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Knowledge, Attitude & Practices towards Ethical Promotion of Pharmaceutical Products with Special Reference to IFPMA Guidelines among Pharmaceutical Executives & MCI Guidelines among Physicians in Mumbai



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ABSTRACT

There is a minor demarcation line between the ethics and the law. The medical profession is considered as a noble profession, and medical doctors have the moral duty to follow the ethics. It is well-known fact that the pharmaceutical industry invests heavily in the promotion, and it has used a variety of promotional strategies to stimulate sales of pharmaceutical drugs. Payments and gifts from the pharmaceutical industry to physicians are ubiquitous despite ample evidence demonstrating their influence on prescribing preferences and decisions. There is no ethical basis for allowing these types of financial exchanges (Payments and gifts) to continue. Some pharmaceutical industries did not follow the WHO guidelines while promoting their products, thus aiming to satisfy their commercial motive rather than fulfill the educational aspect of promotion. Medical representatives provide incomplete medical information to influence prescribing practices; they also offer incentives including conference sponsorship. Doctors may also demand incentives to prescribe the specific product. Current relationships are eroding public respect for medical professionals; further loss of social trust threatens to undermine the profession's future. Though there are ethical guidelines for promotion of pharma products, it is unclear to what extent they have been implemented in actual practice. In this study, we assessed the knowledge, attitude, and practice (KAP) among the executives of pharmaceutical companies and the physicians. Participants were screened according to inclusion & exclusion criteria. Informed consent of the participants belonging to both groups was obtained individually & it was strongly mentioned that the identity of the participants will be maintained as strictly confidential. A validated questionnaire was given to participants of both groups (Group A & Group B) & was collected after completion of answering questions by the participants. Assessment of Knowledge, attitude, and practice (KAP) characteristics for IFPMA/MCI was done with the help of collected questionnaire & by using statistical tests. It was found that the participants of Group B were aware of the MCI (75.78%) & also participants of Group A were aware of the IFPMA/OPPI/ IDMA (74.09%) but having fewer practices of ethical promotion both Group A (66.47%) & Group B (68.13%). The KAP of Pharmaceutical Executives (70.94%) was found to be slightly less than the KAP of Medical Practitioners (73.19%). This study helps to find the knowledge of participants about the Ethical promotion of pharmaceutical products. It has assessed the attitude and practice about ethical promotion. This study will definitely help to increase the awareness about the ethical promotion.

INTRODUCTION

The field of ethics is the study of how people try to live their lives according to a standard of “right” or “wrong” behaviour—in both how we think and behave towards others and how we would like them to think and behave toward us.

We would probably arrive at a list of four basic categories:

1. Simple truth (right and wrong or good and bad).
2. A question of someone’s personal character (his or her integrity).
3. Rules of appropriate individual behaviour.
4. Rules of appropriate behaviour for a community or society. ⁽¹⁾

Ethics need to be taken into account when marketing a business. Businesses have a social responsibility. The impact of their product and activities on society must be ethical. Ethical responsibilities refer to the moral basis for business activity and whether what the business does is right. Advertising and promotion are important marketing tools that, when implemented, must be ethical. For example, advertisements should not be offensive or discriminatory. They must also describe the product truthfully so the consumer is not misled as to what they purchase. Sometimes it is hard to decide whether or not a particular method in marketing is ethical or not. ⁽²⁾

The healthcare industry is highly regulated and most pharmaceutical companies are committed to operating within the law. They have developed their own policies and guidance to ensure that all employees meet the highest ethical standards in their work. An Employee Guide to Business Conduct explains what the Code means in practice. Most pharmaceutical companies are committed to sales and marketing activities that are ethical, responsible, principled and patient focused. They conform to the high, ethical, medical and scientific standards that are set by governments and regulators. On top of the regulatory requirements of governments, they govern their sales and marketing activities through company policy, on Pharmaceutical Marketing and Promotion Activity, and through industry and company marketing codes. ⁽³⁾

The medical profession is considered as a noble profession because people compare doctor with God, so the doctors have the moral duty to follow the ethics. There is a minor demarcation line between the ethics and the law. The law is governed by the court and can be challenged in the

courts, but ethics come and are governed by inner soul and consciences of the human beings. Evidence and ethics are implicitly related, evidence-based practice may be more ethical and ethically sensitive practice more effective. Health promotion practice would benefit by deliberately bringing evidence and ethics together; to specify the concepts, values, and procedures inherent in each; and to achieve this integration through a detailed study of current practices in health promotion. The definition of health promotion is contested and values were driven, but researchers and practitioners widely acknowledge that health promotion occurs at different levels from standardized top down national programs to unique grass-roots initiatives. But still, the central problem in the ethics of health promotion is conceptual vagueness. Health promotion charters promote ethically relevant concepts such as justice, health equity, enablement, and empowerment, and health promotion professionals are undoubtedly deeply committed to these concepts and strive to turn them into sound practices.⁽⁴⁾

