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ORIGINAL ARTICLE

A nationwide assessment of the knowledge, attitude and practices among Filipino physicians on ethical relations with the pharmaceutical industry

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ABSTRACT

Physician interaction with the pharmaceutical industry has effects on drug prescribing practices. Policy regarding prescribing practices is important in countries with high drug prices such as the Philippines. In 2015, the Philippine Department of Health (DOH) and the Food and Drug Administration (FDA) adopted the Mexico City Principles (MCP), as an enforceable code of business ethics guiding pharmaceutical industry engagement with physicians. Although the MCP applies to the pharmaceutical industry, identifying physicians' baseline knowledge, attitudes, and practices with regard to ethical relations with the pharmaceutical industry helps elucidate the former's vulnerability to inducement. Information from the literature and consultations with stakeholders was incorporated to develop a validated survey tool. After pre-testing, the survey was deployed through medical societies and professional networks, following purposive maximum variation sampling. Around 30% (2,030 of an estimated 6,900 physicians) responded. Only 53.0% (1,080) of the respondents were aware of the MCP and 334 (16.45%) reported that they had not previously heard of it. There was a favorable attitude towards industry relations perceived as benefitting patients and facilitating information exchange, even when respondents recognized that these interactions influenced an increase in medicine prescribing. Respondents reported that peers practice "excessive" interactions with pharmaceutical companies; however colleagues and role models in their workplaces deemed these acceptable. Awareness of the concept of conflict of interest was low. These findings suggest the need to increase physician's awareness of the MCP as rules that the pharmaceutical industry must follow. The awareness must be accompanied by recognition that industry influences on their practice affect patient care. An enabling environment and role modeling are crucial to institute ethical attitudes and practices in healthcare education and workplaces. Recognition and management of pharmaceutical industry-related conflict of interest should be introduced early among would-be physicians through training institutions, hospitals and professional societies.

Keywords. pharmaceutical ethics, physicians, Mexico City Principles, Philippines

INTRODUCTION

Physician prescribing practices is a public health concern particularly in countries like the Philippines where spending on drugs and medicines accounts for 50.1 percent of total out-of-pocket medical expenses [1]. By virtue of their legal right to prescribe medications, physicians are targeted by industry marketing strategies to influence product preference [2]. Physicians may assert that they are not susceptible to commercial influence, but judgement and decision-making subject to unintentional and unconscious "self-serving bias" is a well-documented human phenomenon [3],[4]. Evidence supports potential harms of certain physician-pharmaceutical industry interactions. For example, physicians with industry ties may be more inclined to prescribe branded drugs despite the availability of generic versions [3]. Researchers and expert panels influenced by pharmaceutical companies are likely to support evidence biased to push for particular drugs in guideline development [5]. Biased behaviors affect access to safe, effective and quality pharmaceutical products, with a potential negative impact on patients' health outcomes, trust in the system, as well as healthcare costs.

To regulate pharmaceutical companies across the globe, governments have urged compliance with ethically accepted practices in medicines promotion. The "World Health Organization's Ethical Criteria for Medicinal Drug Promotion" [6] and "The Mexico City Principles (MCP) for Voluntary Code of Business Ethics in the Biopharmaceutical Sector" [7] are two common references that provide guidance. There is recognition however, that compliance by the industry is generally voluntary unless governments support the codes with corresponding statutes. Currently, there are no studies that specifically identify the effects of the MCP to the practices of the industry and subsequently to the prescribing behavior of physicians.

The Philippine Department of Health (DOH) and the Philippine Food and Drug Administration (FDA) have adopted The MCP as enforceable administrative policies regulating the pharmaceutical industry [8], [9]. These regulatory policies implement the MCP as a list of acceptable activities with regard to the ethical conduct of the pharmaceutical sector in various areas: engagement with healthcare professionals, nature of promotional information and activities, safety of medicines, involvement in symposia and congresses, informational presentations by industry representatives, entertainment, educational items and gifts, continuing medical education, medical samples, and consultant and speaker arrangements, among others. The aim of the government's regulation of the pharmaceutical sector is to define a clear delineation of what constitutes ethical industry activities with respect to physicians.

