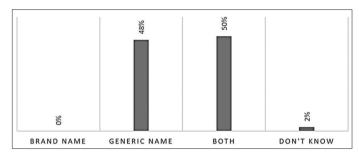


Figure 2: Response to question: What should the name of the drug mentioned in the drug promotional literature contain?

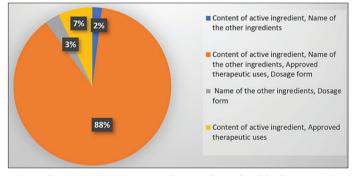


Figure 3: Response to question: What should the complete information regarding the drug should mention?

that only 17% read the text cited in DPLs fully, 66% read the text partially while 17% do not have the time to read it at all. In regard to the relevance of the pictures on the promotional literature to the drug being promoted, 56% of students felt that they were sometimes relevant, 29% felt that they were always relevant, and 15% felt that they were completely baseless. Majority (71%) students felt that the pictures in promotional literatures had no gender bias while 18% felt that it existed sometimes. About 40% were of the opinion that sometimes therapeutically unrelated printed materials are compromising the space given to important information while 37% of students felt that they were always compromising the space and 23% said that they were not comprising the space at all. About 40% of residents said that visual representation sometimes helps, 38% said that images help them remember the brand better, and 22% said that they did not like cluttered promotional literatures. About half (53%) of students felt that the generic name is not given enough prominence in the DPLs and out of the other half,

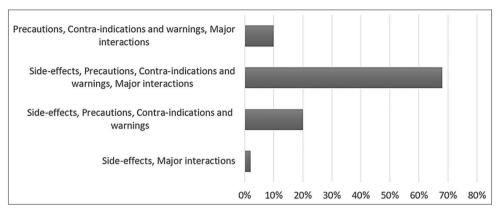


Figure 4: Response to question: What should the safety information contain?

32% felt that sometimes it was not given importance and 15% felt like that was not the case. Table 1 reflects what the residents thought should be given importance in the DPL.

We assessed practices among the residents regarding their preferences regarding presentation of scientific data, accuracy, and authenticity of scientific claims and presence of any possible bias and whether practicing habits are affected by DPL. When asked about which pictorial diagrams most affected their prescribing habits, 63% said that they preferred pictures, 26% preferred scientific tables, and 11% preferred scientific graphs. It was also observed that 41% of students do not check the original article(s) of the reference to the claim(s) in the DPL, 40% check sometimes while only 19% check for the accuracy and authenticity of the claim(s). About 35% of students observed for any bias or any discrepancy in observation in the promotional literature, 38% observed for it sometimes, and 27% did not observe for it at all. Just about less than half of the students (46%) claimed to not observe for any conflict of interest in the references mentioned for the claim(s) while 31% observed sometimes and 23% claim to always observe for conflict of interest. We also asked whether DPLs affected their prescribing habits and 38% claimed that they sometimes did, 32% claimed that they did affect, and 30% refused that they affected their prescribing habits at all.

DISCUSSION

The WHO and OPPI have set standards, globally and in India, respectively, to be followed in regard to the ethical promotion of medicinal products. "The WHO ethical criteria for medicinal drug promotion say that 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." [6] Furthermore, "OPPI defines pharmaceutical product as all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a health-care professional, and which are intended for use in the diagnosis, treatment, or prevention of

Table 1: PG residents' perspective regarding what should be given importance in the DPL

Criteria	Important (%)	Partially important (%)	Not required (%)
Brand name	44	47	9
Generic name	95	5	0
Approved indication	83	15	2
Content of active ingredient	88	12	0
Dosage form or regimen	90	10	0
ADR profile – side effects, precautions, contraindications, and warnings	96	4	0
Drug interaction	79	19	2
Contraindications	89	11	0
Cost and comparison with other drugs	26	72	2
Name and address of manufacturer	54	42	4
References to scientific literature	31	54	15