The pharmaceutical industry invests heavily in the promotion, and it has used a variety of promotional strategies to stimulate sales of pharmaceutical drugs.⁽⁵⁾ Payments and gifts from the pharmaceutical industry to physicians are ubiquitous despite ample evidence demonstrating their influence on prescribing preferences and decisions. It is possible that market forces and evolving regulatory policies that increase generic competition, expand the role of prescription drug formularies, or reduce profit margins in other ways could decrease the importance of detailing and gifts over time. However, it does not diminish the significance of addressing this issue. In addition, how diminished profit margins might affect marketing decisions by pharmaceutical firms or investments in research and development has not been well described. Gifts associated with pharmaceutical detailing are motivated by a single goal, to increase the sales of a company's products.⁽⁶⁾ There is no ethical basis for allowing these types of financial exchanges to continue. Financial relationships with the sole purpose of influencing prescribing should not be disclosed but prohibited. Current relationships are eroding public respect for medical professionals; further loss of social trust threatens to undermine the profession's future. Regulation alone can't fully address the negative influences of marketing.

In India the Drugs and Cosmetics Act, 1940 is one of the major regulatory norms based framework which actively decides on the entry of pharmaceutical products into the market. The purpose of the Drugs and Cosmetics Act is to regulate the sale, manufacture, distribution, and sale of drugs in the country. Also for physicians The Indian Medical Council Act, 1956, and the Code of Medical Ethics, 2002, govern the conduct of physicians in India.

Advertising, as distinct from the promotion is generally used as a direct measure to popularize a particular drug or a remedy. It is governed by the Drugs and Magic Remedies Act (discussed in chapter III). The Drugs Enquiry Committee, 1930 under the chairmanship of Sir R. N. Chopra was the first authoritative attempt by the Government to look which scrutinized the pamphlets of drugs which made spurious claims.⁽⁷⁾

The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines. In India in British Raj The Indian Medical Degrees Act, 1916 An Act to regulate the grant of titles implying qualification in Western medical Science and the assumption and use by unqualified persons of such title.⁽⁸⁾ On 30 September 1956 The Indian Medical Council act, 1956 is formed by Govt. of India which is an act to provide for the reconstitution of the medical council of India and maintenance of a medical register for India and for matters connected thereby. In 2002 MCI adapts the Code of Ethics Regulation. This relates to the ethical aspects of the physician regarding patients, pharmaceutical promotion, and society.

Codes for Pharmaceutical Companies and Physician during Promotional Activity

A) International Federation of Pharmaceutical Manufacturers Association (IFPMA) Code For Pharmaceutical Marketing Practices

The globally pharmaceutical company developed the code for ethical promotion. They set up the IFPMA Code. The code states that the standard of promotional material should follow consistency of product information, accurate and not misleading, substantiation. Also, it gives guidelines regarding promotional material and also the interaction with healthcare professionals for promotional activity. The IFPMA Code applies to IFPMA's member associations and companies. Pharmaceutical companies that are members of neither IFPMA nor its affiliated member associations fall outside the reach of the IFPMA Code. IFPMA encourages such companies and other organizations marketing healthcare products or services to healthcare professionals to follow ethical promotion standards similar to those set forth in the IFPMA Code.

B) Organization of Pharmaceutical Producers of India (OPPI) Code For Pharmaceutical Practices

OPPI established in 1965. It is a premier association of research and innovation driven pharmaceutical companies in India and scientific and professional bodies. It is an active member

of IFPMA, Geneva. OPPI is a signatory to the Code and hence it is obligatory on the Member Companies to adhere to the principles enshrined in this code. As suggested by the IFPMA code, OPPI has adapted the code to provide specific local guidelines. The OPPI Code includes standards for the ethical promotion of pharmaceutical products to healthcare professionals and helps ensure that member company's interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such. OPPI member companies must comply directly with applicable national codes as and when they come into existence. OPPI member companies must comply directly with applicable national codes as and when they come into existence also covers interactions with healthcare professionals, organizations/associations of healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member companies should, of course, comply with these local laws, regulations and/or codes.