While the MCP constitutes a regulatory policy for the pharmaceutical industry, there is no equivalent regulatory policy that applies to physicians. Physicians are expected to be ethical in their practice regardless of how the government regulates the pharmaceutical industry. The implicit expectation is that industry compliance with the MCP will minimize the influence of their marketing activities on physicians' prescribing practices. Moreover, cooperation among physicians is important for strengthening the government's regulation of pharmaceutical industry practices. However, information on Philippines prescribing physicians' knowledge about how the government regulates pharmaceutical industry behavior towards physicians, as specified in the rules of the MCP. The same information gap exists on the knowledge, attitudes and practices of Philippine physicians towards

the industry, including their perception of implications for clinical practice. The Philippines is one of the largest pharmaceutical markets in the ASEAN region. The pharmaceutical industry is one of the fastest-growing sectors in the country. With a compound annual growth rate of 3.7%, the Philippine pharmaceutical market was estimated to be worth USD 3.4 billion in 2016 and is expected to reach USD 4.1 billion by 2020 [10], providing an indication of the potential impact of physicians' prescribing practices in the country.

This study was conducted to determine the knowledge, attitudes and practices of Filipino physicians towards ethical relations with the pharmaceutical industry. The findings were intended to inform the strengthening of the MCP policy for better compliance.

METHODS

This is a cross-sectional self-administered survey conducted nationwide from the start of May 2017 to the end of June 2017. We deployed the survey through both paper-based and online modes, observing compliance with the Philippine Data Privacy Act of 2012 by ensuring that no personal identifiable data were included. We administered 1,811 paper-based survey forms during meetings of health professional societies. We were permitted to share the online questionnaire through seven professional society websites. We also shared the survey link with online physician community groups. The total estimated online reach was 5,089. All surveyed physicians passed the Philippine licensure examinations on or before 2015. This was to ensure that respondents had been in medical practice for at least one year at the time of the survey. Physicians identified as employed by pharmaceutical companies or were employed outside of the Philippines at the time of the survey were excluded. This study received technical approval and funding from the Philippine DOH and Philippine Council for Health Research and Development. The St. Cabrini Medical Center and Asian Eye Institute Institutional Review Board granted the ethics clearance for the study.

Survey development

The initial list of questions corresponding to the constructs of knowledge, attitudes and practice and was generated through literature review of studies that covered these constructs. We conducted preliminary prioritization of the most relevant questions according to our local experiences and observations. We selected items that covered demographics, characteristics of medical practice (e.g. general versus specialist), knowledge, attitudes, and practices related to the topic. *Knowledge* questions referred to awareness of the MCP, conflict-of-interest issues, and dissemination channels through which physicians receive information on these policies. For *attitudes* and *practices*, we based our questions on constructs of the Theory of Reasoned Action and Theory of Planned Behavior [11], [12], which are commonly used in studies on cognitive mechanisms underlying healthcare professionals' behaviors [13]. We asked questions about positive or negative attitudes toward specific interactions between physicians and the pharmaceutical industry. We explored subjective norms on how colleagues perceived and practiced physician - pharmaceutical industry interactions. Finally, we also investigated the perceived degree of influence of these interactions on intentions to prescribe.

We designed a structured and self-administered questionnaire to be distributed in both paper and online forms. We sought to reduce social desirability bias by designing the questions to be non-intrusive (e.g. "*In the past six months, do you know*

of at least one physician who has received the following items from pharmaceutical companies?" Instead of "*Did you receive these items?"*). We also included opt-out choices such as "don't know" or "not applicable" for questions requiring factual answers.

Survey validation and pre-testing

We tested content validity with government and private sector stakeholders who are knowledgeable on the topic. We considered an item to be acceptable if it had reached an item content validity index of 0.8. We then consulted with an ethicist, who qualitatively evaluated each item for acceptability. The survey items were rewritten in a more neutral tone deemed culturally acceptable and less threatening.

Face validity was assessed by presenting the revised survey to eight physicians in active practice of medicine. We used purposive sampling to identify physicians representing public and private practices, urban and rural settings, primary care and specialist care, and length of clinical practice being less than or more than 10 years. Physicians were asked the following questions for each item: "*Did you have any difficulty understanding this question?" "What does the question mean to you?" "Is the question relevant to you?"* The survey tool was revised accordingly. We pre-tested this iteration of the survey tool before final deployment.

Survey deployment

There is no accessible complete list of actively practicing physicians in the Philippines that could have served as a sampling frame. Hence, we performed convenience maximum variation sampling targeting respondents from medical societies and professional networks, and spanning both public and private sectors. Paper-based forms were distributed during medical conferences, and within hospitals, upon consent of concerned authorities. During each conference, at least one member of our research team was present to address any questions, and to do data quality checks on-site. Our online-based survey was distributed through email groups of medical school alumni, professional society webpages, posts on social media page groups with over 10,000 verified physician members, and through smaller physician groups on chat applications. As a survey incentive, respondents were given an option to join a raffle with a cash prize of PhP 5000 (approximately USD 100).