DPL: Drug promotional literature

disease in humans, or to affect the structure or any function of the human body."[9] These standards exist to prevent pharmaceutical companies from making false or exaggerating claims. According to the regulations implemented by the FD&C Act and FDA, promotions (such as promotional labeling for drugs and devices and advertisements for prescription drugs and restricted devices) that make claims about a product are considered misleading if they do not mention the product's potential risks.[10] 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] According to studies conducted by Dixit et al. and Chitnis et al., most respondents felt that drug promotion affects the prescriber's attitude.^[7,8] Hence, it is of utmost importance for prescribers to be able to critically appraise DPLs, and an awareness should be created from the beginning of their careers. Therefore, we conducted

a study to understand the knowledge, attitude, and practices of postgraduate resident doctors in a tertiary care hospital toward DPL. In doing so, we found that most PG residents lacked a sound knowledge regarding ethical DPL, but they contributed significantly toward their prescribing habits.

Ganashree et al. observed in their study that none of the DPLs they reviewed followed all of the WHO criteria.[3] In our study, we found that a high percentage of resident doctors were unaware of the WHO criteria which is also reflected in the study conducted by Jaiswal et al.[12] It is important for practicing doctors from all areas of specialties to be aware of the guidelines and criteria that have been set since they may affect their prescribing habits as observed by our study and further supported by Chitnis et al.[8] According to the WHO criteria, both brand name and generic name are to be mentioned on the promotional literature, but we found that only half of the residents were aware of it but most were of the opinion that generic name is not given enough importance on the promotional literatures. The vast majority seemed to know what the complete information about a drug should mention and what the safety information should contain in a DPL. In our study, we also observed that 42% of the residents knew that the name and address of the manufacturer were to be mentioned while 45% thought the name, address, and private phone number, 4% felt name and private number, and 9% felt that only address of the manufacturer was necessary. [6] Only 38% of the residents were able to choose the correct method of referencing from the options given and only 19% actually cross referenced the claims even though 68% of them knew that it was mandatory to check for reference of the claims made in a DPL. Studies conducted by Agrawal et al. and Jyothi, showed that most of the medical undergraduate students were of the opinion that updates from clinical trials were of utmost importance and have the most influence on the prescription of the physicians. [13,14] Mali et al. and Cooper and Schriger discovered in their study that the maximum number of references given in the DPL were from journal articles and almost one-third of the claims made had no references.^[15,16] Therefore, it is essential for physicians to check whether the references of the claims given in the DPL are accurate and reliable. A large number of DPL tend to print unrelated, eye catching, and big pictures to catch the eye of the prescriber as well as the consumer and they take up most of the space leaving little space for the essential information.^[15,17,18] In contrast, in our study, majority of the residents opined that the pictures on DPLs were relevant and they also preferred pictures over scientific graphs, pseudographs, and scientific tables. We also found that majority residents claimed that the images given in a drug promotion help to change the impression of the drug in their minds most of the times. Hence, the visual representation in DPLs needs to be of the appropriate size and relevant to the drug being promoted. Sharmin et al. discussed in their study that a bias existed in DPL and most of them tend to focus only on the positive aspects of the drug. [19] Either author affiliation to the manufacturer of the product or sponsorship was found

by the Cooper *at al.* study, in a large proportion of the original researches that were cited in the DPLs.^[18] This stresses on the need to look for any conflict of interest, biases, or inaccuracy in the claims mentioned in DPL. Only about a third of residents claimed to always look for biases in accuracy and most of them claimed to not check for conflict of interest in our study.

There were some limitations to our study. It was conducted only among medical postgraduate residents at a single center and it would be more beneficial if it is conducted at multiple sites among all practicing physicians.

CONCLUSION

In our study, we observed that there was a lack of knowledge regarding the guidelines for ethical drug promotion and the prescribing practices were influenced by DPLs. Hence, there is a need to educate physicians early into their careers about the ethical guidelines set for assessing DPLs. This will enable them to understand and assimilate the information in a more critical manner and they will be able to routinely assess DPLs for any inaccurate, exaggerated, or other type of misinformation. In turn, it will encourage a rational use of drugs with safer prescribing habits.