C) Indian Drug Manufacturers Association Marketing Code for Pharmaceutical Industry (MCPI)

On 31st December 2012, the Indian Drug Manufacturers association provides the code for marketing practices. To avoid any inappropriate practice and maintain transparency the companies which are the members they advised to follow this code. It also states that pharmaceutical industry self-regulates the marketing practices by defining marketing code for the pharmaceutical industry and follows international norms.

Medical Council of India

In exercise of the powers conferred by Section 33 of the Indian Medical Council Act, 1956 (102 of 1956), the Medical Council of India with the previous sanction of the Central Government, and made the Regulations to amend the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. These Regulations may be called the "Indian Medical Council (Professional Conduct, Etiquette, and Ethics) (Amendment) Regulations, 2009. The clause 6.7:- "6.8 Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry. 6.8.1 In dealing with Pharmaceutical and allied health sector industry, a medical practitioner shall follow and adhere to the stipulations towards promotional activity.

Rationale of study

The pharmaceutical industry invests heavily in the promotion, and it uses the variety of promotional strategies, financial exchanges (payments and gifts) to physicians or healthcare professionals to stimulate sales of pharmaceutical drugs. On the other side, doctors may also demand incentives. So, it is the need of time to study whether healthcare professionals follow the regulations of MCI and whether the pharmaceutical companies follow their regulations e.g. IFPMA/OPPI/IDMA?

LITERATURE REVIEW –

Jul-2013 -

The study done by Czerw, A & Marek, EM in 2013 had shown that the marketing elements include, apart from the product, the price, and the distribution, also promotion which is inextricably linked with advertising. It is a special type of information message that aims at evoking a specific consumer's attitude and belief. Advertising of medicinal products is subject to detailed legislative and non-legislative regulations. The aim of their article is to present legal regulations within the scope of advertising of medicinal products and violations of these regulations based on example decisions of the Main Pharmaceutical Inspector issued in the years 2008-2010.⁽⁹⁾

Abundant rulings of the Main Pharmaceutical Inspector proved (Disguised) that both advertisements addressed to public attention and those addressed to specialists often diverge from the criteria determined by the Pharmaceutical Law. In the face of still increasing violations of the provisions of the Pharmaceutical Law act, it seems that introducing a ban on advertising or any possible financial sanctions is not a sufficient punishment for advertisers. Thus, an introduction of other, more rigorous legal regulations as a deterrent for those involved in illegal advertising of medicinal products ought to be considered.

May-2013-

In 2013, Mackey, TK & Liang, BA observed that pharmaceutical marketing has become a mainstay in U.S. health care delivery and traditionally has been directed toward physicians. In an attempt to address the potential undue influence of industry and conflicts of interest that arise, states and the recently upheld health care reform act have passed transparency, or "the sunshine," laws requiring disclosure of industry payments to physicians.⁽¹⁰⁾

Aug.2012 -

Pharmaceutical representatives are an important promotional tool for pharmaceutical companies. This cross-sectional, exploratory study was done by Idris, KM, & et.al, in 2012 aimed to determine pharmaceutical representatives' beliefs and practices about their professional practice in Sudan. A random sample of 160 pharmaceutical representatives was interviewed using a pretested questionnaire. ⁽¹¹⁾

Only 65.6% agreed that they provided full and balanced information about products. Not providing balanced information was attributed by 23.1% to doctors' lack of time. However, 28.1% confessed they sometimes felt like hiding unfavourable information, 21.9% were sometimes or always inclined to give untrue information to make sales and 66.9% considered free gifts as ethically acceptable. More attention is needed to the dissemination of ethical codes of conduct and training about the ethics of drug promotion for pharmaceutical representatives in Sudan.

2012

The study done by Brody, H in 2012 elaborated more clearly that ethical issues at the interface between the medical profession and the pharmaceutical industry have generally been approached from the vantage point of medical professionalism, with a focus on conflict of interest as the key ethical concern. Although conflicts of interest remain important, other ethical issues may be obscured unless a wider perspective is adopted. Besides medical professionalism, the ethics of the clinical therapeutic relationship, ethics of public health, and business ethics all provide additional insights. ⁽¹²⁾