Sample size and statistical analysis

We aimed to obtain 3,681 respondents to attain a 3% margin of error, with a conservative assumption that 50% of physicians have good attitudes towards ethical relations with industry at 95% confidence interval, accounting for design effect for cluster sampling (assuming a cluster has 50 physicians, and an intra-cluster correlation coefficient of 0.5). We used standard descriptive statistics to describe knowledge, attitudes, and practices. Missing data were neither replaced nor estimated. We determined the correlation between intention to prescribe and attitude toward a specific interaction by using Spearman's correlation analysis. Null hypotheses were rejected at 5% alpha level of significance. STATA 12 was used for data analysis.

RESULTS

Demographics

We received 2,030 responses out of an estimated total reach of 6,900 survey forms that were sent to physicians. There were 989 (48.7%) paper form responses and 1,041 (51.35%) were through the

online form. The average age of respondents was 41.79 ± 10.9 years, and 71% were females. Respondents had been in medical practice for a median of nine years, and 39.8% had been practicing for more than 10 years. The large island groups in the country were represented: 594 (29.26%) in Metro Manila, 693 (34.14%) in the rest of Luzon, 324 (15.96%) in the Visayas, and 232 (11.43%) in Mindanao. Morever, 59% were practicing in an urban area. The respondents identified themselves as general practitioners (35.37%), specialists (43.74%), and trainees (18.72%).

Awareness and knowledge

Only 53.0% (1,080) of the respondents were aware of the MCP, 746 (36.75%) reported being "aware of it from informal conversations," and 334 (16.45%) learned about it from a formal venue. There were 656 (32.32%) respondents who reported, "This is the first time that I have heard of this." (Table 1). In contrast, 88.97% of respondents reported receiving important updates on medical practice through conferences (Table 2).

Table 1 Physician awareness of the Mexico City Principles for Voluntary Codes of Business Ethics (n = 2,030)

Which of the following accurately describes your awareness of the Mexico City Principles for Voluntary Codes of Business Ethics?	**Frequency (%)**
I am aware of it from informal conversations	746 (36.75)
This is the first time that I have heard of this	656 (32.32)
I learned about it from a formal venue	334 (16.45)
I have read the document	175 (8.62)
No answer	119 (5.86)

Table 2 Channels for receiving medical practice information (n = 2,030)

Where do you receive information on updates about your medical practice?	**Frequency (%)**
Conferences	1806 (88.97%)
Emails	1141 (56.21%)
Newsletters	1068 (52.61%)
Government websites	954 (47.0%)
Hospital memorandum / policies	907 (44.68%)
Social media and messaging apps	424 (20.89%)
Others	142 (7.0%)

Physician perceptions and practices related to conflict of interest are shown in **Table 3**. Nearly half of the respondents (40.5%) believed that research affects drug price more than marketing costs. More than half of the respondents knew that pharmaceutical companies train their medical representatives, and that research funding may influence clinical trial reporting. Of the 1,011 eligible respondents, 315 (31.15%) reported never having provided disclosure on association with pharmaceutical companies during lectures.

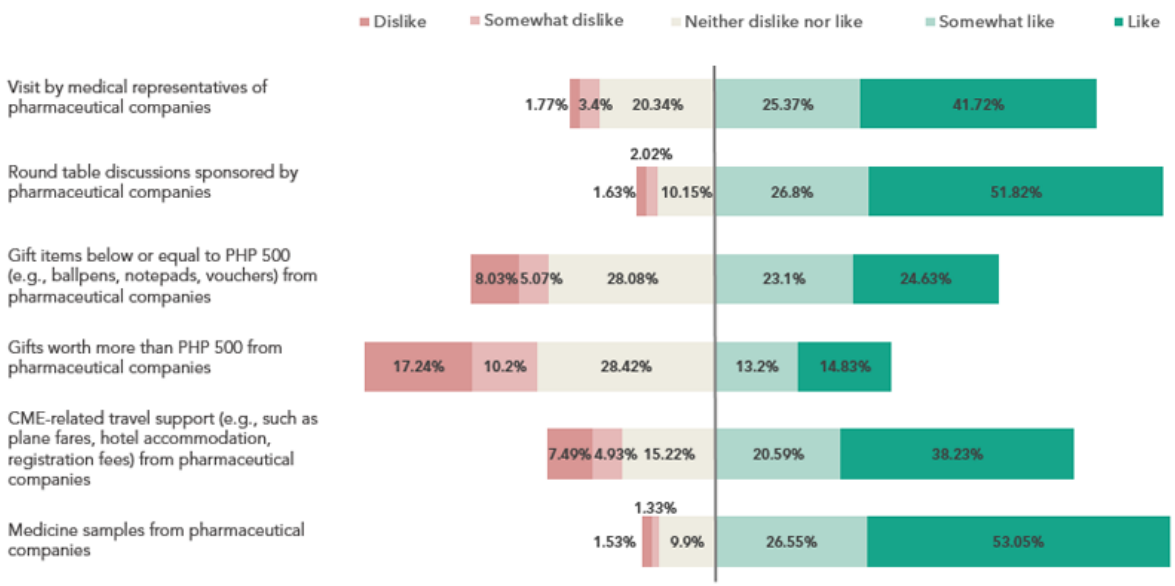
Table 3 Physician perceptions and practice related to conflict of interest (n=2,030)