REFERENCES

- 1. Sonwane PG, Karve AV. Article Drug promotional literature: Does pharmaceutical industry follow WHO guidelines? Int J Basic Clin Pharmacol Orig Res 2017;6:1790-3.
- 2. Jadav SS, Dumatar CB, Dikshit RK. Drug promotional literatures (DPLs) evaluation as per World Health Organization (WHO) criteria. J Appl Pharm Sci 2014;4:84-8.
- 3. Ganashree P, Bhuvana K, Sarala N. Critical review of drug promotional literature using the World Health Organization guidelines. J Res Pharm Pract 2016;5:162.
- 4. Shubha R, Taj S, Bindumathi PL. A cross sectional study of drug promotional literatures in a tertiary care hospital. Int J Basic Clin Pharmacol Orig Res 2017;6:137-40.
- Stryer D, Bero LA. Characteristics of materials distributed by drug companies. An evaluation of appropriateness. J Gen Intern Med 1996;11:575-83.
- World Health Organization. Ethical Criteria for Medicinal Drug Promotion. Geneva: World Health Organization; 1988. Available from: http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip08e/whozip08e.pdf. [Last accessed on 2020 Jul 20].
- Dixit R, Patil P, Chandrashekar R, Madhuri S, Mane A. Drug promotional activities as a source of medical information and its influence on prescribing. Int J Pham Biol Sci 2014;4:113-9.
- 8. Chitnis K, Limaye A, Bhosale M. Pharmaceutical promotional literature: Opinions of physicians in a tertiary care hospital in Mumbai. Int J Basic Clin Pharmacol 2013;2:541-7.
- Organization of Pharmaceutical Producers of India (OPPI). OPPI code of Pharmaceutical Marketing Practices; 2019. Available from: https://www.indiaoppi.com/wp-content/uploads/2019/12/OPPI20Code20of20Pharmaceutical20Practices2020191.pdf.

- [Last accessed on 2020 Jul 18].
- 10. Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion: ucm 155480.
- 11. Wazana A. Physicians and the pharmaceutical industry: Is a gift ever just a gift? JAMA 2000;283:373-80.
- 12. Jaiswal S, Dhruw TS, Hishikar R, Sheohare R, Halwai A. Assessment of knowledge of medical post graduate students regarding promotional drug literature using WHO criteria. Indian J Pharm Pharmacol 2018;5:198-201.
- 13. Agrawal R, Jaiswal MK, Sharma SK, Sharma R. Knowledge and attitudinal survey of drug promotional literature among second year undergraduate students: A questionnaire based study. Int J Basic Clin Pharmacol 2019;8:2548-5.
- 14. Jyothi DB. A questionnaire-based survey on knowledge and attitude towards drug promotional literature among second year under graduate students at tertiary care hospital. Natl J Physiol Pharm Pharmacol 2020;10:257-61.
- 15. Mali SN, Dudhgaonkar S, Bachewar NP. Evaluation of rationality of promotional drug literature using World Health Organization guidelines. Indian J Pharmacol 2010;42:267.
- 16. Cooper RJ, Schriger DL. The availability of references and

- the sponsorship of original research cited in pharmaceutical advertisements. CMAJ 2005;172:487-91.
- 17. Sayyad H, Ghongane BB, Saache S, Tiwari S. Teaching critical appraisal of drug promotional brochures on ability of medical students to identify violations of existing WHO guidelines. J Dent Med Sci 2017;16:43-8.
- Cooper RJ, Schriger DL, Wallace RC, Mikulich VJ, Wilkes MS. The quantity and quality of scientific graphs in pharmaceutical advertisements. J Gen Intern Med 2003;18:294-7.
- 19. Sharmin R, Sharmin ZR, Mosaddek AS, Islam MZ, Rahman MF, Parvin R, *et al.* Medicine promotional literature as a source of updated information in Bangladesh: Do those advertising literatures promote continued medical education or deceptive advertising? Acta Med Int 2017;4:20.

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