2010

Although there are few such large social issues in Japan, the relationship between clinical physicians and the pharmaceutical industry in Japan appears inappropriate. A study on the relationship between Japanese clinical physicians and the pharmaceutical industry was done by Miyata, Y. (2010) & revealed that many physicians received "gifts" from pharmaceutical companies. This is one form of evidence for the inappropriate relationship between Japanese physicians and pharmaceutical industries. Recently, many recommendations to realize an appropriate relationship between physicians and the pharmaceutical industry had been published in the U.S. However, discussion concerning the relationship between clinical physicians and pharmaceutical companies in Japan was not found active. It was received a lot of financial support

for continuing medical education from pharmaceutical industries. Without such support, it might not be able to maintain the same level of medical education. Understanding such present conditions, everyone related with this, need to discuss the appropriate relationship between clinical physicians & the pharmaceutical industry. ⁽¹³⁾

Oct. 2010

Pharmaceutical companies spent \$57.5 billion on pharmaceutical promotion in the United States in 2004. The industry claims that promotion provides scientific and educational information to physicians. While some evidence indicates that promotion may adversely influence prescribing, physicians hold a wide range of views about pharmaceutical promotion. The objective of this review was to examine the relationship between exposure to information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing. Spurling, GK & et.al, (2010) did not find the evidence of net improvements in prescribing, but the available literature does not exclude the possibility that prescribing may sometimes be improved. Still, it was recommended that practitioners follow the precautionary principle and thus avoid exposure to information from pharmaceutical companies. ⁽¹⁴⁾

2009

The new code by the Pharmaceutical Research and Manufacturers of America eliminated small gifts to physicians such as pens and mugs. However, it does not prohibit sponsorship of hospital-based meals and continuing medical education events. ⁽¹⁵⁾

Recent critiques of the role of pharmaceutical promotion in medical practice invoke a nostalgic version of the 1950s and 1960s medicine as representing an uncomplicated relationship between an innovative pharmaceutical industry and an idealistic and sovereign medical profession-a relationship that was later corrupted by regulatory or business practice changes in the 1980s or 1990s. However, the escalation of innovation and promotion in the pharmaceutical industry at mid-century had already provoked a broader crisis of overflow in medical education in which physicians came to use both commercial and professional sources in an attempt to "keep modern" by incorporating emerging therapeutics into their practices.

Greene, JA & Podolsky, SH. 2009 realized & evaluated that this phenomenon was simultaneously a crisis for the medical profession- playing a key role in attempts to inculcate a "rational therapeutics"-and a marketing opportunity for the pharmaceutical industry, and produced the

structural foundations for contemporary debates regarding the role of pharmaceutical promotion in medical practice. Tracing the issue from the advent of the wonder drugs through today's concerns regarding formal CME, they document how and why the pharmaceutical industry was allowed (and even encouraged) to develop and maintain the central role it now plays in postgraduate medical education and prescribing practice. ⁽¹⁶⁾

According to Alam, K & et.al, (2009), there are various methods by which pharmaceutical companies promote their drugs. The most common methods are drug promotion using medical representatives (MR), distributing free samples, advertisement through pamphlets, radio, TV and sponsoring medical events. ⁽¹⁷⁾

The monetary involvement in drug promotion is quite high. A study suggests that the amount of money involved in drug promotion by the manufacturers is at least 30 times more than the money spent on drug information by the government. ⁽¹⁹⁾

It was mentioned by Lexchin J in 1995 that in the booming pharmaceutical market with competitive and aggressive drug promotion by pharmaceutical companies there is every possibility of the promotion being unethical. At the same time, the information provided by the sales representatives is the only source of information about the medicine in developing countries [ConsumersInternational.Penang:1995]. Moreover, evidence suggests that promotion affects attitudes and behaviour. ⁽²⁰⁾

1998-

The study by Gibbons, RV & et.al, (1998) revealed that gifts of relatively low monetary value and related directly to patient care were more acceptable and not considered unethical by both patients and physicians. This is a matter of concern since they are more likely to be affected by the gifts from pharmaceutical companies. ⁽⁶⁾

AIM

To assess the impact of codes for promotional practices among pharmaceutical companies' executives and physicians

EXPERIMENTAL

Study design

This is the cross-sectional and prospective study where the survey was conducted about Knowledge, Attitude, and Practices towards Ethical codes for promotional activities by pharmaceutical companies and physicians. Hence it was carried out in two groups one group was of executives of pharmaceutical companies and another was of physicians. They were provided with two different questionnaires for these two groups.

Study criteria -

Inclusion criteria:-

The Executives of Pharmaceutical Companies who had voluntarily signed & dated informed consent were enrolled in the study and also the physicians who practiced under the MCI act & voluntarily given informed consent were enrolled in the study.

