Alternative Regulatory Models for Pharmaceutical Promotions Involving Civil Society and Other Non-Government Stakeholders

Monet M. Loquias, RPh, MSPharm, MHPEd, PhD
Christine Aileen M. Ching, RPh, MPH
Katrice P. Lara, RPh

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<th>Full Form</th>
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<tbody>
<tr>
<td>AAC</td>
<td>Audit and Appeals Committee</td>
</tr>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
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<td>ACRC</td>
<td>Advertising Review and Content Committee</td>
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<tr>
<td>APA</td>
<td>Advertising Preclearance Agency</td>
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<tr>
<td>AO</td>
<td>Administrative Order</td>
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<td>APEC</td>
<td>Asia-Pacific Economic Cooperation</td>
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<td>ASC</td>
<td>Advertising Standards Canada</td>
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<td>ASC</td>
<td>Ads Standards Council</td>
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<td>ASMI</td>
<td>Australian Self-medication Industry</td>
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<tr>
<td>BFAD</td>
<td>Bureau of Food and Drugs</td>
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<tr>
<td>CDA</td>
<td>Center for Drug Administration</td>
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<tr>
<td>CDRR</td>
<td>Center for Drug Regulation and Research of the FDA</td>
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<tr>
<td>CHC</td>
<td>Complementary Healthcare Council</td>
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<tr>
<td>CPD</td>
<td>Continuing Professional Development</td>
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<tr>
<td>CME</td>
<td>Continuing Medical Education</td>
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<tr>
<td>CPR</td>
<td>Certificate of Product Registration</td>
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<tr>
<td>CPTDA</td>
<td>Consumer Protection Trade Descriptions and Safety Requirements Act</td>
</tr>
<tr>
<td>CRP</td>
<td>Complaints Resolution Panel</td>
</tr>
<tr>
<td>DAV</td>
<td>Drug Administration of Vietnam</td>
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<tr>
<td>DCA</td>
<td>Drug Control Authority</td>
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<tr>
<td>DDMAC</td>
<td>Division of Drug Marketing and Communication</td>
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<td>DOH</td>
<td>Department of Health</td>
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<tr>
<td>DTCA</td>
<td>Direct-to-consumer Advertising</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associates</td>
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<td>EPTC</td>
<td>Ethical Promotions Transparency Coalition</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FTC</td>
<td>Federal Trade Commission</td>
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<td>HAI</td>
<td>Health Action International</td>
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<td>HSA</td>
<td>Health Sciences Authority</td>
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<tr>
<td>IAPO</td>
<td>International Association of Patient Organizations</td>
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<tr>
<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturers and Associations</td>
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<tr>
<td>IPMG</td>
<td>International Pharmaceutical Manufacturers Group</td>
</tr>
<tr>
<td>IRR</td>
<td>Implementing Rules and Regulations</td>
</tr>
<tr>
<td>ITE Law</td>
<td>Information and Electronic Transactions Law</td>
</tr>
<tr>
<td>KBP</td>
<td>Kapisanan ng mga Broadkaster ng Pilipinas</td>
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<tr>
<td>LTO</td>
<td>License to Operate</td>
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<tr>
<td>MACC</td>
<td>Medicines Australia Code of Conduct</td>
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<tr>
<td>MAR</td>
<td>Medical Advertisement Regulation</td>
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<td>MCP</td>
<td>Mexico City Principles</td>
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<td>MHPD</td>
<td>Marketing health Products Directorte</td>
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<td>Medicines and Healthcare Products Regulatory Agency</td>
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<td>MOA</td>
<td>Memorandum of Agreement</td>
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<td>NPCB</td>
<td>National Pharmaceutical Control Bureau</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>OTC</td>
<td>Over-the-counter Drugs</td>
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<tr>
<td>PAAB</td>
<td>Pharmaceutical Advertisement Advisory Board</td>
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<tr>
<td>PAGB</td>
<td>Proprietary Association of Great Britain</td>
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<tr>
<td>PANA</td>
<td>Philippine Association of National Advertisers</td>
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<tr>
<td>PCPI</td>
<td>Philippine Chamber of Pharmaceutical Industry</td>
</tr>
<tr>
<td>PFDA</td>
<td>Provincial Food and Drug Administration</td>
</tr>
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<td>PAPO</td>
<td>Philippine Alliance of Patient Organizations</td>
</tr>
<tr>
<td>PHAP</td>
<td>Pharmaceutical and Healthcare Association of the Philippines</td>
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<tr>
<td>PhAMA</td>
<td>Pharmaceutical Association of Malaysia</td>
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<tr>
<td>PhRMA</td>
<td>Pharmaceutical Research and Manufacturers of America</td>
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<tr>
<td>PReMA</td>
<td>Pharmaceutical Research and Manufacturers’ Association in Thailand</td>
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<tr>
<td>PMS</td>
<td>Post Marketing Surveillance</td>
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<tr>
<td>PPSC</td>
<td>Pharmaceutical Promotions Standards Committee</td>
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<tr>
<td>PRC</td>
<td>Professional Regulation Commission</td>
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<tr>
<td>PSD</td>
<td>Pharmaceutical Services Division</td>
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<tr>
<td>RA</td>
<td>Republic Act</td>
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<tr>
<td>RDPAC</td>
<td>R&amp;D-based Pharmaceutical Association in China</td>
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<tr>
<td>RUM</td>
<td>Rational Use of Medicines</td>
</tr>
<tr>
<td>ROV</td>
<td>Report of Violation</td>
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<tr>
<td>SAIC</td>
<td>State Administration for Industry and Commerce</td>
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<tr>
<td>SAPI</td>
<td>Singapore Association of Pharmaceutical Industries</td>
</tr>
<tr>
<td>SCAP</td>
<td>Singapore Code of Advertising Practice</td>
</tr>
<tr>
<td>SEC</td>
<td>Security and Exchange Commission</td>
</tr>
<tr>
<td>SME</td>
<td>Small and medium enterprises</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>TGACC</td>
<td>Therapeutic Goods Advertising Code Council</td>
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<td>TG Act</td>
<td>Therapeutic Goods Act of 1989</td>
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<td>TG Regulations</td>
<td>Therapeutic Goods Regulations of 1990</td>
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<tr>
<td>TWG</td>
<td>Technical Working Group</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Background

The pharmaceutical industry plays a vital role in health care, being the primary developers and producers of medicines. However because it is also a business, it is highly dependent on marketing to expand product sales which may sometimes be unethical at the expense of the public health priority of rational use. Literature documents impact of medicines promotions on health professionals’ behaviour, knowledge and attitude (HAI Global; WHO and HAI, 2005; Goodman, 2001; Ijoma et al., 2010; Vancelik et al., 2007). These studies found increasing evidence that drug company promotions can distort prescribing choices. Prescribers who reported the highest use of promotion as the main source of information tend to prescribe less appropriately, prescribe more often and adopt new medicines faster (HAI Global; WHO and HAI, 2005; Goodman, 2001; Ijoma et al., 2010; Vancelik et al., 2007).

Unethical promotion practices also affect ethical enterprises seeking to grow local operations or engage in cross-border trade. The Asia-Pacific Economic Cooperation (APEC) states that the small and medium enterprises (SMEs) are especially affected by unethical business practices because they usually pay a higher percentage of their annual revenues to bribes than large companies. It is estimated that more than 70% of SMEs in economies transitioning to a market-oriented environment considers corruption as a barrier to business (APEC, 2014).

While international regulatory standards for pharmaceutical promotion exist, many countries, especially developing countries, are not able to adequately regulate pharmaceutical promotion due to lack of resources needed for pharmaceutical regulation or do not simply prioritize regulation of pharmaceutical promotion. In many instances, only self-regulation is implemented by the industrial associations, and the pharmaceutical and advertising industries. This set-up however may be problematic due to inherent conflict of interest in self-regulation.

Rationale/ Significance

The regulation of medicines promotion was identified as a critical priority in the Philippines in order to encourage rational use, ensure reasonable pricing of medicines and promote growth of SMEs. A system for pharmaceutical promotion which involves the civil society and other non-
state actors as partners in the oversight and monitoring of promotional activities will be significant especially considering the limited resources allotted in the regulation of pharmaceutical promotions. Specific guidelines that define ethical promotion and identify penalties for infringements may also be helpful in ensuring quality use of medicines by patients and at the same time helping the pharmaceutical industry sustain their operations.

**Objectives**

The general objective of this study is to propose various regulatory models on pharmaceutical promotions in the Philippines that articulate clear and active involvement of civil society and other non-government stakeholders. Specifically it aims to:

a) present examples/cases of effective civil society-participated regulatory models for pharmaceutical promotions in other countries;
b) describe the current regulation process for pharmaceutical promotions in the country for the purpose of identifying its strengths, weaknesses and areas for improvement;
c) propose alternative regulatory models for pharmaceutical promotions involving civil society and other non-government stakeholders; and,
d) identify needs, resources and other requirements to support implementation of proposed alternative regulatory models.

**Methodology**

1. **Key Informants.** Key informants were selected from the different stakeholders from the government, pharmaceutical industry, professional and non-government organizations and patient groups.

2. **Data Collection Methods.** This qualitative study primarily used review of records and key informant interviews to collect data. Initial results were presented in a policy dialogue for comments and other suggestions. Participants in this dialogue were likewise from different stakeholders such as the government, pharmaceutical industry, professional and non-government organizations and patient groups.
3. **Data Collection Tools.** Three interview schedules were created for the key informants. These were primarily composed of open-ended questions.

4. **Data processing and analysis.** Data gathered from key informant interviews were first initially transcribed verbatim. These were subsequently analyzed by content analysis.

### Results

#### A. Review of existing regulatory practices for pharmaceutical promotions in other countries

There are two international standards that exist for pharmaceutical promotion – the *WHO Ethical Criteria for Medicinal Drug Promotion* and the *International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Pharmaceutical Marketing Practices*. The *WHO Criteria* is a broad, international code with public health orientation. The criteria constitute general standards for ethical principles which could be used by governments, the pharmaceutical industry, promotion industry, professional associations, patients and consumer groups and the professional and general media (*WHO*, 1988). The *IFPMA Code* is an effort to harmonize and regulate the existing practices based on *WHO Ethical Criteria* by the *IFPMA* and is limited to its member pharmaceutical companies. This Code of Practice serves as basis/ tool for its affiliated country specific member organization to formulate their own Codes of Practice for self-regulation as the most appropriate mechanism to ensure ethical marketing and promotion in addition to Government mandated regulatory mechanisms (*IFPMA*, 2015).

In this study, we reviewed regulatory practices in 12 countries including the Philippines. The other 11 countries reviewed were United States of America (USA), Canada, United Kingdom (UK), Germany, Australia, China, Indonesia, Singapore, Malaysia, Thailand and Vietnam.

**The American Region**

**United States**

The quality and safety of drugs in the US is ensured by the Food and Drug Administration (FDA). Advertising and promotion is likewise within FDA’s jurisdiction. Control on advertisements is a
collaborative work with the Federal Trade Commission (FTC), which ensures accurate presentation of benefit and risk information to patients. FDA, on the other hand, ensures that advertising is truthful and not misleading (Dave, 2013). The FDA’s Division of Drug Marketing and Communication (DDMAC) is responsible for prescription drug advertising oversight to help assure that ads are in compliance with the FDA’s rules and regulations. It also monitors prescription drug promotion to physicians in many venues, including audio conferences, pamphlets distributed at professional meeting, mailings to health care professionals and all others. The US is one of the two industrialized countries¹ that presently allow direct-to-consumer-advertising (DTCA).

Self-regulation in the pharmaceutical industry exists which is largely influenced by the IFPMA Code of Practice. The Pharmaceutical Research and Manufacturers of America (PhRMA) is the IFPMA-recognized organization in the United States that sets appropriate standards with regards to pharmaceutical marketing and promotion. There are four IFPMA-linked national codes for the pharmaceutical industry but only two of these are particularly important for marketing and promotional activities namely – PhRMA Guiding Principles on Direct to Consumer Advertisement about Prescription Medicines and the Code of Interactions with Health Care Professionals. (PhRMA, 2009)

The PhRMA Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines recommends that companies must submit all television ads to the FDA before airing,² so if an advertisement is in violation of the regulations, the FDA can prevent it from running or require that the violating promotion be stopped immediately to prevent any misleading information that can affect public safety. It can also require a remedial campaign to correct any misimpressions caused by an advertisement. The Code on Interactions with Health Care Professionals, on the other hand, provides guidelines for interactions with health care professionals, which is aimed at relaying accurate medical information for the benefit of the

¹ The United States of America and New Zealand are the only two countries in the world that allow DTC advertising.
² FDA however does not require approval of ads of prescription medicines prior to airing. However some companies do request for FDA for inputs/ review before the ad is used. If FDA believes that the ads released violate the law, a letter is sent to the drug company so that the ads can be stopped right away.
patients. These two industry codes of practice guide pharmaceutical promotion to help ensure accurate information and to educate the public regarding safe use of medicines. (PhRMA 2009)

While pharmaceutical promotion is primarily self-regulated, the US has the *Physician Payment Sunshine Act* which was approved in 2010 to increase transparency of financial relationships between health care providers and the pharmaceutical manufacturers. This requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually all payments and other transfers of value to physicians and teaching hospitals.