Questions	Frequency (%)
Which of the following do you perceive to be true?	
The cost of drug development research affects drug price more than marketing costs	822 (40.5%)
The cost of drug development research affects drug price equal to marketing costs	318 (15.7%)
The cost of drug development research affects drug price less than marketing costs	392 (19.3%)
I don't know	323 (15.9%)
No answer	175 (8.6%)
Are medical representatives trained by their parent company on product-specific information and standards?	
Yes	1436 (70.7%)
No	145 (7.1%)
I don't know	309 (15.2%)
No answer	140 (6.9%)
Can the source of research funding affect how clinical trial results are reported?	
Yes	1173 (57.8%)
No	273 (13.5%)
I don't know	464 (22.9%)
No answer	120 (5.9%)

Questions	Frequency (%)
When you deliver formal lectures, do you disclose any association with pharmaceutical companies?	
Always	482 (23.47%)
Sometimes	214 (10.45%)
Never	315 (15.52%)
Not applicable	889 (43.79%)
No answer	130 (6.40%)

Physician attitudes and subjective norms

Physician attitudes were generally positive towards visits by medical representatives, round table discussions, Continuing Medical Education (CME)-related travel support, and medicine samples, while it was neutral to negative towards gift items (Figure 1).



Note: CME = continuing medical education; Php 500 = USD 10.00

Figure 1 Physicians' attitudes toward specific interactions with the pharmaceutical industry (n = 2,030)

Over 60% of the physician respondents perceived that their colleagues, mentors, medical societies, and workplace consider their interactions with the pharmaceutical industry as "Somewhat Acceptable" to "Acceptable" (Figure 2).

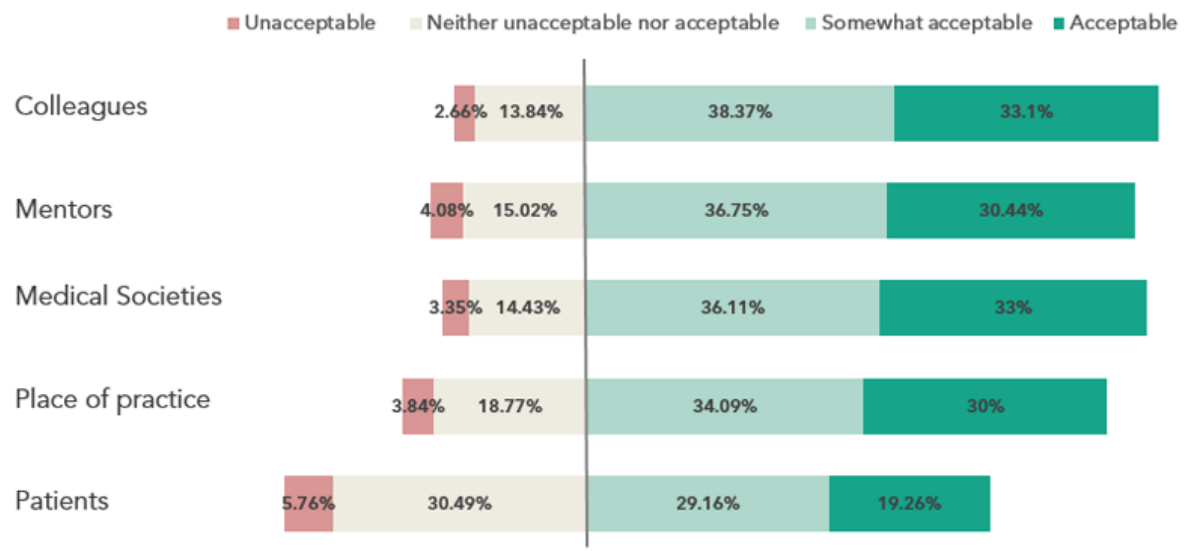


Figure 2 Subjective norms: physicians' perception of how their peers and patients accept physician - pharmaceutical industry interactions