Exclusion criteria

The management trainees & the interneers were not enrolled in the study. The physicians not under the MCI Act were not enrolled into the study.

Study duration

1 & ½ Years.

Methodology

The study was carried out among two groups, in one group we enrolled the executives from pharmaceutical industries in Mumbai region mostly from marketing sector and in another group there were physicians. Both were provided with the questionnaire and then as per our study objectives, we assessed them in Knowledge, Attitude, and Practices.

Reasons for use of questionnaire:

The questionnaire is a useful method to investigate patterns, frequency, ease and success of use, user needs, expectations, perspectives, priorities, and preferences. User satisfaction with

collections and services shifts in user attitudes and opinions, the relevance of collections and services to user need trends.

About Questionnaire

Questionnaire for our study was mainly in 3 domains. These were knowledge, Attitude, and Practices about the codes and practices about ethical promotion. There were two different questionnaires but these two questionnaires contain these three domains. There are closed-ended questions in both questionnaires. The response was recorded in YES or NO manner. The total number of questions in both questionnaires' is different and their content is different still they focus on those three domains. It was provided to them on paper.

Steps for study:

1. The study participants were pharmaceutical executives from different companies and physicians & were being participated voluntarily in the study after taking informed consent from them.
2. The study participants were provided with the questionnaire as per their field. Data was collected in one visit given to these participants. For filling the questionnaire, sufficient time was given. The approximate time required to fill up the questionnaire was 15-20 min.
3. Then the data was generated from those questionnaires and that was entered into the electronic form by using the computer system.
4. After study period completion, data analysis was done and the result was generated by using appropriate statistical test.

About Confidentiality of Participants in Study

This is a somewhat sensitive issue in the community hence the person to whom we were approached, their all data and information regarding their personal identification or information which can reveal their personal identity that will not be disclosed at any condition to anyone.

Steps for maintaining confidentiality:

Each participant was provided with the code which only can reveal to an investigator. The original document (where data was recorded) and source document from which study data was

obtained i.e. questionnaire were kept confidential as per ethical guidelines. Any identity of the participants will not be revealed in publication.

Sampling technique

For this study the sampling technique was convenient sampling, hence as per our exclusion and inclusion criteria, the participants participated in the study period. It is Non-Probability Purposive type of sampling.

Data collection

Data was collected as per questionnaire and then after it was entered into the computer for analysis purpose. The data which we were not getting that was entered as N/A. Source documents retained safely as per ICH-GCP guidelines requirement.

Ethical consideration

The study was performed in accordance with the ethical principles of the Declaration of Helsinki and that are consistent with Good Clinical Practice and all applicable Indian regulatory requirements including ICMR guidelines & Schedule Y. Information about study participants was kept confidential and managed according to the regulatory requirements.

Statistical methods

The data was compiled in tabular form and was studied in details. Descriptive statistics (Mean, Standard Deviation, Range, and Percentage) was used for analysis of data. The information was presented as percentage characteristic among sample size. Classification of data under different headings in different classes on the criteria was used for the study and analyzed under the instructions of the statistician. Then finally results were produced.

RESULTS

29.41% of Female Physicians while 20.45% of the Female Executives involved in the study.

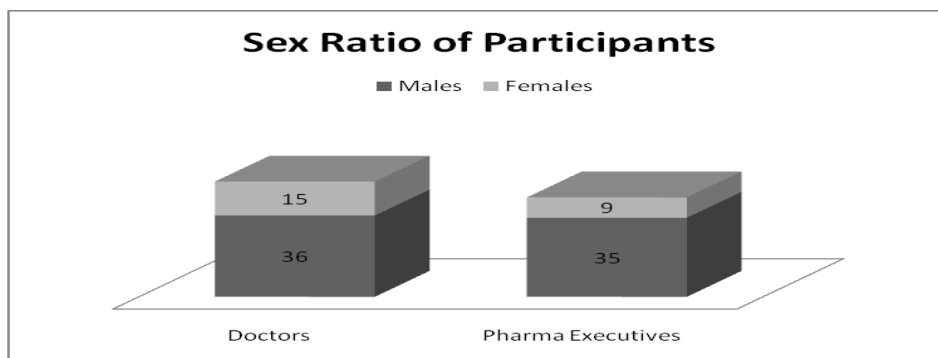


Fig. 1. Sex Ratio of the participants of both groups (i.e. Pharmaceutical Executives & also Physicians group)

76.47% of the General Practitioners were being enrolled in the study.