**Canada**

The *Federal Food and Drugs Act* (abbreviated as FDA by Health Canada) establishes the basic criteria for acceptable advertising of drugs and medical devices in Canada. As a general rule, the Act provides that no person shall advertise any drug or medical device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. Furthermore, it sets out specific rules with respect to certain types of advertisement to prevent any drug or medical device to be advertised to the general public for the treatment, prevention or cure of any diseases referred to in the Act. The Act is primarily administered by Health Canada. (Mendelsohn, 2007)

Health Canada is the national regulatory authority for health product advertisements that sets out the standards for health product advertising and promotional material to help advertisers produce messages that are not false, misleading or deceptive. While it is the responsibility of Health Canada to administer the Food and Drugs Act and related Regulations, it is the responsibility of market authorization holders (manufacturers and distributors) to ensure that their advertisements comply with the relevant legislation and regulations. For instance, the pharmaceutical industry associations, particularly *Canada’s Research-Based Pharmaceutical Companies (Rx&D)* has prescribed a *Code of Marketing Practices* that include a host of self-regulation initiatives that strongly supports the IFPMA’s mission and the principles of the *IFPMA Code of Pharmaceutical Marketing Practices*. At present, Health Canada strongly encourages all

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3 France also has a similar policy which was adopted in 2011, although implemented only in 2013, the *Loi Bertrand* or the *French Sunshine Act*. Similarly, the Czech Republic also has its *Act on Medicinal Product and Medical Devices* which requires detailed reporting requirements for certain marketing expenditures and benefits provide to health care professionals. This was approved in 2011 and implemented in 2012.
market authorization holders to have their advertising and promotional materials for their registered health products “pre-cleared” with independent advertising preclearance agencies (APAs) prior to dissemination. Health Canada likewise provides guidance documents and policies in support of meeting these requirements. However, industry compliance with pre-clearing their advertising is voluntary. (Health Canada, 2011)

The Independent APAs, namely Advertising Standards Canada (ASC) and Pharmaceutical Advertising Advisory Board (PAAB), provide ‘copy review’ services to advertisers and advertising agencies to help ensure that the promotional products (all types of media) meet the relevant regulatory requirements and APA’s advertising codes. Furthermore, they must possess and make publicly available in both official languages (French and English) the policies, procedures and standards they use to ensure that their services comply with Health Canada’s requirements. (Health Canada, 2011)

The ASC is the Canadian advertising industry self-regulatory body. It is a not-for-profit organization governed by a volunteer Board of Directors which includes representatives from Canadian advertisers, advertising agencies, media organizations and the public. Members of ASC include Canadian advertisers, advertising agencies, media organizations and suppliers to the advertising sector. Its principal instrument of self-regulation is the Canadian Code of Advertising Standards. ASC is primarily responsible to review and pre-clear advertising and promotional material for non-prescription drugs (OTCs) and natural health products directed to consumers prior to dissemination.

The PAAB is also a not-for-profit, self-financing organization. Its 13 member-organizations come from the academe, professional organizations, consumer groups and the pharmaceutical industry which have official representatives to the Board of Directors of PAAB. The PAAB is responsible to review and pre-clear advertising materials for prescription drugs and other health products directed to licensed members of most medical and health professionals.

Both ASC and PAAB provide advisory opinions on messages directed to consumers for prescription drugs and on educational material discussing a medical condition/disease to ensure that they meet regulatory requirements. The advisory opinions are forwarded to Health Canada
for their information. Questions however about health product advertising are directed to Health Canada. Health Canada will then discuss the issue with the APA. Likewise, should Health Canada have concerns regarding product advertising, these are directed to the APA. (Health Canada, 2011)

Advertising complaints regarding all Health Canada authorized health products are coursed through the APAs except those related to direct-to-consumer-advertising (DTCA) of prescription drugs and Schedule D drugs where it should be forwarded directly to Health Canada. Processing of complaints is according to provisions and time frames specified by the different agencies. Complaints submitted to APAs may also be forwarded to Health Canada. For all complaints received by Health Canada, the Marketed Health Products Directorate (MHPD) determines non-compliance and assesses health risks posed by the advertising material. Once these are determined, immediate risk management actions may be taken by Health Canada which include the following:

- Warning letter to the advertising sponsor and/or broadcaster
- Requesting immediate cessation of the advertisement
- Contacting and/or referral to the APAs
- Issuance of a risk communication
- Suspension or cancellation of marketing authorization/product license
- Prosecution

Other general laws regarding advertisements and pharmaceutical promotions also apply to pharmaceuticals such as the Federal Competition Act and various provincial consumer protection statutes that aimed to protect the general public against inappropriate promotional activities.

The regulatory model of Canada provides a good example of empowering independent stakeholders outside both government and pharmaceutical industry to participate in regulation of advertising and promotion.
The European Region
The European Federation of Pharmaceutical Industries and Associations (EFPIA), an IFPMA-affiliated organization, represents the pharmaceutical industry operating in Europe. At present, it has a direct membership of 33 national associations and 39 leading pharmaceutical companies undertaking research, development and manufacturing of medicinal products in Europe for human use. Its mission is to promote pharmaceutical research and development and the best conditions in Europe for companies to bring to market medicines that improve human health and the quality of life around the world. Through its membership, EFPIA represents the common views of 1,900 large, medium and small companies including the entire European research-based pharmaceutical sector whose interests also include an important part of the generics segment. (AALEP, 2015)

EFPIA believes that interactions between the pharmaceutical industry and healthcare professionals affect the quality of patient treatment and the value of future research and that such interaction can create potential conflicts of interest. In order to ensure that these interactions meet high standards of integrity that patients, governments and other stakeholders expect and consistent to IFPMA’s mission of promoting high standards in marketing and promotion, the EFPIA codes were created namely – Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “HCP Code”) and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (the “PO Code”).

The HCP Code seeks to ensure that pharmaceutical companies conduct promotion and interaction in a truthful manner, avoiding deceptive practices and potential conflicts of interest with healthcare professionals, and in compliance with applicable laws and regulations. It also implies self-regulation among members of national pharmaceutical industry associations and companies, but the ultimate regulatory powers concerning marketing and promotion still rely on the hand of the member country-specific government mandated regulatory body tasked to oversight the regulation of drugs and medical devices. (EFPIA HCP code, 2014)

The PO Code was created because of the increasing concern that pharmaceutical companies are harboring very close relationships with patient groups, allowing these companies to directly
advertise their products to patients, and the absence of specific provisions in the law which prohibits such activities. The *PO Code* is a self-regulating guideline to provide the pharmaceutical industry with a set of ethical guidelines for governing the relationship with patient support organizations. It provides a transparent mechanism for appropriate conduct of pharmaceutical industry with patient organizations in accordance with the principles of neutrality and independence. This also makes clear to the public that such relationships will not be used in a manner to circumvent the laws prohibiting direct advertising.

In response to the evolving demands of the society specifically the growing interest of patients and other stakeholders on the transparency of the interactions between corporations and society, *EFPIA* adopted a “List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector” (the “Guiding Principles”). In line with these “Guiding Principles”, the *HCP and PO Codes* were supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organizations. These Codes now provide for disclosures of transfers of value to healthcare professionals, whether directly or indirectly. Disclosure of transfers of value will commence with reporting in 2016 in respect of transfers of value for the calendar year 2015.

The different countries in the European Region have their own national codes of conduct/ practice consistent with *EFPIA* Codes (and/or other international codes of conduct/ practice) and the national laws or policies governing pharmaceutical promotions and advertising in the specific country. In this review however, we will only discuss regulatory frameworks for Germany and the United Kingdom.

**Germany**

The advertising of healthcare products in Germany is governed by the *Law on Advertising in the Field of Healthcare* and the provisions of the *Law against Unfair Competition*. Self-regulation among the industry is the main regulatory mechanism for ensuring quality advertising practices within the pharmaceutical industry. Codes of conduct governing self-regulation are consistent with the mentioned laws.
The members of the organization, “Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V (FSA)” (“Voluntary Self-regulation of the Pharmaceutical Industry”), are governed by its Code of Conduct. A large part of the industry also agreed to comply with this code of conduct – the FSA Code of Conduct on the Collaboration with Healthcare Professionals. This code of conduct takes into account the “Common Position of the Assessment in Criminal Law of the Cooperation between Industry, Medical Institutions and their Employees” which was published in October 2000 by the major trade associations and other organizations in the healthcare sector, and the Professional Rules for German Physicians issued by the German Federal Chamber Physicians. The FSA Code of Conduct on Collaboration with Healthcare Professional was revised to reflect the recent requirements of the EFPIA Code of Practice to ensure adherence to IFPMA principles.

Another self-regulatory organization “Arzneimittel und Kooperation im Gesundheitswesen e.V. (AKG)” (“Pharmaceuticals and Cooperation in the Health Care Sector”) was founded which likewise has its own code to govern its members – the AKG Code of Conduct. With regards to its content on collaboration between industry and health care professionals, this was also based on the recommendations of the collaboration of physicians issued by the German Association of Research-based Companies (VFA), the German Federal Association of the Pharmaceutical Manufacturers (BAH) and the German Association of Pharmaceutical Industry.

While the codes of conduct mentioned have no legal force, these are considered binding on their members. Monitoring and sanctions are done by both FSA and the AKG.

Transgressions of the regulation on advertising maybe considered as a criminal offense which is punishable by imprisonment, fines or both. The public prosecution authorities investigate criminal offenses and bring them before a criminal court. The responsibility of imposing and enforcing regulatory fines rests with the relevant competent authorities who are responsible for the administrative supervision of the pharmaceutical company in question. (Dieners and Klumper, 2008)

**United Kingdom**

In the United Kingdom, advertising of medicines is acceptable provided that it is in line with legislation and agreed standards of good practice. In general, advertising any commodity and services to the public must be of high standards and it should not cause serious or widespread
offence, create unrealistic expectations in the consumer or be misleading. To ensure accurate, fair and balanced dissemination of information through different advertising and promotional methods, the control of medicines is principally carried out by self-regulatory bodies, guided by the Human Medicines Regulation 2012 and by the statutory role of the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA is the Government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. Its work is underpinned by robust and fact-based judgments to ensure that the benefits to patients and the public justify the risks. The MHRA will only act when there is a clear case for protection or if self-regulation fails. (MHRA the Blue Guide, 2014)

Self-regulation in the pharmaceutical industry is carried out by two British associations namely; the Association of the British Pharmaceutical Industry (ABPI), which is IFPMA-affiliated, and the Proprietary Association of Great Britain (PAGB). Each one has a code of practice that is consistent with the Human Medicines Regulation 2012. These organizations are likewise responsible in ensuring compliance of its members to their respective codes (Taylor Wessing, 2015).

ABPI represents the small, medium and large innovative research-based biopharmaceutical companies in UK. It is recognized by the government as the industry body negotiating on behalf of the branded pharmaceutical industry, for statutory consultation requirements. PAGB is the UK trade association representing the manufacturers of branded over-the-counter medicines and food supplements.

The Asia-Pacific Region
The Asia-Pacific Economic Cooperation (APEC) is a regional economic forum established in 1989 to leverage the growing interdependence of the Asia-Pacific. It has 21 member countries namely – Australia, Brunei Darussalam, Canada, Chile, People’s Republic of China, Hongkong China, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, The United States and Vietnam. APEC aims to create greater prosperity for the people of the region by promoting balanced, inclusive, sustainable, innovative and secure growth and by accelerating regional economic integration.
In 2011, APEC convened expert working groups to develop the APEC principles for codes of ethics which resulted in the Kuala Lumpur Principles for the medical device sector and the Mexico City Principles for the biopharmaceutical sector. Both these principles are fully aligned with the IFPMA’s global Code of Pharmaceutical Marketing Practices. These APEC principles were intended to serve as guidelines to assist industry associations within each APEC economy to develop and implement codes of their own that will regulate marketing and promotion within the prevailing practice standards. Self-regulation within the pharmaceutical industry is considered essential to contribute to the advancement of marketing and promotional practices within each APEC member countries but the overall regulation of drugs and medical devices is still under the control of government regulatory bodies and pertinent laws and regulations. (APEC, 2014)

The Mexico City and Kuala Lumpur Principles were APEC’s initiatives to promote growth of small and medium enterprises (SMEs) in the biopharmaceutical and medical device industries, respectively. The SMEs were identified as the most affected by unethical promotional practices in the industry, which operates in a highly competitive market. The limited resources of these industries are diverted to finance inappropriate inducements to healthcare professionals to extend market base instead of investing these resources in health innovation. This likewise results to higher costs for the patients. With these APEC Principles, the industries can develop codes of ethics to self-regulate their business practices and ensure adherence to ethical standards.

