

DOES THE PROMOTION OF PHARMACEUTICAL PRODUCTS IN SUDAN COMPLY WITH THE ETHICAL CRITERIA? PERCEPTION AND CURRENT PRACTICES OF PHARMACEUTICAL REPRESENTATIVES IN KHARTOUM STATEAhmed Tagelsir*¹ and Awatif Esam²¹M.Sc, Department of Pharmacology and Therapeutics, National University –Sudan.²B. Pharm, Department of Pharmacology and Therapeutics, National University –Sudan.

*Corresponding Author: Ahmed Tagelsir

M.Sc, Department of Pharmacology and Therapeutics, National University –Sudan

Article Received on 24/08/2016

Article Revised on 15/09/2016

Article Accepted on 06/10/2016

ABSTRACT

Background: The objectives of this research were to assess the promotion of the pharmaceutical product in Sudanese market and its compliance with ethical parameters and recommendations. Also the research addressed the perceptions of the pharmaceutical representatives on the influence of their promotion on the prescription patterns of doctors and assessed the awareness of medical representatives about ethical aspects of pharmaceutical promotion.

Methods: This was a descriptive cross-sectional study. About 127 medical representatives of pharmaceutical companies were included using a pre-tested questionnaire in the period from January to April 2016. **Results:** About 94.5% of pharmaceutical representatives reported they used free medical samples, gifts and brochure and thought that these have an impact on prescribing behaviors of the doctors. Almost 42.5% of them considered giving free drug samples to prescribers was the most effective tool in promotion. From the participants pharmaceutical representatives, about 74% claimed that they had the sufficient knowledge about the drugs they promoted; and 67.7% were familiar with interactions and contraindications. Moreover, about 81.9 % of medical representatives thought that generally the promotional practice of pharmaceutical companies wasn't complied with ethical standards. The majority (73.2%) of respondents believed that the companies' financial benefits would be affected negatively if they follow the ethical requirements for promotion. **Conclusion:** the study revealed that there was poor compliance to the pharmaceutical promotion. An important issue to be appropriately addressed is the common perception of pharmaceutical representatives that complying with ethical criteria of promotion would negatively influence the companies' profits.

KEY WORDS: Ethical criteria, Medicines promotion, pharmaceutical representatives.

INTRODUCTION

Pharmaceutical promotion refers to all informational and persuasive activities by manufacturers and distributors which are meant to induce the prescription, supply, purchase and/or use of medicinal drugs.^[1]

Scientific knowledge about medicines is very important for health of the patient and rational use of medicine.^[2] Although there are many sources of medicine information, drug promotion has become a matter of interest over the recent years. It is very important to understand the effects that drug promotion has on prescribing and the use of medication bearing in mind the financial burden on the pharmaceutical companies and the drug consumers.^[2,3] Doctors are the main targets for the promotional activities of pharmaceutical companies in developing countries. With the power to prescribe and a high status in society their opinion of a pharmaceutical product very often determines its sales success.^[3]

Similar to other industries, the main objective of pharmaceutical marketing is to increase the profitability of the organization by accommodating the needs and wants of consumers. In different commercial industries other than pharmaceuticals, it is much easier for the customer to make the choice to which brand and item ought to be obtained consistent with their necessities and prerequisites. In contrast, in the pharmaceutical marketing, customers and the people who consumes fall in two distinctive classes.^[4,5]

Promotion should be in keeping with national health policies and in compliance with national regulations, as well as with voluntary standards where they exist. All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or activities by manufacturers statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. The word "safe" should only be

used if properly qualified. Comparison of products should be factual, fair and capable of substantiation. Promotional material should not be designed so as to disguise its real nature.^[1,6]

More than eighty percent of physicians see drug representatives or sales personnel regularly.^[7] The interpretation of what is ethical varies in different parts of the world and in different societies and is affected by cultural, environmental and religious factors.

This study aimed to assess the promotion of the pharmaceutical products in Sudanese market and its compliance with ethical parameters and recommendations. Also the research addressed the perceptions of the pharmaceutical representatives on the influence of their promotion on the prescription patterns of doctors and assessed the awareness of medical representatives about ethical aspects of pharmaceutical promotion.

MATERIALS AND METHODS

Study design: This was a descriptive cross-sectional study.

Inclusion criteria: all adult medical representatives who were working at Khartoum state and willing to participate in the study were included in the research.

Exclusion criteria: medical representatives who refused to participate in the study were excluded.

Sample size and sampling technique: About 127 medical representatives of pharmaceutical companies were included using a pre-tested questionnaire in the period from January to April 2016. Medical representatives who were working in Khartoum State at the study period were addressed using convenient sampling method. They were targeted at the hospitals and main polyclinics. Those who accepted to participate after clarification of study objectives were asked to fill a pretested questionnaire.