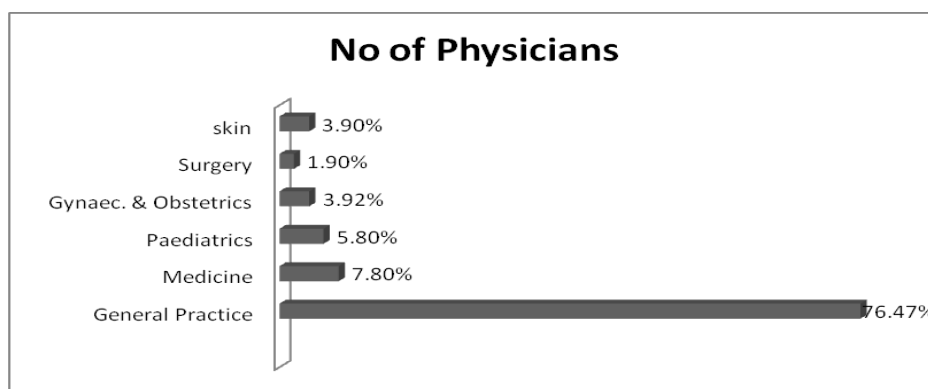


Fig. 2. Number of Physicians with the specialty of practice.

46% of the Executives were from Product management team while 34% of the managers were directly related to Field Promotion.

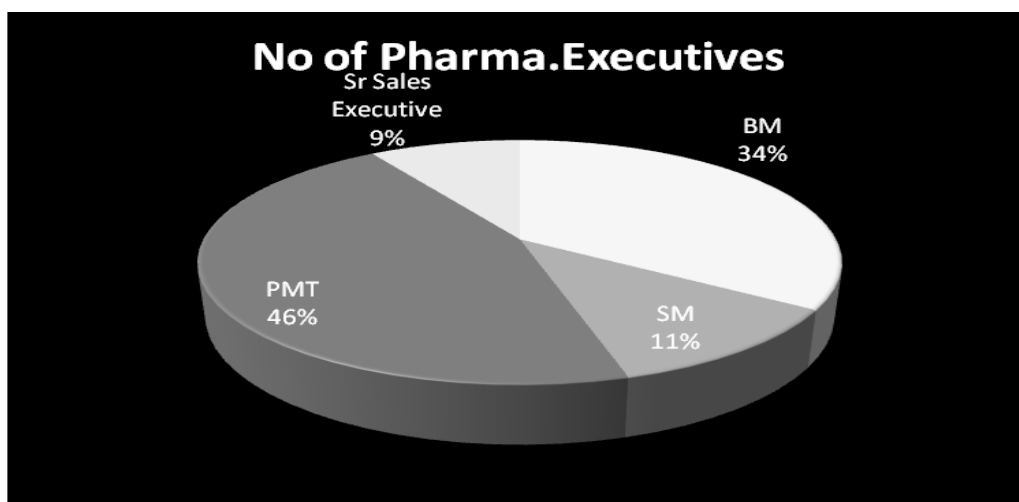


Fig.3. A number of Pharmaceutical Executives with a working designation.

KAP of the participants from both groups indicates that the participants have sound knowledge of their respective guidelines of ethical promotion or code of practice. Also, the attitude towards Ethical promotion is quite satisfactory & positive but the practice of these guidelines is lacking something in both the groups.

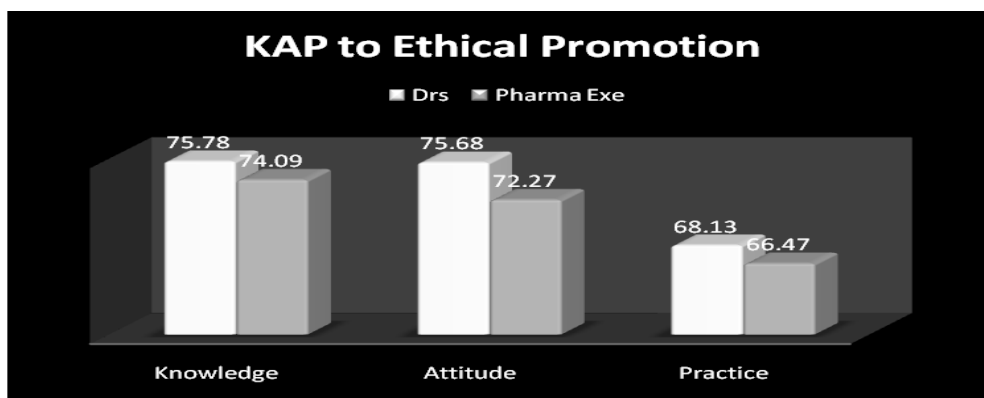


Fig.4. KAP of the study participants.