The Mexico City Principles define how companies in the biopharmaceutical sector shall market, distribute, promote and advertise their products. These principles ensure that companies’ interactions are professional exchanges designed to benefit patients and enhance medical practice. The Kuala Lumpur Principles is the first ever code of ethics for the Asia Pacific region’s medical devices industry. This Code is aimed to improve quality of patient care, encourage innovation and eliminate corruption. This code likewise provides guidelines on how to promote ethical interactions between medical device diagnostics companies and the healthcare professionals.
Pharmaceutical promotion and advertising in Australia is governed by the *Therapeutic Goods Act of 1989* (The “TG” Act), the *Therapeutic Goods Regulations of 1990* (“The TG Regulations”) and the *Therapeutic Goods Advertising Code* (2007). Promotion is also subject to the requirements of the *Trade Practices Act* (1974). The Therapeutic Goods Administration (TGA), the agency responsible for evaluating the safety and efficacy of medicines and for licensing their use, is also responsible for the control of drug promotion (Doran, 2013). Advertising therapeutic goods is also subject to other laws that regulate advertisements such as the *Competition and Consumer Act of 2010* and the *Australian Consumer Law*, both of which ensure consumer protection and safety. (Ultz, 2015)

Promotional activities are also guided by Codes of Practice/conduct that are consistent with existing laws. The *Medicines Australia Code of Conduct* (MACC) is intended to guide promotion toward supporting quality use of medicines, that is, timely, safe and appropriate prescribing. This is administered by a Committee accountable to the Medicines Australia Board. The *Medicines Australia* is the only IFPMA-affiliated member organization in Australia. The *Australian Self-Medication Industry Code of Practice* sets out standards for advertising non-prescription health products and member companies must comply with the provisions of the code to have marketing approval (Ultz, 2015).

The advertising of therapeutic goods to consumers and health professionals is administered via a co-regulatory system which is representative of all key stakeholders – consumers, health professionals, the regulated industry sectors, the media, advertisers and the government. Advertising of prescription medicines to consumers is prohibited but this is permitted to health professionals and is regulated by a self-regulatory mechanism operated by *Medicines Australia*. Advertising of non-prescription medicines\(^4\) (includes both over-the-counter and non-prescription complementary medicines) is generally allowed to both consumers and the health professionals. This is regulated by both co-regulatory and self-regulatory arrangements operated by the TGA under *the Act and Regulations*, the *Therapeutic Goods Advertising Code*

\(^4\) Regulations prohibit advertising to consumers of pharmacist-only medicines.
Council\(^5\) (TGACC), the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC) now known as Complementary Medicines Australia (CMA). Prior approval is required for advertisements and generic information of non-prescription medicines in various forms of media (broadcast media like TV and radio; print media which includes newspapers and magazines including inserts), outdoors (including billboards, bus shelters, sides and interiors of buses, taxi displays) and cinema films. The Secretary of the Department of Health and Ageing or his/ her delegate is tasked to approve advertisements however under the co-regulatory arrangements this has been delegated to industry associations. The ASMI approves all advertisements to be transmitted in broadcast media and OTC advertisements appearing outdoors or in print while CHC approves advertisements for complementary medicines appearing outdoors or in print media.

The ASMI is the peak body representing companies involved in the manufacture and distribution of consumer healthcare products in Australia supporting the progress and development of the non-prescription medicines industry which incorporates both over-the-counter and complementary products. CHC/ CMA, on the other hand, is the leading expert association composed of importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi level marketers and consumers. It is principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary healthcare industry.

Complaints about direct-to-consumer advertising in the different media are forwarded to the Complaints Resolution Panel (CRP). The CRP is a partnership between government and non-government stakeholders to exercise controls. The membership of the panel consists of representatives from the industry, consumers, advertising agencies, healthcare professionals and government. It is chaired by a person elected by the TGACC. The Panel evaluates all complaints for validity based on the materials submitted and results of its enquiries. To ensure fairness, the parties involved are given opportunities to respond. After which the Panel makes a

\(^5\) The TGACC comprises of representatives from all key stakeholders and is established under the Regulations. Key responsibilities are to ensure that the Therapeutic Goods Advertising Code is current, relevant and reflects community values and standards, ensure a level playing field for all advertisers and make recommendation to the Minister of the Department of Health and Ageing regarding uniform standards; appeals; submissions for exemptions; application of public interest criteria and policy advises.
final determination on whether the complaint is justified or not and the involved party is notified of the decision. The final determination is made publicly available and is posted in the website of the CRP. The TGA may intervene should breaches in advertising are of serious nature especially where consumer safety is a concern. For complaints that involve advertisements appearing in other media, these are handled by the relevant industry association according to their codes of practice. Figure 1 illustrates the complaints handling process for direct to consumer advertisements requiring prior approval. (Department of Health and Ageing)

![Complaints Process for OTC Advertising](Reference: Department of Health and Ageing, TGA)
The CRP is part of a system of advertising arrangements for therapeutic goods designed to ensure public health and safety while allowing a dynamic and fair environment for the manufacturing of products. This panel was established, together with TGACC, as a result of the amendments made to the *Therapeutic Goods Act and Regulations* in December 1997. These arrangements control promotional messages and general information about products to the public and are in place to ensure that all communications are truthful, valid and not misleading, such as by arousing unwarranted expectations or downplaying possible risks.

Australia also has a very active civil society groups who are strong critics of drug promotion. In fact, due to sustained critiques by groups such as *Healthy Skepticism* and the *Australian Consumers Association*, the perception has steadily grown that drug promotion to doctors requires stricter controls to ensure quality use of medicines. This resulted to imposition of restrictions by the regulatory agencies such as the Australian Competition and Consumer Commission’s (ACCC) requirement of public disclosure of industry hospitality provided to medical professions (Doran, 2013).

Healthy Skepticism is an independent, international, non-profit organization based in Australia whose membership primarily includes doctors and pharmacists. Among the activities of the organization are to (1) investigate and communicate marketing practices, (2) promote healthy skepticism about marketing practices via advocacy, research, and education, (3) initiate reform of regulations and incentives, and (5) evaluate drug promotions through an evidence-based approach in order to improve health care decision making.

The Australian Consumers’ Association (CHOICE) is a non-profit organization in Australia which has been researching and campaigning on behalf of consumers since 1959. They played an important role in the drafting of the Trade Practices Act of Australia, and the Australian Consumer Law.

**China**

Promotion and advertisement of drugs in China are regulated by two main policies, the *Advertisement Law* and the *Drug Administration Law*. The China Food and Drug Administration (CFDA) and the State Administration for Industry and Commerce (SAIC) have concurrent jurisdiction over drug promotion. At the provincial level, the regulatory authorities are the
Provincial Food and Drug Administrations (PFDAs) and the local Administrations for Industry and Commerce (AICs).

China prohibits advertisement of prescription drugs directly to the public. This is limited to state-approved medical and pharmaceutical professional publications. China regulates advertisement content and requires approval prior to launch whether this is for prescription or OTC drugs. The PFDAs of the provinces, in which the applicant is located, are tasked to pre-approve advertisements. The PFDA submits report to the CFDA for recording. Manufacturers who wish to post their advertisements to different provinces must obtain advertisement licenses from each of the PFDAs where it will be advertised. Under Chinese law, the administrative penalties for launching drug advertisements without pre-approval from the appropriate PFDA include:

- Issuance of an administrative order to stop advertising,
- Confiscation of funds or fees for the advertisement,
- Issuance of a fine of one or five times the advertisement fee,
- Temporary suspension of drugs sales regionally, and
- Issuance of public notice about the violation.

The first three penalties are administered by the SAIC or the local AICs. The last two are administered by the CFDA or the PFDA.

Because of the strict regulation on advertisements, most promotion of prescription drugs takes the form of non-advertising promotion. There are no specific legal requirements for non-advertising promotion of drugs. There is no law that requires promotional information to include material facts or to present balanced information. This results to unethical non-advertising promotion (Ma and Lou, 2013)

Because of the lack of regulation, the industry group, R&D-based Pharmaceutical Association Committee in China (RDPAC), which is IFPMA affiliated, created a voluntary self-regulatory code. The code includes provisions for the pre-approval of advertisements, provisions for printed

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6 Because pre-approval of the advertisement is conducted at the provincial level, differences in their resources and competence result in disparate levels of regulation and enforcement.

7 Non-advertising promotion is the provision of on-label or off label information merely for academic or scientific purposes and not for promotional or marketing purposes.
promotional materials, interactions with healthcare professionals, giving samples, clinical research and clinical examination are also provided in the code. Complaints may also be submitted to the RDPAC. (RDPAC, 2012) But because the code is voluntary and not all companies are members, Ma and Lou (2013) commented that this is unlikely to have market impact.

**Indonesia**

The advertisements in Indonesia are generally governed by the Consumer Protection Law. Separate laws for each media platform are being implemented: the Press Law for print and electronic media, the Broadcasting Law for television and radio, and the Information and Electronic Transactions (ITE Law) for digital media. The Ministry of Health has posted specific guidelines in advertising medicines in 1994. (World Trade Press, 2013)

Under the *Medicine Advertising Guidelines* of the Ministry of Health, only over-the-counter drugs and non-medical traditional drugs are allowed to be advertised to the general public. Prescription drugs are promoted to the healthcare professionals through medical representatives, seminars and medical magazines.

The advertisements and promotions require the approval of the Indonesian Department of Health. An application of advertising license should be filed by the company to the local government. The pharmaceutical company, advertising company and the local government must sign an agreement regarding the terms of the advertisement. Advertisement tax is paid by the pharmaceutical industry after the approval of the advertisement.

The pharmaceutical industry associations in Indonesia mainly rely on self-regulation. The *International Pharmaceutical Manufacturers Group (IPMG)* has published a code of ethics to be followed by its member organizations. IPMG is a member of the IFPMA.

**Singapore**

Advertising and promotion of medicinal products are controlled under the *Medicines Act 1975 (MA)* and its subsidiary legislation, the *Medicines (Medical Advertisements) Regulation 1977*
(MAR). Apart from these, the general consumer, The Consumer Protection (Trade Descriptions and Safety Requirements) Act (CPTDA), and trade legislation, The Consumer Protection (Fair Trading) Act (CPFTA), may also apply. Advertisement control of medicinal products ensure that medicinal products advertised or promoted for sale to the public do not affect public health, mislead or induce unnecessary use. The Health Sciences Authority (HSA) is the designated authority to regulate advertisements and promotions.

The HSA, established by the Health Sciences Authority Act, operates under the oversight of the Ministry of Health. The HSA is responsible for the administration of Singapore's health-related laws and regulations and regulates the health products sector. It ensures that drugs, innovative therapeutics, medical devices and health-related products are regulated and meet safety, quality and efficacy standards. The HSA also helps to formulate national drug policies.

In general, any advertisement or sales promotion relating to a medicinal product requires prior approval from the HSA. Reference advertisements\(^8\) and trade advertisements\(^9\) however do not require a permit.

Generally the aforementioned legislations do not spell out permissible forms of advertising/marketing practices but state which acts are prohibited. There are however industry guidelines and codes that may be helpful to determine acceptable advertising/marketing behavior. The more relevant ones include the following (Leck and Jun Lim, n.d.):

- A Guide on Advertisements and Sales Promotions of Medicinal Products (Medical Advertisement Guide). This is issued by the HSA which offers guidance on how HSA applies MA and MAR. It provides detailed information on advertisements and promotion permits to be secured and other information relevant to application of these permits, guidelines on medical advertisements and sales promotion and offenses and penalties.

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\(^8\) Reference advertisements – product information pertaining to the sale and correct use of a medicinal product, published by a person or company with no commercial interest, for dissemination to practitioners and pharmacists

\(^9\) Trade advertisements – documents for the purpose of a sale by way of wholesale dealing which does not contain any recommendation on product use.
- **The Singapore Code of Advertising Practice (SCAP).** This is a set of guidelines regulating advertising activities in Singapore which is administered by the Advertising Standards Authority of Singapore. The general and specific principles applicable to medicinal products are similar to the Medical Advertisement Guide General Principles.

- **The Singapore Association of Pharmaceutical Industries Code of Marketing Practice (SAPI Code).** This is an industry code which addresses marketing practices concerning pharmaceuticals, medicinal and biological products between SAPI members and healthcare professionals. These marketing practices include sponsorship of meetings and symposia, hospitality and entertainment provided at sponsored meetings and symposia; gifts and promotional items and donations and grants.

- **The Singapore Medical Council’s Ethical Code and Ethical Guidelines (SMC Code).** This Code is applicable to registered medical practitioners only. It sets out what SMC regards as minimum standards of registered medical practitioners discharging their professional duties, including conducting respect of financial interests, sponsorships and gifts. This also serves as guidance in disciplinary proceedings against erring medical practitioners.