Data analysis

Data was processed by the Statistical Package for Social Sciences (SPSS), (Version20). Frequencies and proportions/percentages were used to describe all variables. Logistic regression analysis was performed. Participants' background characteristics also tested for possible associations. The 5% level of significance was used as the cut off for statistical significance.

RESULTS

About 76.4% of the participant pharmaceutical representatives were male. The majority (89.9%) of the respondents aged 22-28 years and another 8.7% were 29-35 years old. About 72% of the studied representatives had an experience as pharmaceutical representatives for 1-5 years and the remaining (28%) for 5-10 years. Almost 63% of the respondents reported that they

sometimes used medical jargons while they communicated with prescribers compared to 26% who reported they used it all the time in their communications.

Regarding their perception, about 94.5% of the respondents admitted that providing the promotional tools (namely; free medical sample, brochures and gifts) to the prescribers would affect the prescribing decision. However, almost 85% of the participants claimed that using free medical samples was highly important in the promotion of drugs.

In response to a question on the most effective promotional tools to be used to promote medications for prescribers, responses varied from free medical samples (42.5%) to gimmicks (36.2%) and brochures (21.3%). About 48% of the respondents denied that they had never promoted drugs which they hadn't confidence on their effectiveness, while about 44.1% admitted that they did so sometimes. Near 82.7% of the representatives claimed that they checked the expiry date of the free samples before giving them to the prescribers.

About 45.7 % of the study sample answered positively when asked whether they have received any requests from the doctors to sponsor their travel for a conference or scientific sessions. In addition, almost 35.4% reported that they have received other requests for non scientific purposes (i.e. provide tools or furniture for their clinics). About 29.1% of medical representatives admitted that they had received requests from doctors to pay for personal items.

Almost 89.8% of the participants believed that using free medical samples and gifts to promote medications was ethically accepted by them. This was in contradiction to the perception of the same sample where only 38.6% considered offering other services than scientific-oriented tools for prescribers to be ethical too. In general, near 82.7% of the representatives claimed that they were aware with the ethical criteria and compliance guidelines for the pharmaceutical promotion.

Concerning the knowledge of the medical representatives, one quarter of the sample (25.2%) rated themselves as not having the adequate knowledge about drugs they promoted to doctors. Moreover, about 31.6% of them admitted they haven't sufficient information about interactions and contraindication of the drugs they promoted. About half of the studied sample had not been trained adequately about the medications they should promote by their pharmaceutical companies (of them, 5% had never any training sessions).

DISCUSSION

The research revealed that the vast majority (95%) of the representatives rely mostly on the free medical samples and gifts as important tools to promote their medicines to prescribers. These respondents believed that offering

these tools would affect the prescribing decisions of the doctors.

The results showed that 42.5% of medical representatives thought that providing free samples to be the most important tool of pharmaceutical promotion, while 36.5% used gifts and 21.3% ranked brochures as the most effective tools. The results of a similar study revealed that 56% of medical representatives preferred free samples for their promotion.^[8] These findings contradicted with the WHO ethical criteria of pharmaceutical promotion about presenting free sample of legally available prescription drugs which recommended to be provided in modest quantities to prescribers, generally on request.^[1]

Moreover, it is founded that 89.8% of the respondents believed it is ethical to use free samples and gifts to promote medications. Almost 61.4% of the sample considered offering services for prescriber in order to promote drug unethical. This finding disagrees with another study where 90% of the studied population that considered it wasn't ethically wrong to use free samples.^[8]

A similar descriptive, hospital-based study was carried out in Khartoum State teaching.^[9] The research addressed the perception of the doctors on the role that pharmaceutical representatives play. The results indicated that 79.1% of doctors claimed that they were influenced by discussion with medical representatives; from whom about 98.6% stated that they were positively influenced. Almost 82% of surveyed doctors considered that the most un-ethical method of promotion is giving financial incentives to prescribers. About 91.6% of the interviewed doctors believed that information provided by medical representatives are valuable. Almost 99.5% of the respondents reported that they use this information particularly for newly registered medicines.^[9]

In a research for the types of services that medical representatives received by doctors to be offered, it was found that 45.4% of prescribers requested to travel for conferences, 35.4% asked for furniture or tools for their clinics, 29.1% requested personal services, 24.4% demanded sponsorship for workshops and 18.9% requested other services.^[10] Another U.S study found that 8 out of each 10 doctors received gifts, usually free food at their workplace, another 8 out of 10 received free drug samples and 4 out of each 10 had their expenses paid to attend meetings and conferences.^[11] However, WHO ethical standards don't allow p gift or services just allow to free sample and not in all time and status.