Table.1: KAP Assessment Questionnaire of Ethical Promotion of Pharmaceutical Products among Physicians

Sr No	For Physicians- KAP Questionnaire	% True Answer
1	Guidelines for doctors by Government of India? MCI /MARD/ IMA/ICMR	90.1
2	The dealing with Pharmaceutical promotion comes under (Professional Conduct/Etiquette/Ethics/GMP)	78.43
3	There are regulations to pharmaceutical companies same as that of physicians? IFPMA/ WHO/ OPPI/All	66.66
4	In MCI guidelines, the substituted clause 1.5 in notification published in Gazette of India on 08.10.2016 is..? (Dr should prescribe drugs with generic names)	70.58
5	In dealing with Pharmaceutical and allied health sector industry, an RMP can do takeout of these? (Gifts/Travel Facilities for CME-Workshop/ Medical Research Funding/Hotel accommodation for Workshop/None)	74.5
6	Do you think that there is a role of ethical guidelines in your routine-practices?	86.27
7	Do you think, whether the ethical-guidelines regarding promotional activities will make the change in routine practices?	68.62
8	Do you think that promotional activities by medical representatives (MR) can	70.58

	help in writing the prescription?	
9	Do you think that promotional activities can help pharmaceutical companies to increase the sale of products?	86.27
10	What do you think, Is the promotional-product made by pharmaceutical company acts as a valuable source of knowledge of that particular product?	66.67
11	Do you ever attend the conference sponsored by any pharmaceutical-company?	58.82
12	Do you update your knowledge regarding pharmaceutical product through ...? (Ethical-promotion/MR/Media,TV,Internet/CME)	72.54
13	Do the pharmaceutical companies offer gifts to physicians?	78.43
14	'The medical representatives (MR) talk only about pharmaceutical-product and not about the market of the product' does this happen?	49
15	Are medical representatives (MR) well trained to explain the things regarding the pharmaceutical-product?	60.78
16	Does it happen that as promotional activities increase, prescription also increase?	76.47
17	In Practice, pharma industry generally does access to physician prescription information. Is it ethical?	78.43
18	Do Physicians give company sponsored educational lectures to other healthcare workers?	70.58

Table.2: KAP Assessment Questionnaire of Ethical Promotion of Pharmaceutical Products among Pharmaceutical Executives

Sr No	For Executives of Pharmaceutical companies- KAP Questionnaire	% True Answer
1	IFPMA is?	75
2	Your pharmaceutical-company follows OPPI/IDMA/IFPMA ethical guidelines or not?	88.63
3	Can the physicians legitimately take gifts from pharmaceutical companies?	75
4	Do you know that OPPI code is based on? IFPMA/PhRMA/ MCI/DCGI	68.18
5	Is it ethically acceptable for Pharma Company to exclude less obvious drug information i.e drug interactions (if these risks are relatively rare) in package insert?	63.63
6	What do you think; Should Drug companies have promotional encounters	68.18

	with physicians?	
7	Do you think that there is the role of ethical guidelines in the promotion of pharmaceutical-product?	75
8	Do you think, whether the guidelines regarding promotional activities will make change in routine practices of pharmaceutical companies?	70.45
9	Do you think that offering gifts to the physicians will make the change in the sales of the pharmaceutical-product?	75
10	Do you think, is it ethical for the pharma company to have access to physician prescription information?	72.72
11	Do your company offer gifts to the physicians?	77.27
12	Do you train/educate your field-force for a promotion of the pharmaceutical-product as per ethical guidelines?	68.18
13	Do you update your knowledge regarding pharmaceutical-promotion through different ways such as conferences/meetings?	61.36
14	Do physicians demand gifts from the medical representatives (MR) in the field?	79.54
15	Does it happen that as promotional activities increase, prescriptions also increase?	72.72
16	Is there any product in your view had been achieving market after promotion with gifts, sponsoring conferences?	59
17	Are all related to making marketing strategies they all executives are aware of these codes for ethical promotion?	56.81
18	Should company refrain from inviting Doctors to promotional meetings & from serving free food?	56.81

DISCUSSION

It was shown by Katz, D et.al, (2003) that professional guidelines recognize industry gifts as a conflict of interest and establish thresholds prohibiting the exchange of large gifts while expressly allowing for the exchange of small gifts such as pens, notepads, and coffee. Considerable evidence from the social sciences suggests that gifts of negligible value can influence the behaviour of the recipient in ways the recipient does not always realize. ⁽⁸⁾