**Malaysia**

The regulatory control of pharmaceutical products and traditional medicines in Malaysia is carried out by the National Pharmaceutical Control Bureau (NPCB), formerly known as the National Pharmaceutical Control Laboratory, an institution under the Pharmaceutical Services Division (PSD) of the Ministry of Health, which ensures the quality, efficacy and safety of pharmaceutical products as well as the quality and safety of traditional medicines and cosmetics marketed in the country. It handles the registration of pharmaceutical products and traditional medicines as well as the notification of cosmetic products under the Control of Drug and Cosmetics Regulations of 1984. (Pharmaceutical Industry in Malaysia, 2012)

The advent of the Control of Drug and Cosmetics Regulations in June 1984 provided the establishment of Drug Control Authority (DCA) which regulate the pharmaceutical industry and acts as the executive committee responsible for product registration and licensing of manufacturers, importers and wholesalers of all marketed products in the country, whereby the NPCB functions as the operational arm and the secretariat to the DCA. Aside from the clear function of the DCA as the primary regulatory body that oversee the pharmaceutical industry,
self-regulatory practices within the industry has played a part in ensuring accurate information disseminated to consumers. (Pharmaceutical Industry in Malaysia, 2012)

The *Pharmaceutical Association of Malaysia (PhAMA)* is an IFPMA-affiliated organization that sets out two codes of conduct for self-regulation of pharmaceutical marketing and promotion in Malaysia which include codes of conduct for prescription product and a separate code for OTC products. The objective of the Code is to provide as clear as possible guidelines in disseminating accurate, fair and objective information to the medical and allied profession so that rational prescribing decisions can be made. In so doing, members are obliged to adopt the high standard of conduct and professionalism in the marketing of pharmaceutical products and companies outside the association are strongly recommended to accept and observe the code. (PhAMA, 2015)

**Thailand**

Drug promotion in Thailand is regulated by the Thailand Food and Drug Administration. The Thailand FDA strongly believes that drug information is as important as drug quality. Drug advertisements of registered drug products are therefore submitted first to the Thai FDA for review and approval. Prescription drugs are only allowed to be advertised to healthcare professionals. According to the *Drug Act*, the Drug Committee is appointed by the Minister of Public Health every two years to advise him/her on both regulatory and technical aspects concerning the administration and regulation of pharmaceuticals. The committee then appoints subcommittees to assist them in regulating pharmaceutical products, one of them is the subcommittee for review and evaluation of drug advertisements and promotions which is responsible for final approval of drug product promotions and for ensuring that it is not misleading and follows pertinent Thai laws and regulations. (Thai FDA, 2004)

Aside from the government final approval of drug promotion as advised by the subcommittee, self-regulation in Thailand is primarily administered by the *Pharmaceutical Research and Manufacturers’ Association (PreMA)* in Thailand which self-regulates the advertisements of its member organizations. They have published a code “*PreMA Code of Sales and Marketing Practices*” which is in accordance with the IFPMA. The code includes general principles of promotion as well as very detailed provisions for advertising in journals, providing samples,
providing gifts and hospitality and sponsoring events. Complaints regarding advertisements of member companies may be submitted first to the organization while complaints for non-members are forwarded to the Thai FDA. The procedure for complaints and sanctions for violations are also included in the code. (PReMA, 2012)

**Vietnam**
The laws that govern drug marketing activities in Vietnam include the following: *Law on Commerce No. 36* (Commercial Law), *Decree No. 37* on trade promotion activities, *Law on Advertising No. 16* (Law on Advertising), *Law on Pharmacy No. 34* (Law on Pharmacy), and *Decree No. 79* implementing the Law on Pharmacy, and *Circular No. 42* on the list of active ingredients and herbal products that can be advertised and broadcasted through radio and television. Advertising in Vietnam is regulated by the Drug Administration of Vietnam (DAV). The government agency only allows advertising of non-prescription drugs with a marketing authorization number in Vietnam. Advertisements for over-the-counter drugs, however, require the approval of the DAV prior to broadcasting. Monitoring, supervision and suspension of marketing activities to consumers and healthcare professionals are also responsibilities of the DAV. Pharmaceutical companies do not follow any code of practice for self-regulation. The Vietnamese companies only follow the law for advertising drug products. (Trinh, TN and Nguyen, D, 2013)

The *Vietnam Pharmaceutical Companies Association* is a pharmaceutical industries organization which aims to enhance the brand of Vietnamese pharmaceuticals in the market. However, the organization neither has an affiliation with the IFPMA nor a code of practice for self-regulation of pharmaceutical advertisements and promotions. (Trinh, TN and Nguyen, D, 2013; VNPCA, 2009)

**Comparison of Pharmaceutical Promotion Regulation across Countries/Regions**

Pharmaceutical promotions in different countries reviewed are governed by pertinent national laws and very often the under the jurisdiction of the Ministry of Health or its counterpart. The legislative and regulatory controls limit to whom and how pharmaceutical products can be
advertised or promoted. Self-regulation is common to all countries reviewed except for Vietnam. Self-regulation is guided by the Codes of Conduct/ Ethics of the pharmaceutical industry and health care professionals. Civil society involvement seems to be limited, albeit significant, to advocacy campaigns on ethical promotions which led to imposition of stricter controls on legislations for pharmaceutical promotions such as what happened in Australia and the European Region. In Canada, the involvement of non-government stakeholders is demonstrated in the APAs which are recognized by the government as legitimate clearing houses for advertising and promotional materials and source of advisory opinions on drugs and medical conditions prior to public dissemination. In Australia, the creation of CRP is a concrete example of partnership between government and non-government stakeholders to exercise controls. Non-government stakeholders are likewise involved in pre-approval of advertisements of both OTC and prescription medicines.

Tables 1 and 2 show the summary of listing of regulations and code of ethics provisions for the different countries reviewed.
<table>
<thead>
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<th>Australia</th>
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<td>Medicines and Healthcare Products Regulatory Agency</td>
<td>Federal Institute for Drugs and Medical Devices (BfArM)</td>
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<td>“Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V (FSA)” (“Voluntary Self-regulation of the Pharmaceutical Industry”)</td>
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<p>| Guidelines for Medical Representatives | ✓ | ✓ | ✓ | ✓ | ✓ |
| Interaction with healthcare professionals/pharmaceutical industries | ✓ | ✓ | ✓ | ✓ | ✓ |
| Gifts and payments to doctors or other health professionals | ✓ | ✓ | ✓ | ✓ | ✓ |</p>
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Civil society involvement:
- Consumers Union
- No Free Lunch
- Carlat CME Institute
- Corporations and Health
- Transparency International
- Transparency International
- ASC and PAAB
- Federation of German Consumer Organizations
- Transparency International
- CHOICE – Australian Consumers Association Council
- Association for Consumers Action on Safety & Health
- Transparency International
- CRP
- ASMI and CHC

✓ Means that a provision for this area exists in the Code of Ethics/ Practice identified
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| List of regulations relevant to pharmaceutical promotions | • The Drug Administration Law (2001 revision)  
• The Implementation Regulation of the Drug Administration Law (2002)  
• Drug Registration Regulation (2007 revision)  
• The Advertisement Law (1995)  
• The Criminal Code (1997)  
• Regulation for the Administration of Adverse Drug Reaction Report and Monitoring (2004)  
• Temporary Regulation on the Administration of Prescription and OTC drugs (2000)  
• Regulation on Drug insert Sheets and Labeling (2000)  
• Government of DKI Jakarta Regulation No. 9 of 2014 regarding Advertisement Operations  
• Law No. 32 (2002) Broadcasting Law  
• Law No. 40 (1999) Press Law  
• Law No. 8 (1992) Film  
• The Health Products Act of 2008  
• Medicines (Medical Advertisement) Regulations  
• Medicines (Advertisement and Sale) Act | • Medicines (Advertisement and Sale) Act 1956 – Revised 1953  
• Medicine Advertisements Board Regulations 1976 | • Drug Act, BE 2510 (1967)  
• Consumer Protection Act, BE 2522 (1979)  
• Consumer Protection Act, BE 2522 (1979)  
• Direct Sales and Direct Marketing Act, BE 2545 (2002) | • Law on Advertising No. 16/2012/QH13 (2012)  
• Governmental Decree No. 181/2013/ND-CP (2013)  
• Governmental Decree No. 37/2006/ND-CP (2006)  
• Governmental Decree No. 158/2013/ND-CP (2013)  
• Joint Circular No. 85/2008/TTLT-BVHTTDL-BTTTT (2008)  
• Circular No. 13/2009/TT |
<p>| Enforcing agency | China Food and Drug Administration | Indonesian Department of Health | Health Sciences Authority | Malaysian Drug Control Authority | Thai Food and Drug Administration | Drug Administration of Vietnam |</p>
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</tr>
<tr>
<td>Sponsorship of scientific meetings</td>
<td>✓</td>
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<td>Country</td>
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<td>Interaction with Non-HCPs (Patient Organizations, Public)</td>
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<td>✔</td>
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</tr>
<tr>
<td>Sanctions/ Penalties</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>NA</td>
</tr>
</tbody>
</table>
| Civil society involvement | • China consumers Association  
• Transparency International | • Institute for Consumer Development and Protection  
• Transparency International | Consumer Association of Singapore  
• Transparency International | Transparency International  
• Foundation for Consumers  
• Transparency International | • Vietnam Standards and Consumers Association (VINASTAS)  
• Transparency International |

✔ Means that a provision for this area exists in the Code of Ethics/ Practice identified

For Vietnam:
- Governmental Decree No. 37/2006/ND-CP (2006) on Trade Promotion Activities
- Governmental Decree No. 158/2013/ND-CP (2013) Regulations on administrative penalties in cultural, sports, tourism and advertising activities
- Joint Circular No. 85/2008/TTLT-BVHTTL-D-TTTT (2008) Guiding the licensing, registration, and placement of advertisements in the press, online communication networks and publications, and the inspection, examination and handling of violations
- Joint Circular No. 06/2007/TTLT-BVHTT-BYT-BNN-BXD (2007) guiding the one-stop shop procedures for the granting of advertisement permits
- Circular No. 13/2009/TT-BYT of the Ministry of Health in Guiding Drug Information Provision and Advertising
B. Situational analysis of pharmaceutical promotions regulation in the Philippines

1. Legal Framework
The Philippines, unlike some countries, does not have an advertising law. Despite this, there are several laws in the country that provide the basis for regulation of pharmaceutical advertisements and promotions.

**Consumer Act of the Philippines (RA 7394)**
Republic Act No. 7394, otherwise known as the *Consumer Act of the Philippines* was enacted in 1992 to protect the interest of the consumer, promote his welfare and establish standards of conduct for business and industry. Among the objectives of the State to be implemented in this Act is to protect consumers against deceptive, unfair, and unconscionable sales acts and practices, and to provide information and education to facilitate sound choice and proper exercise of rights by the consumer (Article 2, RA 7394).

The terms “Advertisement” and “Sales Promotion” are clearly defined for the purposes of the Act (Article 4, RA 7394). “Advertisement” is defined as advertising matter that is applied, disseminated or circulated through any form of mass medium. “Sales promotion” is defined as techniques involving broad consumer participation, as well as techniques intended to increase sales, patronage, and/or goodwill of a product.

The implementing agency concerning advertising and sales promotion of drugs is the Department of Health (Chapter VI, Article 109, RA 3794). Special advertising requirements for drugs are outlined in the Act (Chapter VI, Article 112, RA 3794):

- Claims in advertisements should only cover those which are approved or contained in the label.
- Advertisements should not bear false impression regarding the character, value, quantity, composition, merit and safety of the product
- Any advertisements should not use in reference any laboratory report/s of analysis which is not approved by the FDA.
- Only drug products that are registered and approved may be advertised.
Sales promotion campaigns are required to secure a permit from the DOH-FDA at least thirty (30) calendar days prior to commencement. However, campaigns involving medical prescriptions for raffles or a promise of reward is prohibited (Chapter VI, Article 116, RA 3794).

Penalties for violative advertisements and sales promotion activities are as follows:

- For violative advertisements, a fine of not less than five hundred pesos (P 500) but not more than five thousand pesos (P 5,000) or imprisonment of not less than one (1) month but not more than six (6) months or both
- For violative sales promotions, a fine of not less than two hundred pesos (P 200) but not more than six hundred pesos (P 600) or imprisonment of not less than one (1) month but not more than six (6) months or both

Publishers, radio, broadcast, television licensing, or other mass media involved in the dissemination of the violative advertisement are exempted from liability. Only the manufacturer, packer, distributor or seller and the advertising agency are subject to the penalties stated.

**Foods, Drugs and Devices, and Cosmetic Act (RA 3720, as amended by EO 175)**

Republic Act No. 3720 declares that it is the policy of the State to ensure the right to health of the people and establish and maintain an effective food and drug regulatory system (Section 3, EO 175). Thus, it creates the Food and Drug Administration (later on renamed to be the Bureau of Food and Drugs) under the Department of Health (Section 4, RA 3720). In this Act, the functions of the FDA are centered on ensuring product safety, quality and efficacy through inspection, licensing, and analysis. The regulatory role of FDA in pharmaceutical advertisement and promotions is not yet described (Section 4, RA 3720).