Practices and intention to prescribe

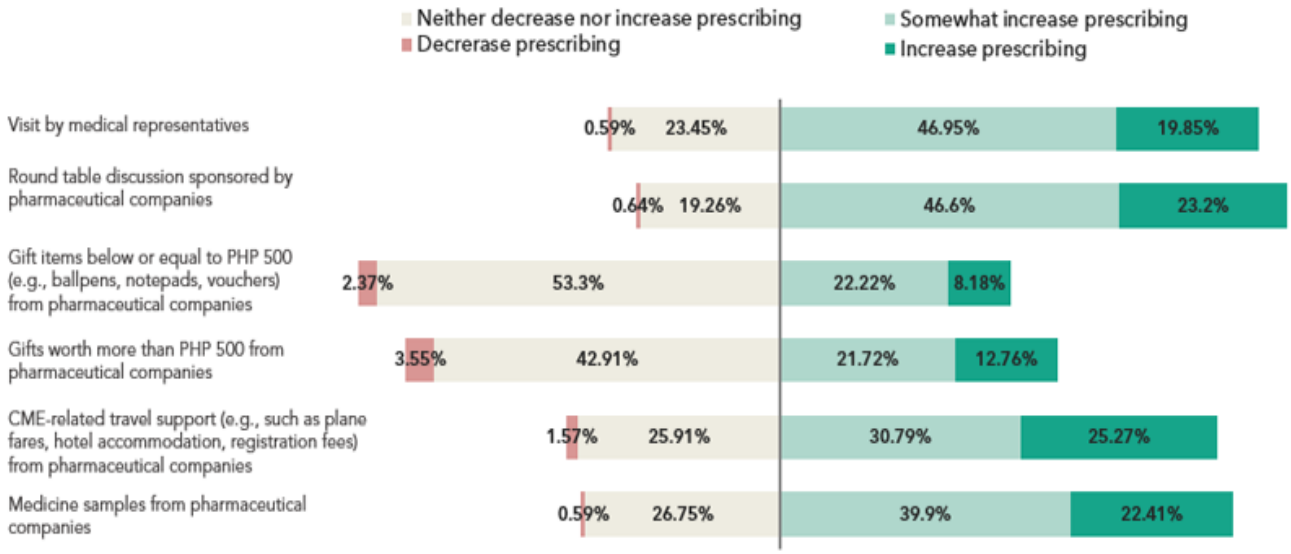
More than half of the respondents knew of at least one physician who had received a clinic visit by a medical representative (88%), free drug samples (85%), an invitation to attend round table discussions (77%), and CME-related domestic travel support (57%). Other common practices are enumerated in Table 4.

Table 4 Interactions between physicians and pharmaceutical companies in the Philippines (n = 2,030; multiple responses allowed)

In the past six months, do you know of at least one physician who has received the following from pharmaceutical companies?	**Frequency (%)**
A visit by medical representative	1787 (88.03)
Drug samples	1727 (85.07)
Invitation to attend round table discussions	1574 (77.54)
CME-related domestic travel support	1157 (57.0)
Invitation to be a speaker in round table discussions	1007 (49.61)
Support for institutional activities	971 (47.83)
CME-related international travel support	810 (39.9)
Gift items below or equal to PHP 500 (USD 10)	791 (38.97)
Meals delivered within health facilities	674 (33.2)

In the past six months, do you know of at least one physician who has received the following from pharmaceutical companies?	Frequency (%)
Other support for CME	651 (32.07)
Consulting work for pharmaceutical companies	532 (26.21)
Meals outside of a physician clinic	483 (23.79)
Personal services	431 (21.23)
Non-CME related domestic or international travel support	346 (17.04)
Gift items exceeding PHP 500 (USD 10)	234 (11.53)

Physicians perceived that each type of interaction with the pharmaceutical industry had a different level of effect on how they prescribe the medicines promoted to them by medical representatives (Figure 3). Nearly half of the respondents were of the opinion that medical representative visits (47%) and round table discussions (47%) somewhat increased physicians' prescribing of medicines promoted by the sponsoring pharmaceutical company. Meanwhile, respondents generally viewed that gifts, regardless of the price, had no effect on prescribing. Free drug samples (89%) and CME-related travel support (82%) tended to have a neutral to positive effect on the prescription of promoted medicines.