Mali, S.N. et.al, (2010) studied & verified that pharmaceutical industries did not follow the WHO guidelines while promoting their products, thus aiming to satisfy their commercial motive rather than fulfill the educational aspect of promotion. ⁽²¹⁾

Roy, N & et.al, (2007) concluded that medical representatives (MR) provide incomplete medical information to influence prescribing practices; they also offer incentives including conference sponsorship. Doctors may also demand incentives, as when doctors' associations threaten to boycott companies that do not comply with their demands for sponsorship. Manufacturers, chemists and medical representatives use various unethical trade practices. ⁽²²⁾

36.37 % of the pharmaceutical executives told that pharmaceutical companies are only ethically obliged to include the main risks information associated with taking the drug. They should not be obliged to include information about drug-drug interactions (DDIs), especially if these interactions are rare; rather, it is the responsibility of the physician to know this information and to communicate it to the patient.

63.63 % of the pharmaceutical executives told that pharmaceutical companies are ethically obliged to include DDI risks since these have the potential to affect patient health. Physicians cannot be expected to know every risk associated with a drug.

DDIs are a real health threat, especially in complicated cases or in elderly patients, as these patients are likely to take more prescription drugs than the norm. DDIs may adversely affect or harm the patient, and so information about DDIs must be made easily available in the package insert. Since new drugs are constantly being released, it is unrealistic to expect physicians to know this information off the top of their heads. Rather, it is the responsibility of the pharmaceutical company to include these risks. (ConsumerProtectionLawFirms.com, 2012)

68.18 % of the Pharmaceutical Executives said that the promotional encounters will create bias in physicians about medications, influencing their clinical judgments, when really physicians should only be considering patient needs. While 31.82 % of the Pharmaceutical Executives told that promotional encounters with physicians help to educate busy physicians about medical drugs.

21.57% of the physicians told that by having access to physician prescription data, pharmaceutical companies can tailor their interactions to physicians' needs so that physicians are notified only about those medications they are likely to find useful. This approach helps both the

physician and the pharmaceutical company: the physician does not have to deal with irrelevant marketing calls, and the pharmaceutical company has a higher chance of selling its drugs by accessing the physician prescription information.

78.43% of the physicians told that pharmaceutical companies often use this information to provide perks and biased information to physicians, so as to influence their prescription habits. This activity is unethical since physicians' medical decisions should be based on the best interests of patients, not on incentives.

A doctor's prescription record is a powerful tool in a pharmaceutical representative's hands. Although such records can serve as important data sources in medical research, they are also frequently used by pharmaceutical companies to inform drug marketing strategies and to tailor drug marketing to individual physicians.

A pharmaceutical representative may use the prescription information to encourage the physician to write more prescriptions for the company's drug, and fewer for a competitor's drug. Often these representatives are even paid bonuses for increasing company sales. Many physician-pharma interactions also feature incentives, such as pharma-provided gifts or meals. Doctors who receive these benefits may form positive associations with the company, and/or feel obliged to return these favours, potentially biasing their prescription behaviours.

Doctors should be allowed to decide whether or not they want the pharmaceutical industry to have access to their prescription data. Wherever possible, doctors should also strive to obtain drug information from more objective sources than pharmaceutical representatives, who (given their conflict of interest) are more likely to be a biased source of information. Particularly when incentives are involved, physician-pharmaceutical interactions become ethically problematic.

45.19% of the Pharmaceutical Executives told that the marketing activity of inviting doctors to free meals is unethical, as it biases doctors' judgment. Needless to say, if doctors also receive other benefits from the company (besides the free meals) then this is definitely a major breach of ethics, as it may add to the doctor's bias. Although there is supposedly no difference between the original and the generic drug, the doctors may have had no real data on which to justify their preference for the original drug. Doctors should be very conscious of the reasoning behind their use of different medications — "because it is better" is not a sufficient answer to the colleague's inquiry.

56.81 % of the Executives told that it is assumed that both the doctors and the pharmaceutical company are honest and careful to avoid undue influence, making it unlikely that the good meal would skew the doctor's prescription decisions. On the other hand, it is reasonable to believe that the company will present its data in a favourable light, making it important that the doctor also gains first-hand access to the data. The company should also use these meetings as an opportunity to ask doctors for feedback about the quality of its drugs and drug information provided, so as to ultimately improve this quality.⁽²³⁾

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