**Food and Drug Administration (FDA) Act of 2009 (RA 9711)**

The FDA Act of 2009 was created to enhance and strengthen the administrative and technical capacity of the FDA in its monitoring and regulatory activities. It amends several sections of RA 3720, expanding the powers and functions of the FDA. This Act mandates FDA to prescribe standards, guidelines, and regulations with respect to marketing activities about health products.
such as information, advertisements, promotions, and sponsorship, among other functions (Section 5, RA 9711). Centers within FDA were also created, and it is the Center for Drug Regulation and Research (CDRR) that holds regulatory power over drug products, veterinary medicine, vaccines, and biologicals (Section 6, RA 9711).

Several subsections in RA 3720 on prohibited acts were also amended in RA 9711, adding to the list the advertisement and promotion of unregistered drug products (Section 10, RA 9711). Misbranding of products, which includes inclusion of misleading data in product information materials is also prohibited. Penalties for violations of this Act are as follows:

If the offender is a person
- Imprisonment ranging from one (1) year but not more than ten (10) years or
- A fine of not less than fifty thousand pesos (P 50,000) but not more than five hundred thousand pesos (P 500,000) or both

If the offender is a manufacturer, importer, or distributor
- Imprisonment ranging from one (5) year but not more than ten (10) years and
- A fine of not less than five hundred thousand pesos (P 500,000) but not more than five million pesos (P 5,000,000)

An additional fine of one percent (1%) of the economic value of the violative product, or one thousand pesos (P 1,000), whichever is higher, shall be imposed for each day of continuing violation. In addition, health products that are found in violation may be seized and held in custody without hearing or court order.

**Generics Act of 1988 (RA 6675)**

Republic Act No. 6675 is a policy enacted by the government with the primary objective of promoting and encouraging the use of generic terminology in all activities involving drugs, such as advertising and promotion. It emphasizes the scientific basis for the use of drugs in order for health professionals to become more aware and cognizant of their therapeutic effectiveness. It also aims to promote drug safety by avoiding duplication in medications with similar or interacting active components (Section 2, RA 6675).
In all advertising and promotional materials, the pharmaceutical company shall ensure that the generic name shall appear prominently and immediately above the brand name of the product. The exclusive use of generic terminology in marketing activities for those in the Essential Drug List shall be promoted through an incentive system promulgated by the Department of Health in coordination with the Board of Investments (Section 4, RA 6675).

Any violation of the Generics Act warrants the following penalties:

- A fine not less than five thousand pesos (P 5,000) but not more than ten thousand pesos (P 10,000) and
- Suspension or revocation of the license to operate

2. Specific Regulations and Issuances

In order to carry out its mandate to prescribe standards, guidelines, and regulations with respect to marketing activities, the FDA issued several regulations and issuances guiding pharmaceutical advertisements and promotions. These are summarized in Table 3.
<table>
<thead>
<tr>
<th>Regulation/ Issuance</th>
<th>Title</th>
<th>Year Issued</th>
<th>Relevant Provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>BFAD Regulation No. 5 S. 1987</td>
<td>Guidelines on Advertisement and Promotions of Prescription Pharmaceutical Products</td>
<td>1987</td>
<td>• Distribution of prescription drugs directly to the lay public is strictly prohibited</td>
</tr>
</tbody>
</table>
| Administrative Order No. 65 S. 1989              | Guidelines on Advertisement and Promotions to Implement the Generics Act of 1988 | 1989        | • “Advertisement” includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any pharmaceutical product  
• “Promotion” means the practice of giving temporary additional value to a brand, product, or service to achieve specific marketing objectives. Promotion includes the distribution of free/sample pharmaceutical products.  
• The generic name must be the most prominent element in all advertising and other promotional material, whether in print, visual, or auditory materials.  
• Print and static visual materials such as posters or billboards must comply with the pertinent provisions of Administrative Order No. 55 s. 1988 or the generic labelling requirements.  
• For visual materials such as those shown in television or cinemas, the generic name shall appear prominent within the outlined box, immediately above and in larger point-size than the brand name, if any.  
• For auditory materials, the same principle shall apply, adopted according to the convention of medium.  
• The drug establishment under whose name the drug product is registered shall be responsible for ensuring that its advertisement and other promotional materials comply with guidelines.  
• The drug establishment shall establish suitable mechanism for internally reviewing such materials, specifically with the participation of its medical directors.  
• Drug establishments may also participate in other industry-wide mechanism for self- or voluntary regulation.  
• Monitoring and processing of violations and complaints regarding advertisements and promotions were also laid out in the policy, but was later amended by the IRR of Republic Act No. 9711.                                                                                                                                                                           |
| Joint AO for DA AO 41 s. 1991 and DOH AO 111-D s. 1991 | Guidelines on Advertisement and Promotion of Veterinary Drugs and Products | 1991        | • Veterinary drugs and products refer to any substance, including biological products applied or administered to food producing, companion, aquatic, laboratory and exotic animals, whether used for therapeutic, prophylactic or diagnostic purpose or for modification of physiological functions or behaviors.  
• No person shall advertise or promote veterinary drug and product unless such
<table>
<thead>
<tr>
<th>Regulation/ Issuance</th>
<th>Title</th>
<th>Year Issued</th>
<th>Relevant Provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>products are duly-registered with the FDA and/or BAI</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• All therapeutic claims for veterinary drugs and products made in advertising or promotional materials must be based on adequate scientific, pharmacological, technical, and clinical evidence, responsible veterinary medical opinion, or long experience demonstrating their safety, efficacy, and therapeutic value, and must be within their therapeutic indications approved by FDA and or BAI.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Veterinary drugs and products classified by FDA or BAI as prescription or ethical drugs can be advertised or promoted in any form of mass media provided a veterinarian should be prescribing the veterinary drugs and products.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Veterinary drug and product companies and the veterinary medical director/officer shall be responsible and accountable for the content and form of their advertisement and promotion materials.</td>
</tr>
<tr>
<td>Administrative Order No. 119 S. 2000</td>
<td>Additional Guidelines on the Promotion of Over-the-Counter (OTC) Drugs to the Public</td>
<td>2000</td>
<td>• The promotion of OTC drugs to the public will only be allowed if its known adverse effects are also cited</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Any sales promotion campaign using medical prescriptions or any part thereof or attachments relative thereto for travels (particularly travels abroad) or a promise or reward shall not be allowed</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Permit to conduct promotion, sponsored and promoted by manufacturing enterprises must in all cases secure the necessary approval from FDA</td>
</tr>
<tr>
<td>Department Circular No. 2011-0101</td>
<td>The Rules and Regulations Implementing Republic Act No. 9711 – The Food and Drug Administration Act of 2009</td>
<td>2011</td>
<td>• Provides the general rules on advertisements, promotions, sponsorship, and other marketing activities. These include: (1) product involved is registered; (2) claims are consistent with the approved labels; and (3) the reference number for the approval of such activity must be clearly stated.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• The manufacturer, owner, distributor, advertiser, and/or their agents are mandated to strictly observe the above prohibitions and strictly adhere to the standards, guidelines, and rules and regulations prescribed by FDA.</td>
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<tr>
<td></td>
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<td></td>
<td>• The director general of the FDA is mandated to rationalize the marketing practice through promulgation of policies and directives, such as but not limited to, scientific and product information dissemination and advocacy activities when appropriate.</td>
</tr>
<tr>
<td>FDA Circular No. 2013-024</td>
<td>The Adoption and Implementation of “The Mexico City Principles for Voluntary Codes of</td>
<td>2013</td>
<td>• The policy provided for a general implementation of the Mexico City Principles – from the crafting of general guidelines by the CDRR; monitoring, surveillance and</td>
</tr>
<tr>
<td>Regulation/ Issuance</td>
<td>Title</td>
<td>Year Issued</td>
<td>Relevant Provisions</td>
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</tr>
<tr>
<td>FDA Memorandum Circular No. 2013-028</td>
<td>General Guidelines on the Promo Permit Applications and For Other Purposes</td>
<td>2013</td>
<td>• Providing guidance on the filing and processing of promo permit applications.</td>
</tr>
<tr>
<td>FDA Memorandum Circular 2013-030</td>
<td>Guidelines on the Use of the FDA Logo and Name in Promotional Advertisement, Sponsorship, Marketing, or Commercial Materials</td>
<td>2013</td>
<td>• This Circular was implemented to (1) stop the inappropriate use of the FDA name and logo in promotional, advertisement, sponsorship, marketing, or commercial materials which is misinterpreted by the public as endorsement by FDA; and (2) reiterate that the appropriate authorization numbers are required to be reflected.</td>
</tr>
</tbody>
</table>
| Administrative Order No. 2014-0040           | Revised Guidelines on the Need/Role of a Medical Director in the Pharmaceutical Industry | 2014        | In relation to advertisements and promotions, the medical director is tasked to:  
• Ensure that (a) all product information is science-based and product claims are well substantiated, factual, balanced, and rational, and (b) marketing and promotions are strictly based on ethical practices;  
• Approve all package inserts, labels, brochures, and other labeling and promotional materials;  
• Provide assistance in the training program of professional sales representatives, supervisors, pharmacists, and other personnel of the drug establishment.                                                                                                                                                                          |
3. The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

A Joint Ministerial Statement promoting cooperation of SMEs was issued during the 17th APEC SME Ministerial Meeting in 2010. Recognizing that unethical business practices create market barriers and higher costs for SMEs, the APEC Ministers endorsed the creation of principles for voluntary codes of ethics in the biopharmaceutical industry. Through the efforts of an Expert Working Group, “The Mexico City Principles for Voluntary Codes of Business Ethics” (Mexico City Principles) was officially endorsed for adoption by APEC member economies. President Benigno Aquino III, in 2011 signed an APEC Leader’s declaration of the Mexico City Principles, signifying the support of the Philippines to the standardization of business ethics (In August 2015, the Philippines was recognized by APEC through the Lighthouse Award for Business Ethics for the country’s collective effort in developing and implementing guidelines on ethical business practices in the biopharmaceutical and medical device sector).

There are six guiding principles that form the basis for the Mexico City Principles:

a) Healthcare and Patient Focus
b) Integrity
c) Independence
d) Legitimate intent
e) Transparency
f) Accountability

The central theme of the Mexico City Principles is ensuring ethical interactions in order to safeguard patient welfare. Interactions between companies and healthcare professionals must be based on the provision of objective information about medicines in order to ensure that medicines will lead to maximum patient benefit. Other salient points of the document are outlined below:

- Promotion of medicines by companies should comply with applicable laws and regulations in the concerned APEC economy. Promotional information should be clear, legible, accurate, balanced, fair, objective, and sufficiently complete.
- Medicines provided by companies should adhere to high standards of quality, safety, and efficacy.
• The purpose of company sponsorship in symposia and congresses is to inform healthcare professionals about products and/or provide scientific or educational information. Hospitality should be moderate and reasonable based on local standards, and should only be provided to the participants of the event.

• Meals provided during informational presentations by company representatives must be conducive to scientific or educational communication and must not be part of entertainment or recreation.

• Companies should not provide any form of entertainment or recreational items to any healthcare professional.

• Educational items may be given to healthcare professionals, if permitted by law or codes of ethics, as long as the items are of modest value. It should not subsidize normal routine operations of a medical practice. Cash or cash equivalents and personal gifts must not be provided or offered to healthcare professionals.

• Support for continuing medical education (CME) should be based on objective criteria and should not be an incentive for prescribing decisions.

• Provision of samples of medicines must have adequate systems of control and accountability and must neither be used as inducements, nor resold.

• Healthcare professionals who are invited to consulting or speaking arrangements may be compensated provided that the arrangement is bona fide and the compensation is based on fair market value.

• Companies should institute and document Internal compliance procedures to the Mexico City Principles.

• Company representatives must possess sufficient knowledge on general science and product-specific information, as well as applicable laws, regulations, and industry codes of ethics.

• Companies involved in the government procurement process must not attempt to exert inappropriate influence to the decision-making process.

• Clinical trials and research involving patients sponsored or supported by companies should be conducted in a bona fide and ethical manner. Presentation and publication of research results must be done in the spirit of transparency and accountability.
• Donations by companies to charitable purposes should not involve product promotion purposes.
• Companies should respect the autonomy of patient organizations.

It is recommended in the Mexico City Principles that APEC Economies formulate clear laws and regulations, and work towards ethical collaboration with other stakeholders. Biopharmaceutical companies and industry associations should also cooperate to develop codes of ethics consistent with the Mexico City Principles. Once implemented, industry associations should consider publicizing members who support the industry codes, and training healthcare professionals and students regarding the codes. Healthcare professional organizations should likewise develop and implement their own codes of ethics.

**Adoption of the Mexico City Principles**
Pursuant to the mandate of FDA to prescribe standards, guidelines, and regulations on advertisements and other marketing activities (Section 4, RA 9711), FDA Circular No. 2013-024 was issued with the objective of adopting and implementing the Mexico City Principles. This Circular covers all drug establishments regulated by the FDA, as well as the FDA itself, healthcare professionals, and other stakeholders such as advertisers and media.

According to this Circular, the Center for Drug Regulation and Research (CDRR) of the FDA is tasked with the primary responsibility of creating guidelines for the application and approval of marketing materials for pharmaceutical and biologic products, as well as implementing and monitoring compliance with the Mexico City Principles. All sanctions and penalties for violation of the Mexico City Principles are to be imposed by the CDRR in consultation with the Office of the Director General of the FDA. Monitoring, surveillance, and investigations on complaints and violations shall be conducted with the assistance of the Regional Field Operation (RFO) Unit.