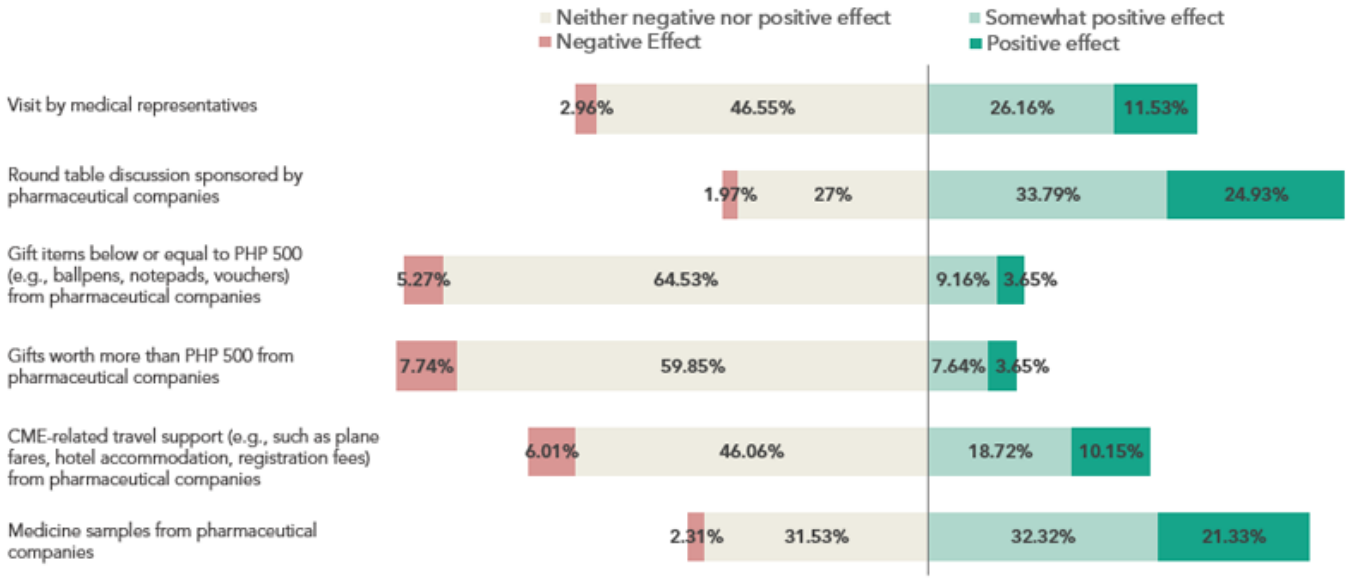


Note: CME = continuing medical education; Php 500 = USD 10.00

Figure 3. Perception of the effects of activities on prescribing the medicines promoted by medical sales representatives

Evaluation of behavioral outcomes

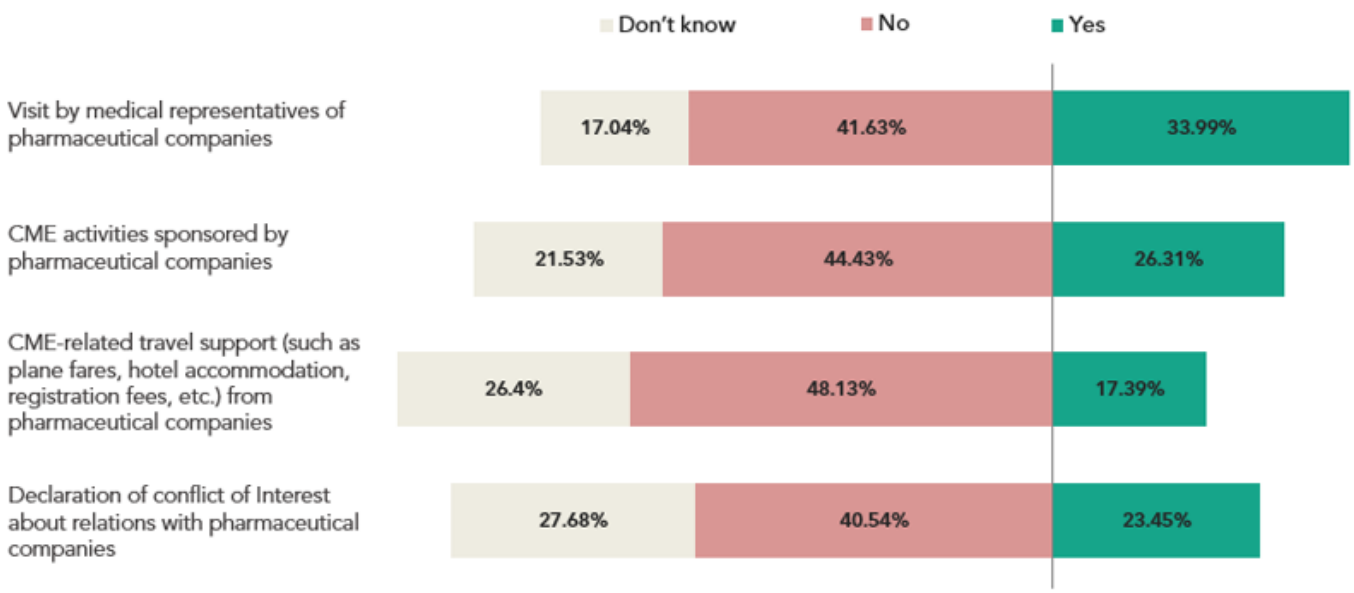
Prescribing practices shape the therapeutic regimen of patients and could influence health outcomes. Physicians considered roundtable discussions (33.79%) and receiving medical samples (32.32%) as having "Somewhat Positive Effects" on patient outcomes (Figure 4). The rest of the interactions were seen as having "Neither Negative nor Positive Effect."