Another research showed that about 82.7% of medical representatives claimed that they were aware about ethical criteria of pharmaceutical promotion while 56.7% of them were familiar specifically with WHO ethical criteria and 43.3 had never known about it.^[12]

The WHO Ethical criteria of pharmaceutical promotion requires the representatives to be familiar with and fairly tell the prescribers about major indication(s) for use and major precautions, contra-indications and warnings.^[1] The research illustrated that 74% of the studies sample claimed they knew pharmaceutical information about the drugs they promoted, 67.7% reported they were familiar with interactions and contraindications. Also it was shown that about 57.5% of the representatives depended on their own knowledge of pharmacological, clinical and chemistry information of drug. These findings are of interest because researches revealed that doctors rely on the information about drugs provided by pharmaceutical representatives. Almost 97.5% of surveyed doctors considered information from medical representatives of value and reliable.^[13] This necessitates that the pharmaceutical companies and regulatory bodies to ensure that the scientific knowledge of the representative about drugs to be accurate, precise and updated so as the doctors could prescribe accordingly.

The results of this study revealed that 50.4% of the respondents had been provided training courses or scientific sessions by their employers to update their knowledge on drug promotion. Nearly, 65.4% of the surveyed medical representatives used internet as a reliable source of information about drugs. In their study in Saudi Arabia, the researchers illustrated that more pharmacists perceived drug companies as a useful way to gain knowledge about drugs than physicians. A higher proportion of both groups were accepting drug promotion than those skeptical about it.^[14] According to the WHO ethical criteria of pharmaceutical promotion, employers are responsible for the basic and continuing training of their representatives. Such training should include instruction regarding appropriate ethical conduct taking into consideration the WHO criteria. In this context, exposure of medical representatives and trainees to feedback from the medical and allied professions and from independent members of the public, particularly regarding risks, can be salutary.^[1]

CONCLUSION

The study revealed that there was poor compliance to the pharmaceutical promotion. An important issue to be appropriately addressed is the common perception of pharmaceutical representatives that complying with ethical criteria of promotion would negatively influence the companies' profits.

RECOMMENDATIONS

The formulation of national code of ethics for the promotion of medicines is highly essential. Also it is necessary to develop and update the legislations and laws that govern the practices of promotions to comply with national consensus and the WHO ethical standards. Moreover, the education institutes should give a great consideration to aware the pharmacy students with these ethics and standards to minimize the malpractices that might arise.

REFERENCES

1. WHO Technical Report Series, The use of essential drugs: second report of the WHO Expert Committee on the Use of Essential Drugs, Report No. 1985; 722: 43.
2. Gehlbach S, Wilkison W, Clapp N, Finn A, Taylor W, Rodell M. Improving Drug Prescribing in a Primary Care Practice. *Medical Care* 1984; 22: 193-201.
3. James C, Peabody J, Solon O, Quimbo S, Hanson K. An Unhealthy Public-Private Tension: Pharmacy Ownership, Prescribing, and spending in the Philippines. *Health Affairs* 2009; 28: 1022-1033.
4. Pitt L, Nel D. Pharmaceutical promotion tools – Their relative importance. *European. J Marketing* 1988; 22: 7-14.
5. Wazana A. Physicians and the pharmaceutical industry, is a gift ever just a gift? *JAMA* 2000; 283: 373-80.
6. Campbell E, Gruen R, Mountford J, Miller L, Cleary P, Blumenthal D. A national survey of Physicians-Industry relationships. *N Engl J Med* 2007; 356: 1742- 1750.
7. Liu S. A comparison of pharmaceutical promotional tactics between Hong Kong and China. *J Business and Industrial Marketing* 1995; 10: 34-43.
8. Streiner D, Norman G. *Health Measurement Scales – A practical guide to their development and use*, 2nd edition, Oxford, Oxford University Press, 2001; 123-127.
9. Liela H, Habab k. The Impact of Drug Promotion Practices on Health Professional Prescribing in Teaching Hospitals, Khartoum State. *Sudan Journal of Rational Use of Medicine* 2012; 1: 8-9.
10. Spurling G, Mansfield P, Montgomery B, Lexchin J, Doust J, Othman N, et al. Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review. *PLoS Med* 2010; 7(10): e1000352.
11. Grande D. A national survey of physician-industry relationships. *N Engl J Med*. 2007; 357(5): 507-8
12. Narendran R, Narendranathan M. Influence of pharmaceutical marketing on prescription practices of physicians. *J Indian Med Assoc*. 2013; 111(1): 47-50.
13. Grande D. A national survey of physician-industry relationships. *N Engl J Med*. 2007; 357(5): 507-8.
14. Zaki N, Assess exposure and attitudes to, and acceptance of, drug promotion among pharmacists and physicians. *Saudi Pharm J*. 2014; 22(6): 528–536.