**Creation of a Committee for Implementation**
In addition to the FDA Circular, the Department of Health, through DOH Department Circular 2014-0389, created a committee for the Implementation of the Mexico City Principles. This Committee is chaired by an Undersecretary of the Department of Health, with the FDA Director General as the Vice-Chair. Composition of the committee comes from members of both public
and private sectors, notably including representation from the DOH, Professional Regulatory Commission (PRC), pharmaceutical industry, hospital associations, and professional associations. This committee does not include representation from patient organizations or the general public.

The Committee is tasked to formulate and develop guidelines for implementation of the Mexico City and Kuala Lumpur Principles, including penalties and sanctions. These guidelines were to be submitted to the Secretary of Health for approval within ninety (90) days after the effectivity of the Circular (the Circular was issued October 2, 2014). The Circular also cites the following parameters to be included in these implementing guidelines (Section 5, DOH Circular 2014-0389):

a) Creation of policies and programs that address the different aspects of ethical pharmaceutical business practice
b) Strengthening of the surveillance, monitoring, and evaluation capacity of the implementing agencies in the area of pharmaceutical promotion
c) Ensuring compliance to ethical standards stated in the Mexico City Principles
d) Continuous training and education on ethical practice in the healthcare system
e) Conduct of research on the impact of standardization of code of ethics among stakeholders

4. Self-Regulation Mechanisms
The stakeholders involved in pharmaceutical promotions are encouraged to keep their interactions and activities ethical through self-regulatory mechanisms governed by codes of ethics and practice. These codes are usually enforced among members of the industry associations such as the Pharmaceutical and Healthcare Association of the Philippines (PHAP) and the Philippine Chamber of the Pharmaceutical Industry (PCPI), and nationally accredited professional organizations like the Philippine Medical Association (PMA) and the Philippine Pharmacists Association (PPhA). The mechanisms and guidelines of these organizations will be discussed in the next paragraphs together with another notable self-regulatory mechanism in place for advertisements implemented by the Ads Standards Council (ASC).
Pharmaceutical and Healthcare Association of the Philippines

Members of the PHAP, which represents research-based pharmaceutical companies, are subject to a Code of Practice which was last updated in 2014. This code fully adopts and aligns with the Expanded Code of Practice of the IFPMA and the Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector. It also incorporates local requirements and practices in relation to registration, labelling and scientific claims, approved by the Philippine FDA.

Advertisements

The PHAP Code requires advertisements to be ethical, accurate, balanced and not misleading. The guiding principle for promotional materials is that they must support proper assessment of the risks and benefits of the product and its appropriate use. Unqualified superlatives are not to be used and claims should not imply unsubstantiated uniqueness or special merit, quality or property. The use of clinical terminology is encouraged to describe improved benefits rather than claims that a product is better, stronger or more widely prescribed. In addition, promotional information should not imitate devices, copy, slogans or general layout adapted by other manufacturers in a misleading or confusing manner.

There are also provisions on the appropriateness of product information and labels. The Code makes it the responsibility of the companies, their employees and their medical/technical advisers to ensure that the contents are balanced, accurate, correct and fully supported by the product literature or appropriate industry source.

Prohibited for advertising and promotion are unregistered products or unapproved indications by the FDA. Prescription products are not allowed to be advertised in lay media but are allowed to be in professional journals with the required details.

Interactions with Health Professionals

Pharmaceutical Sales Representatives of PHAP members are required by the Code to possess sufficient medical and technical knowledge to present information in an accurate and balanced manner. They are also required to be cognizant of the provisions of the Code of Practice and
further undergo continuing competency training under the Integrity and Proficiency Program in the Pharmaceutical Sector, which is accredited by the PRC.

The Code recognizes pharmaceutical companies as responsible for providing accurate, balanced and scientifically valid data on products, but any interactions with stakeholders must at all times be ethical, appropriate and professional. Information provided must include knowledge gained from the research and development of medicines as well as from their clinical use and Philippine healthcare providers should have access to similar data as those being communicated in developed countries. The code also describes limits of hospitality which includes meals. No financial benefit or favors may be offered to a healthcare professional in exchange for prescribing or recommending the product.

Sponsorship and organizing of events for healthcare professionals outside the home country is not allowed unless it is deemed appropriate and justified on basis of logistics or security. Only economy class fare is allowed for travel. In addition, the primary reason for the sponsorship must be the event’s scientific agenda and must not be imposing upon individuals a condition to prescribe or promote any product.

Post Marketing Surveillance is allowed for risk management, but members are prohibited from compensating healthcare providers who participate in such activities. The code also emphasizes that the intent of scientific research and clinical trials that are sponsored, must be for the development of knowledge and advancement of science and medicine for the benefit of patients. Clinical trials are required to be transparent and in accordance to FDA requirements.

Pharmaceutical Promotions

For pharmaceutical promotions, the PHAP Code specifically allows the distribution of promotional giveaways even without product information as long as no promotional claims are made. Items that cost more than P1,000 can only be donated to institutions such as medical societies, professional organizations and hospital departments but never to individuals.

Furthermore, raffles and competitions are permitted only during official conventions organized by the Philippine Medical Association or its affiliates and must not be in conflict with any of the
official convention activities. Competitions are required to be based on medical knowledge or the acquisition of it and the process must be relevant and specific to the practice of medicine. Prizes are required to be of low monetary value, albeit the amount is not specified or be of educational use. Entry to a competition on basis of prescribing, ordering or recommending a product is prohibited.

*Interactions with Patients/ Consumers*

The *PHAP Code* does not allow discounts or coupons to be given directly to patients and requires qualified oversight of a prescriber. It cannot be advertised and not tied to sales promotion, raffles, or promises of reward that may encourage self-medication.

Free samples may be supplied to consenting health professionals and must not be sold or misused. The quantity should be enough to initiate therapy or gain clinical experience and it may be given for humanitarian reasons with healthcare provider during dispensing. These must comply with the labeling requirements of FDA and be accompanied by product inserts. The *PHAP Code* allows companies to work with patient organizations but the interaction must not be intended for promotion.

*Implementation*

Self-regulation within *PHAP* basically rests on the notion that an errant member would affect the image of all other members of the association. Thus, *PHAP* members are compelled to subscribe to their Code of Practice upon joining by signing a pledge. The code is administered by the Ethics Committee of the Association, which is composed of 8 members who are selected from outside the association and must have no affiliation with any of its members. It is the committee which decides whether or not a breach has occurred and may seek additional external expert advice. Table 5 shows the summary of cases deliberated by the Ethics Committee of *PHAP* from 1999-2015.
### Table 4. Summary of Cases deliberated by the Ethics Committee of PHAP from 1999-2015

<table>
<thead>
<tr>
<th>Year</th>
<th>Type of Breach</th>
<th>Total # of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>CME Sponsorship, Infomercial, Independence of HCPs, Marketing Practices</td>
<td>56</td>
</tr>
<tr>
<td>2000</td>
<td>CME Sponsorship, Competitions and Raffles, Infomercial, Independence of HCPs</td>
<td>46</td>
</tr>
<tr>
<td>2001</td>
<td>Independence of HCPs, Infomercial, CME, Advertising, Literature, Marketing Practices, Communications with the General Public</td>
<td>13</td>
</tr>
<tr>
<td>2002</td>
<td>Literature, Communication with the General Public, CME, Comparative Statements, Competitions and Raffles, Independence of HCPs, Promotion and Educational Materials</td>
<td>21</td>
</tr>
<tr>
<td>2003</td>
<td>Comparative Statements, Promotional Materials, Communication with General Public, CME, Competition and Raffles, Independence of HCPs</td>
<td>14</td>
</tr>
<tr>
<td>2004</td>
<td>Post Marketing Surveillance, CME, Communications with the General Public, Advertorial, Independence of HCPs, Relationship Building, Promotional Materials, Gifts, Advertising, Literature</td>
<td>48</td>
</tr>
<tr>
<td>2005</td>
<td>Advertorial, PMS, Relationship Building, CME, Marketing and Promotions, Infomercial, Literature, Gifts</td>
<td>21</td>
</tr>
<tr>
<td>2006</td>
<td>Literature, PMS, advertising, CME, Gifts</td>
<td>13</td>
</tr>
<tr>
<td>2007</td>
<td>Clinical Trials, Literature, PMS, Infomercial, Lay Media Advertising, CME, Medical Info and Claims</td>
<td>9</td>
</tr>
<tr>
<td>2008</td>
<td>CME, Promotional Give-Aways, Independence of HCPs, Lay Media Advertising, Medical Information Claims, Communication to General Public</td>
<td>7</td>
</tr>
<tr>
<td>2009</td>
<td>CME, Medical Information Claims, Discount Guidelines</td>
<td>2</td>
</tr>
<tr>
<td>2010</td>
<td>Marketing Practices, Independence of HCPs, CME,</td>
<td>6</td>
</tr>
<tr>
<td>2011</td>
<td>Independence of HCPs, Post-marketing Surveillance</td>
<td>2</td>
</tr>
<tr>
<td>2012</td>
<td>Post-marketing Surveillance, Advertisement and Taglines, Discount Cards</td>
<td>8</td>
</tr>
<tr>
<td>2013</td>
<td>Taglines, Independence of HCPs, Promotional Materials</td>
<td>3</td>
</tr>
<tr>
<td>2014</td>
<td>Independence of HCPs, Post-marketing Surveillance</td>
<td>3</td>
</tr>
<tr>
<td>2015</td>
<td>Promotional Materials, Appeal on Ethics Committee Decision</td>
<td>2</td>
</tr>
</tbody>
</table>

(Reference: Presentation by Ramonito Tampos, 17 August 2015. 15th Asia Pacific Pharmaceutical Compliance Congress & Best Practices Forum, Sofitel Philippine Plaza)

In handling complaints, it must be noted that PHAP actually encourages the member companies to settle matters among themselves first before elevating the matter to the Ethics Committee.

Complaints submitted in writing or by email are required to include the complainant’s true identity, with contact details for correspondence. Private individuals lodging complaints may however, request anonymity. The company in violation must also be specified, including the name of any product or products that are involved. For each case, a brief description of the complaint with reference to the provision in the PHAP Code must be written and a copy of the material in question provided. The date and place of the alleged breach of code must also be
indicated. The complaints are all received by the Secretariat which will validate and determine whether the complaints merit the attention of the Ethics Committee. The Secretariat may entertain inquiries and clarifications pertaining to the Code before submission to the Ethics Committee.

If the information provided is insufficient, the complainant must provide the required information within 5 working days to ensure that the complaint appears to be genuine, submitted in good faith and have sufficient information to enable processing. For complaints that cannot be validated, these will not be processed and the complainant will be informed accordingly.

Within 5 working days, from receipt of the valid complaint, a copy, including any supporting evidence will be sent to the general manager and compliance officer of the respondent company. The respondent company may then make a response no more than 15 working days from the responder’s receipt of the document. No extension will be granted. Otherwise, the complaint will be submitted to the Ethics Committee for resolution based on the evidence submitted by the complainant. The Ethics Committee shall decide within 30 days after receiving the respondent’s reply or if there was no response, from the lapse of period from submitting such response. The PHAP Ethics Committee may convene an experts’ panel to provide technical advice and may thus extend timelines. For all cases, the Ethics Committee must resolve the case and transmit the ruling to both complainant and respondent within 60 working days.

In the instance that the complainant or the accused contests the decision, it may file an appeal within 15 working days to the PHAP Board of Trustees from the receipt of the decision. To process the appeals, an Appeals Board may be drawn from an independent pool of experts and an administration fee is charged to the party who files the appeal. All appeals are then decided 30 days after receipt of the appeal. If a company is found in breach of the PHAP Code, the company will have 10 working days to provide written details of the action taken to comply with the ruling via a compliance statement that is signed by the general manager.

Penalties for breach of the Code include a fine of PhP 200,000 for first offense. Succeeding offenses of the same nature or within the same section of the code within 12 months shall be
fined PhP 750,000 for each offense. The status of a company returns to clean slate if no violations of the same offense are committed within a 12 month period.

Outcomes are published on the PHAP website which includes summary of the case, key facts and results, based on the Executive Committee/ Appeals Board Ruling. The respondent company, complainant and products however, are not named. This is not the case for companies with multiple violations of any provision of the code, whose name, product and other relevant information will be disclosed. In addition, the headquarters of the company will be notified of the violation.

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**Figure 2. Complaints System of PHAP**
**Philippine Chamber of Pharmaceutical Industry (PCPI)**

The PCPI is an industry organization composed of 100% Filipino-owned pharmaceutical manufacturers and traders/distributors. Like PHAP, it also has its own Code of Business Ethics which espouses transparency in dealing with the health sector stakeholder. Its code is based on the 2011 Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector. It also refers to the Code of PHAP and the Code of Ethics of the former Chamber of Filipino Drug Manufacturers and Distributors, Inc. (CFMD). However, the PCPI’s Code is still in its infancy stage and will still be improved.