Note: CME = continuing medical education; Php 500 = USD 10.00

Figure 4 Perceived influence of different physician-pharmaceutical industry interactions on patient outcomes (e.g., mortality, morbidity, quality of life)

Amidst these ongoing practices, half of the respondents were in workplaces that did not have written policies regulating pharmaceutical company relations pertaining to CME-related travel support (48%), pharmaceutical-sponsored CME activities (44%), visits by pharmaceutical representatives (42%), and declaration of conflicts of interest (Figure 5).



Note: CME = continuing medical education

Figure 5 Physicians' knowledge of written policies in their workplace with regards to possible conflicts of interest (n = 2,030)

DISCUSSION

While the government regulates the pharmaceutical industry's practices, the eventual outcome of interest in this study is whether physicians practice ethical prescribing of medicinal drugs. Physicians' knowledge of what constitutes an ethical relationship with the pharmaceutical industry, their attitude towards the industry, and how they respond to possible inducements by the industry are therefore important for the government. Our findings suggest that prescribing physicians have a low level of knowledge about MCP as a set of rules that their peers in the pharmaceutical industry are expected to follow. Policy documents on the MCP are not widely disseminated through their preferred information channels (e.g. medical conferences).

Most physicians are unaware that marketing costs of the industry drive drug prices. Physicians' attitudes towards interactions with the pharmaceutical industry are generally positive, particularly regarding three aspects: conduct of roundtable discussions, visits by medical representatives and accepting medicinal drug samples. These three interactions are likewise perceived as having positive effects on patient outcomes. Furthermore, physicians consider interactions with the pharmaceutical industry as common and acceptable practice among their colleagues. Healthcare workplaces in general do not have written policies on interactions between physicians and the pharmaceutical industry. The low level of awareness of acceptable practices, the legitimization of the physician-pharmaceutical industry interactions as a mechanism to help patients and a highly tolerant environment may all contribute to prescribing practices that eventually favor the industry rather than patients.

Sales representatives of pharmaceutical companies, known in the Philippines as "medical representatives" or "medreps" are critical industry touchpoints for physicians. They enjoy intimate access

to physician networks. . Encounters are mainly informal, last a few minutes and are rarely scientific. Our findings confirm physicians' belief that medical representatives are highly trained on the scientific nature of the medicinal drugs that they promote. This carries an implicit expectation that the information shared by medical representatives is generally based on high quality research-based evidence. This high regard for the 'messenger' does not seem to be affected by the general understanding among physicians surveyed, that drug research can be biased by the source of funding. In a country where physicians generally exercise a high level of power in the health sector, this pathway of influence to their prescribing behavior should warrant close scrutiny.

The Philippine case is consistent with the findings from a systematic review of studies on knowledge, beliefs, and attitudes of physicians in other low and middle-income countries (14). The review showed that the top perceived benefits of pharmaceutical industry-physician information and rewards. Quick access to scientific updates is an important currency for a physician's practice. Furthermore, in the same systematic review, they found a general perception that the influence of industry-physician interactions on the physician's prescribing behavior was minimal. When physicians are asked directly about the influence of such interactions on their own prescribing behavior, the perception of influence is even lower. However, physicians' attachment to the medical representatives that visit them was demonstrated in another study (15) in which 42% of physicians admitted that their prescribing habits were influenced by the medical representatives.