Like PHAP, PCPI believes in self-regulation and encourages its members to monitor themselves. Complaints may be filed by member companies to the Board of Executives.

The board members discuss the issue with the company at fault. Appeals from the pharmaceutical company are considered during the discussion of the board. The case is then forwarded to the FDA depending on the resolution of the board. The creation of an ethics committee is not considered by PCPI, primarily to avoid protraction of the complaint process.

According to PCPI, many of the local companies cannot really afford sponsorships unlike multinational companies, and thus a very low number of complaints is received. No monetary penalties are imposed upon violators but companies may receive a suspension of membership as a sanction depending on the severity of the case and on the decision of the Board.

**Professional Organizations (PMA and PPhA)**

The two health professions most often targeted by pharmaceutical promotion activities are represented by the accredited professional organizations, the PMA and the PPhA. These professional organizations have existing codes of ethics. While the PPhA has an existing code of ethics, its provisions, however, are written in a general manner. There are 8 principles that serve as fundamental bases of their roles and responsibilities toward patients, other health professionals and the society as a whole. On the other hand, PMA has a more detailed Code of Ethics with an article specifically detailing the expected relationship of its members with the
health products industry. The specific contents of the article in the PMA Code of Ethics are the following:

1. The physician shall not derive any form of material gain from product samples.
2. Physicians may participate in post-marketing or similar activities where they are asked to try new products on patients provided that the patients are properly informed and have given their informed consent. Physicians are encouraged to report or share the result of such activities to the duly constituted authorities.
3. Only gifts of reasonable value that primarily entail benefit to patient care or related to physicians’ work may be accepted by a physician from a health product company.
4. Physicians may request donations for a charitable purpose for as long as it does not redound to his or her personal benefit.
5. Research activities shall be ethically defensible, socially responsible, and scientifically valid. Any remuneration should be reasonable and should not constitute an enticement.
6. Research trials conducted by physicians for an industry should be done in accordance with the national or institutional guidelines for the protection of human subjects.

Ad Standards Council

The Ad Standards Council (ASC) is the self-regulatory body of the local ad industry established by the major stakeholders of the advertising industry – KBP (Kapisanan ng mga Brodkaster ng Pilipinas), PANA (Philippine Association of National Advertisers) and 4As (Association of Accredited Advertising Agencies) to handle screening of advertising content and settlement of disputes regarding advertising content. ASC took over the function of Advertising Content and Review Committee (ACRC) of the Advertising Board of the Philippines (AdBoard).

The ASC believes that the successful regulation of advertisements is because of the collaborative efforts of the three major sectors in advertising – the advertiser, the agencies and the media platforms. The ASC has its Code of Ethics and Rules of Procedures which apply to members of KBP, PANA and 4As and all advertising materials that are owned, cours ed through, handled or placed with them.

The ASC screens pharmaceutical advertisements under a memorandum with the FDA, which endorses to them the screening of OTCs and food supplements provided they are able to
provide the Certificates of Product Registration and documents that support the claims of the manufacturers. The FDA is invited to sit in on the daily screenings, but because of limited personnel, FDA is only expected to be available as a resource person for some cases that involve complaints and disputes on pharmaceutical products.

Aside from FDA, ASC also has several Memoranda of Agreement with other organizations and government agencies and the provisions state that they respect the Codes of Ethics of each of the organizations to avoid conflicts of interests in different fields.

The two main activities that ASC is involved in are the screening of advertisements and the handling of complaints. The pre-clearance is divided into two phases, the pre-production and post-production screening. In pre-production screening, the industry submits the proposed storyboard and supporting documents for claims to the ASC office for clearing. Once the storyboard is approved, the advertising agency may now execute it and create the advertising materials. After production, the advertisers are required to return to the ASC prior to airing the advertisement to the public. The screeners check if the storyboard or the advertisement material was properly carried out based on what was approved beforehand. The ASC provides certificates of approval for those advertisements that pass the post-production screening.

The volunteer screeners mainly consist of advertisers with over 20 years of experience who are appointed by their respective offices to sit in the ASC to screen advertisements. Usually from 10am – 2pm, they screen about 30 advertisements per screener a day with a minimum of 6 screeners volunteering per day. The ASC has over 70 screeners voluntarily working for ASC. For Pharmaceutical products, the screeners are not necessarily healthcare professionals but are experienced in the advertising of similar products. When technical knowledge is required in certain cases, resource persons are invited to help. No compensation or benefit is received by the volunteer screeners of ASC other than lunch.

In case of complaints filed by competitors against an advertiser, a filing fee is charged to prevent irrelevant complaints. However, civil society or concerned citizens may also file complaints free of charge. The evidences are presented to the ASC but they are not allowed to confront the advertiser being complained. The respondent may then submit appeals for the complaint and
ASC will provide a decision after a panel discussion. In this process, a resource person may be called if the issue necessitates technical expertise.

Currently, ASC is able to monitor advertisements in Metro Manila, but is planning to expand its scope in other provinces through online screening. Their guidebook is also undergoing revision to include online advertising such as social media, but they still have no control over other outlets like blogs, personal websites, etc.

**Patient Organizations**

There are different patient groups and organizations in the country. Some of these are disease-based and are formed by either patients themselves or through the support of pharmaceutical companies. The *Philippine Alliance of Patient Organizations (PAPO)* is a non-stock, non-profit entity that serves as a coalition of formal/registered patient groups in the country. Currently, it has 15 members and is affiliated with the *International Association of Patient Organizations (IAPO)*. *PAP*, which aims to empower Filipino patients in promoting their rights to become productive members of the society, is mainly involved in policy-making regarding patient rights, safeguarding the strict implementation of laws pertaining to patient needs, disseminating information, forging partnerships and promoting patients’ rights.

According to *PAPO*, patient organizations in the Philippines usually follow and implement their own ethical standards because there is currently no unified code of ethics that will define how patient organizations should interact with pharmaceutical companies who usually serve as donors and sponsors. Some patient organizations claim to abide by ethical principles in dealing with pharmaceutical companies especially in receiving sponsorships and donations but these have yet to be documented.

Patient organizations may play a significant role in the self-regulatory framework. At present, there is an evident lack of transparency in most cases and decisions involving violations of codes of ethics, which go unreported to the proper authorities like the FDA. If these patient organizations are made aware of the unethical practices and their implications, they can help in the reporting and provide insight on ongoing unethical practices provided they are given the proper venue. While the interaction between companies and professionals are often vulnerable
to unethical practices, patient organizations may also be vulnerable to these practices. Without clear policies regarding interactions with patients' groups, it can actually allow pharmaceutical companies to directly advertise their products to the patients through sponsorships and donations.

5. Current Regulatory Framework
The regulatory framework for implementation of codes and policies regarding pharmaceutical advertisements and promotions is illustrated in Figure 3.

![Figure 3. Current Regulatory Framework for Drug Advertisement and Promotion](image)

Within the FDA, active surveillance on advertisements and promotional activities of companies is currently being done through the Ethical Market Communications Unit (EMC), which is part of the Office of the Deputy Director for Regulatory Operations. The unit is currently composed of two regulatory officers. With respect to advertisement and promotion of pharmaceuticals, both the EMC and the CDRR may receive and evaluate complaints regarding violative marketing activities.

Regulation of pharmaceutical advertising is largely governed by a self-regulatory mechanism through the Ad Standards Council and the industry associations. No approval from FDA is required prior to the dissemination of a drug advertisement. Pre-clearance of advertising materials is voluntarily coursed by advertisers through the ASC, regardless of whether claims were made in the advertisement. The ASC is in partnership with the FDA through a
Memorandum of Agreement (MOA). The FDA supplies technical assistance to the ASC by providing them with relevant regulations and guidelines, and updating the ASC whenever changes are made to these regulations. The ASC fully abides by AO 65 in screening pharmaceutical advertisements. In August 2015, upon request by the FDA, the ASC implemented AO 2014-004, which requires that all advertising and promotional materials be approved by the medical director of the pharmaceutical company. Hence, all materials submitted to the ASC required the signature of the medical director.

For sales promotion activities defined in RA 7394, a sales promotion permit is to be secured from the FDA at least thirty (30) calendar days prior to the commencement thereof. For drugs, application for the sales promotion permit is submitted by the company to CDRR. Processing of the permit is expected to take ten (10) working days upon receipt. After ten days, the company may follow-up the permit application with the FDA.

Companies that are members of pharmaceutical industry associations such as PHAP or PCPI are subject to the code of conduct/ethics of the association. Thus, any violation to these codes may be subject to internal complaints-handling processes, which have been described earlier.

In ensuring that pharmaceutical advertisements and promotions are compliant with current regulations, any person or entity may file a complaint with the FDA. Industry associations may report to the FDA violations of their members for imposition of sanctions. Companies may submit complaints against other companies, and healthcare professionals or civil society members may report directly to FDA based on their personal experiences with violative practices. According to FDA, companies usually monitor their competition for violative acts and submit complaints whenever a violation is committed. There have also been some cases in the FDA when individuals submitted complaints against violative marketing practices.

The complaints and appeals process for violative advertisement and promotional materials is outlined in Figure 4.
Guidelines on Handling Consumer Complaints by the FDA is outlined in FDA Circular 2013-022. The FDA is authorized to receive complaints on violations of its rules and regulations. For drugs, the complainant shall proceed to the Center for Drug Regulation and Research. Complaints on dangerous drugs are not handled by the FDA, but the Philippine Drug Enforcement Agency (PDEA). Complaints may be coursed through the Public Assistance, Information, and Receiving (PAIR) Unit of the FDA via landline or email (report@fda.gov.ph). Complaints may also be directed to any of the FDA Regional Offices. Complaints on drug advertisements and promotional materials may then be forwarded to EMC or CDRR. A thorough interview on the matter is conducted by the concerned FDA center/office personnel, at the same time filling out a complaint form with details needed. Information on the complaint must be based on the complainant’s personal knowledge, and the complainant shall affix his/her signature on the form. Supporting documents or pieces of evidence such as photographs, receipts, or materials must then be attached to the form. All received complaints are subject to a document tracking (DocTrack) system which issues an identifying number to the submitted complaint, enabling the complainant to follow-up and monitor the progress of the submission (From www.fda.gov.ph).

Within FDA, the complaint is verified and assessed by the CDRR and/or the EMC. Advertisements involved in complaints are verified with the ASC to determine if the product was cleared for advertising. Once the violation is validated, a Report of Violation (ROV) is then submitted to the Legal Services Support Center of the FDA for appropriate legal action, such as
filing of administrative sanctions. A warning letter is issued by FDA to the alleged company, and the establishment is expected to provide a statement indicating the corrective action to be taken. If corrective action is not taken, FDA may then issue a cease-and-desist order of the advertisement, prompting ASC to automatically remove the erring advertisement. Succeeding the decision of the Legal Services Support Center, sanctions and penalties to the involved company or individual may be imposed through the FDA Regional Offices.

The ASC likewise accepts complaints regarding advertisements that have been pre-cleared with them. The complaint and settlement of disputes system of the ASC is well elaborated in its Guidebook. If an advertisement must be discontinued from airing, the ASC may either issue a cease-and-desist order or recall clearance to air/publish/display even without the government’s intervention or advise.

6. Multi-stakeholder Initiatives
Various initiatives from different stakeholders working together to help make pharmaceutical promotions more ethical has already begun. The Medicines Transparency Alliance (MeTA), a global health initiative with presence in various countries including the Philippines, brings together government, private sector and civil society to work towards improving access to quality-assured medicines by increasing transparency and accountability in the pharmaceutical’s supply chain and industry. Using a multi-stakeholder approach to improve efficiency and encourage responsible business practices in the healthcare sector, they were able to initiate 2 movements and conduct activities that promote ethics in healthcare including pharmaceutical promotions.

*Ethikos Movement*

The *Ethikos Movement* (Ethics in Healthcare) was launched in March 27, 2014 bringing together stakeholders from different sectors such as the government, academe, industry, civil society, patient organizations, professional organizations and the youth in one venue to learn about the perspectives of the different representatives and better understand how ethics in healthcare can move forward through complementary actions and efforts.
Training Workshops on Understanding and Responding to Pharmaceutical Promotion

In 2013, MeTA Philippines, in collaboration with the World Health Organization (WHO), commissioned a study to pilot the methodology developed by Health Action International (HAI), to assess the nature and extent of pharmaceutical promotion regulation and its impact on promotional practices (“Medicines Promotion: Assessing the Nature, Extent and Impact of Regulation”). This provided a comprehensive profile of the system in the Philippines, highlighting the strengths and weaknesses of the regulatory framework, as well as an analysis of various stakeholder perspectives.

Among the possible interventions proposed by the study is the integration of courses in medicine and pharmacy schools that will “train students to recognize and respond to pharmaceutical promotion before they start prescribing and dispensing medicines.” A long-term objective is to incorporate training tools in the regular curriculum of medicine and pharmacy schools, as well as in the continuing education sessions for health professionals. To address this need, WHO and HAI have made available a manual – “Understanding and Responding to Pharmaceutical Promotion: A Practical Guide” – that can be used to develop a customized pilot course applicable in the Philippine setting.