A survey of 275 primary care physicians working in Saudi Arabia from 2011 to 2012 reported that they prefer to use textbooks as a prescribing preference and 43.6% reported that they are not affected by drug representative visits. However, 61% believed that the prescribing behavior of their peers could be affected by such visits (16). This may suggest the physicians' perception of self-control is high but their actual ability to remain objective is lower than their self-estimation, and thus, the impact of physician - pharmaceutical industry interactions should not be underestimated.

When physicians are unaware of ethical boundaries in relating with the pharmaceutical industry, a positive attitude towards these interactions may influence prescribing behavior. Physicians may favor a brand not in response to promotion/marketing, but rather as a consequence of not knowing the cost of such decisions. Without explicit policies in the workplace, professional societies, and similar environments, shared behavior among important personalities prevails (14). Explicit messaging on ethical boundaries that is reinforced by a conducive environment can therefore facilitate perceived control over their prescribing behavior.

Given the profile of knowledge, attitudes and practices of physicians with regard to ethical relationship with the pharmaceutical industry, we recommend enabling physicians through knowledge building and normalizing the acceptability of ethical practices. Physicians must be made aware about the government's regulation of the pharmaceutical industry behavior towards clinicians and the rationale for restricting such interactions (i.e., to minimize influence on prescribing practices). While physician autonomy should be respected, providing them with information about these government rules could in turn inform guidance over for how physicians should behave towards the pharmaceutical industry.

Professional physician groups are also key partners that could incorporate these ethical guides within their own code

of ethics. The practice of medicine has long been heavily influenced by tradition and a strong sense of ethical conduct among peers. Because of the influence of unethical inducements by the pharmaceutical industry to the practice of physicians which is documented in literature, the government can make a case to include this aspect in the code of ethical practice of medicine. Awareness of ethical conduct can be introduced even in the formative stage of physician training. A study in Pakistan among clinical year students suggests that the perception of acceptability of interactions with the industry may begin developing as early as medical schools and may require clear guidance that should be incorporated in the curriculum (17). Role modeling by senior physicians is important. Establishment of clear rules reduce interactions between physicians and medical representatives may also play an important role in minimizing their influence on prescribing behavior (18)

Physicians rely on formal clinical conferences, society emails and society newsletters as sources of information about their practice. The government can work with professional groups to regularly disseminate information on relevant government regulation such as the MCP through these channels, which are trusted by physicians.

Finally, unethical and inappropriate business practices in the pharmaceutical sector affects patients' access to safe, effective and quality pharmaceutical products, and can potentially have a negative impact on patients' health outcomes, their trust in the systems, and the cost of their healthcare. Accordingly, the government is creating an environment where there should be no inducements on physicians by the pharmaceutical industry. While the government rules (e.g., MCP) aim primarily to place controls and ethics boundaries on the practices of the pharmaceutical industry, understanding the state of physicians' knowledge, attitudes and practices will also be helpful in understanding how to reduce the potential for unethical inducement. The results of this study suggest that physicians already recognize the influence of industry activities on the prescribing practice of their peers, and underscores the need for the government to approach the issue of regulating unethical practices as a continuum of interventions. Policies to strengthen existing laws regulating physician prescribing would also make a direct contribution to patient outcomes.

Limitations

It was difficult to generate a representative sample for this survey because the lack of a central database of actively practicing physicians in the Philippines. Opportunities to assemble these data in the future may become feasible as the country improves its information system on health human resources. Future cross-sectional surveys on physicians' role on MCP implementation could also consider expanding the collection of information about prescribing at the point of care. This could give a more complete picture of the implications of the MCP policy for physicians' prescribing practices.

RECOMMENDATIONS

The government will need to work with professional societies and academic institutions in informing physicians about regulations such as MCP. Knowledge about the extent of activities that the government allows from the pharmaceutical industry can improve physician decision-making with regard to boundaries that they in turn will set when approached by the industry representatives. Academic and training institutions, hospitals and professional societies must provide access to this

information beginning from the formative stage of physician training and reinforce this training in the workplace. Hospitals and other healthcare workplaces must enable ethical relationships between physicians and the pharmaceutical industry through practical guidance such as code of ethics, explicit rules, and role modeling. Interventions that could target ways of changing subjective norms are synergistic with the government's regulation of the industry's activities. Ethical interactions between the pharmaceutical industry and physicians must become the norm. In the same vein, recognition and management of possible conflicts of interests must be supported in all areas of practice.

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