Dr. Tim Reed, Executive Director of Health Action International (HAI) conducted the Training for Trainers Regional Workshops in Manila in April 13-14, 2015 and in Cebu on April 16-17, 2015 to pilot the tool / methodology / module on responding to pharmaceutical promotion in the Philippines. Since then, other more workshops have been conducted to make both practicing and future health professionals recognize unethical pharmaceutical promotions and respond to them.

Guardians of Integrity Fostering Transparency and Safety (GIFTS)

During the training workshops on Understanding and Responding to Pharmaceutical Promotions in Manila, the participants made and signed a declaration of commitment against unethical pharmaceutical promotion to personally critique pharmaceutical promotion and work with colleagues and future health professionals to ensure that clinical decisions will not be influenced by biased information. When this document was brought to Cebu for the 2nd leg of the workshop, an unexpected outcome was that the participants took the commitment a step
further by forming an organization called GIFTS which stands for Guardians of Integrity Fostering Transparency and Safety with 45 faculty members of schools of pharmacy and medicine in Cebu, including six deans of schools, ceremoniously signing a declaration of commitment to challenge unethical pharmaceutical promotion. It was officially launched on July 28, 2015 as an advocacy group calling for adherence to ethical standards of pharmaceutical promotion.

7. Observations
In summary, the following are the general observations on the Philippine Situation:

- Guidelines for ethical medicines promotion exist loosely through current policies related to consumers and adoption of international standards in ethical pharmaceutical promotion practices. Thus it is recommended that there at least be a unified code with specific details and restrictions that will serve as a minimum standard for the companies and organizations to base their codes upon. A step further may be taken by issuing a policy that will provide a standard, make the guidelines very clearly defined, and articulate provisions on implementing heavier sanctions on violators.

- The current regulatory system relies heavily on voluntary self-regulation for implementation, which is governed by Codes of Ethics of each company or organization. The implementation of which, varies greatly and most have insufficient mechanisms to make these issues more transparent. Significant improvements are needed in monitoring compliance to these codes.

- While self-regulation is able to at least hold some pharmaceutical companies and individual health professionals accountable, companies and individuals that are not members of these groups are not subject to their codes, making it more challenging to make them more accountable and transparent with their activities.

- Although ethical standards and guidelines exist for the process of regulating pharmaceutical promotion, there is low public awareness, in addition to inadequate participation from civil society and patients in monitoring and in the complaints system. All these contribute to the inability of improving monitoring through vigilance.

- As shown in the process of regulating advertisements through the ASC, self-regulation may be effective in capturing most of the advertisements by working with the right stakeholders. However, there are more improvements needed especially in monitoring
the technical aspects of the content. This may be addressed by providing specific guidelines for the ASC to follow in their screening process.

C. Strengths, weaknesses and areas for improvement of the country’s existing regulatory framework for pharmaceutical promotions

The country’s existing regulatory framework has several strengths and weaknesses as seen in the previously discussed mechanisms and capabilities. In this section, we present the strengths, weaknesses and areas for improvement.

Strengths

The Philippines has several laws and policies governing pharmaceutical promotions which clearly articulated the State’s policy to protect consumers from misleading advertisement and fraudulent sales and promotion practices. These policies also have clearly defined FDA’s role and responsibilities on the issue of pharmaceutical promotion.

The use of generic names is well-implemented in advertisements and promotions in most of the media platforms. This shows that having clear implementing guidelines allows for easier compliance and screening.

An efficient self-regulatory mechanism exists for advertisements in general which can be used as a model for ensuring that all advertisements are captured. There is also some degree of self-regulation in the pharmaceutical industry. PHAP has a very extensive Code of Ethics (although applicable to prescription medicines only) which is aligned with the Expanded Code of Practice of the IFPMA and the Mexico City Principles. It likewise incorporates local requirements and practices in relation to registration, labelling and scientific claims approved by the Philippine FDA. PHAP’s member companies which are usually multi-national companies are likewise bound to comply with the standards set by their home companies. PCPI also has its own set of Code of Ethics which is also based on the Mexico City Principles. Both codes of ethics enumerate what are permissible and what are not in terms of pharmaceutical promotion unlike the existing national policies.
Weaknesses and Areas for Improvement

**Availability of clear guidelines on implementing regulatory policies.** Clear and specific guidelines on ethical promotions practice for pharmaceuticals are lacking. The current policies are silent on how the pharmaceutical industry must interact with health care professionals or patient groups which may make them vulnerable to corruption through conflicts of interest. The adoption of the *Mexico City Principles* by the FDA in 2013 could have addressed this lack of guidance but the implementing guidelines of these principles have not been released.

**Monitoring and enforcing capacity of government regulatory agencies.** While FDA was clearly identified as the primary government regulator with jurisdiction over medicines promotion by RA 9711, it lacks monitoring and enforcing capacity hence failing to regulate unethical marketing practices of the pharmaceutical industry. The sanctions for non-compliance are weak and fines indicated are ridiculously low. These should be considerably increased. These fines must be used to fund the activities related to monitoring pharmaceutical promotions. FDA must be aggressive enough to assert for this considering that the present system is inefficient.

**Evaluation of technical content of advertisements.** The self-regulatory system for advertisements may be further improved to ensure a more ethical impact on patients by enhancing the evaluation of technical content particularly in the pre-screening process. As pharmaceuticals and their uses greatly vary, judgment of pharmaceutical advertisements for accuracy and impact on patient behavior is not easily achieved through the provision and interpretation of simple FDA guidelines about the clinical use of products. Therefore, a very specific and clearly defined guideline is necessary as a reference to be used by the Ads Standards Council which screens these advertisements. This can also be achieved by ensuring that FDA or a technical expert should be present as the screening should not only look at compliance to ads guidelines but remain truthful in all technical claims. The current self-regulatory model of advertisements, show however, that even without legislation, a framework that is effective in capturing all possible means of creating and releasing advertisements through collaboration with all involved stakeholders can indeed exist in the Philippine setting and can serve as a model for other self-regulatory systems.
Minimum standards on codes of ethics. Unlike PHAP, the PCPI code still lacks specific guidelines especially relating to complaints of transgressions on the Code. In addition, other companies that are neither members of PHAP nor PCPI are free to follow their own codes of ethics. Because of the current weaknesses in the regulatory framework for ethical promotion and the possible absence of codes of practice/ ethics for some pharmaceutical companies, member companies of PHAP and PCPI are disadvantaged in terms of market sales when they abide by ethical principles enforced by the associations. At the same time, this may also work to the disadvantage of these local companies as resources are diverted to promotional/ marketing activities instead of research or innovation. It is thus imperative that a minimum standard in the form of a policy or unified code be available as a guide and reference for all.

Familiarization with the system and process of filing complaints. Civil society and patient organizations may be an untapped resource in promoting vigilance against unethical practices. Unfortunately, the mechanisms of the complaints system are not very well known to the lay public despite having several mechanisms available. Means of filing complaints through FDA, the industry or professional organizations are available but not known. They may also find it complicated which can likewise make reporting tedious. Personal feedback to the complainant is also lacking which can also discourage people from reporting in the future.

D. Need for a strong regulatory framework

The findings of this study regarding the country’s present regulations on pharmaceutical promotions are consistent with two previous studies – Survey of Promotional Practices in the Philippine Pharmaceutical Industry Compendium Edition and Pilot of the HAI/ MeTA Tool Medicines Promotion: Assessing the Nature, Extent and Impact of Regulation in the Philippines. These studies likewise concluded that the current regulations on pharmaceutical implementation are poorly implemented and there is lack of clear policies, guidelines or standards on pharmaceutical promotions. These imply that the gaps in the current regulatory framework need to be resolved (Table 6).
The FDA’s issuance of *Memorandum Circular 2013-024* on the country’s decision to adopt the *Mexico City Principles* is clearly a step forward to address some of the gaps indicated in the present system of regulation of pharmaceutical promotions. However, the government needs to operationalize this to properly guide all relevant stakeholders. The government needs to explicitly state what it wants to be done rather than leaving to the public how it wants to translate the said circular. While self-regulation is currently in place for organizations with their codes of conduct/ ethics governing them, the government must also consider the other companies who are not part of these organizations and without codes of ethics governing them to level the playing field.

Among the areas that the national policy must clarify are the following:

1. **Interactions with Healthcare Professionals and Medical Societies** – The *FDA Circular 2013-024* stated that professionalism and high ethical standards must be maintained between the pharmaceutical companies, the health professionals and the regulatory body but it does not provide specific guidelines on how this will be ensured. A policy that will explicitly provide guidance to both the industry and health care professionals is warranted. This should...
include among others specific provisions to cover gifts and payments to doctors or other health professionals; assistance in research activities; sponsorship in any fund raising activity or educational activities for medical interns, residents and fellows in training; hospitality and other related payments.

2. **Sponsorship of healthcare professionals to local or foreign travels** – At present, there is no policy indicating conditions related to sponsorships to local or foreign travels regardless of purpose of the travel. Symposia, conferences or other scientific meetings are useful for disseminating information. Sponsorships however to these events must not serve as inappropriate inducements to prescribe, recommend or promote any product. A guideline that will explicitly state permissible (ethical) sponsorships (that will keep it to a modest level) of the industry for healthcare professionals must be in place to discourage inappropriate inducements. These should include among others justification for sponsorship, plane and accommodation arrangements.

3. **Distribution of free medicine samples** – The existing policy (BFAD regulation 5 1987 s6) states that distribution of free sample of prescription medicines is limited to prescribers and should not be given to the lay public. In the previous study on Survey of Promotional Practices in the Philippines, it was found that free medicine samples are sometimes sold to the public by both prescribers and medical representatives. Clearer guidelines regarding distribution of free medicine samples must be in place. These guidelines should likewise require companies to have adequate systems of control and accountability for the distributed samples in order to avoid unethical practices such as selling of these samples. In other countries like Germany, Canada and the UK, medicine samples are provided only upon written request of the health professional, clearly labeled as “free” sample and may not be sold and are properly documented.

4. **Promotional content of materials** – To properly guide the industry on the content of promotional materials, a policy that clearly enumerates these must be present. **AO 65** provides specific guidelines for advertising in compliance with generic labelling but lacks guidelines relating to claims; prohibited words, phrases and activities; proper use of data from clinical studies and use of visuals, graphics and tables among other things.

5. **Advertisements** – **RA 7394** outlines specific provisions related to advertising and sales promotion. At present, advertisements are also subject to clearance from the ASC prior to its release to the public. While the self regulatory framework of ASC is efficient, there are
criticisms with respect to technical evaluation of the content of the advertisements cleared with them. The ASC, during our interview, explained that in compliance with the existing policy on advertisements, only those claims that are approved by FDA maybe advertised. Advertising companies however have their own creative way of interpreting these claims which sometimes lead to the so-called “misleading” advertisements claimed by critics. The presence of FDA during technical evaluation has been suggested and ASC in fact stated that FDA has always been invited during evaluations. But FDA acknowledges the fact that it cannot maintain its presence during such technical evaluations due to lack of personnel. In order to improve technical evaluation of the content of advertisements materials, the FDA may instead provide a clear and detailed set of guidance documents to help ASC in their evaluation. This could include definition of terms, as well as what is permissible and not permissible to be included in these ads. The ASC claimed that they have always been compliant to national policies and should there be additional guidance documents from the FDA, these will be followed accordingly.

6. **Interaction with patient/consumer groups** – At present, there is no policy on how the industry should relate with patient groups. Guidelines on how to establish relationships with these groups must be provided such that their neutrality and independence are respected and maintained.

7. **Monitoring** – RA 9711 clearly indicated that FDA is the primary government regulator with jurisdiction over medicines promotion. With a more explicit set of guidelines outlining permissible acts of promotion, monitoring of compliance will also be an easier task to handle. However without sufficient budget and additional efficient and capable personnel, this monitoring task will likely remain to be daunting. A complaints system for “unethical” promotion practices must be in place. This should be coupled with a feedback system to the complainant. A computerized system of reporting equipped with automatic generator of replies right after submission may be created. After an action has been made on the complaint, a feedback should again be sent to the complainant informing him/her of the decision.

8. **Sanctions** – Sanctions to transgressions to the policy must be in place. Should there be monetary penalties, this should be high enough to hurt and discourage pharmaceutical companies to engage in practices that are in conflict with the policy. Publication of transgressing companies/ health care professionals in the FDA website may also be
instituted to increase transparency in the system. The government may also opt to release seals of excellence or transparency seals to compliant companies.

E. Alternative regulatory models for pharmaceutical promotions involving civil society and other non-government stakeholders

There are four models/ frameworks proposed in this study. For each model, the context (present situation which rationalizes the proposed model), assumptions (what will make the model work) and risks (what will cause the framework to fail) are presented. Each of these models rests on the assumption that there exists a clear and a strong regulatory framework governing pharmaceutical promotions, the details of which have been elaborated in the previous section (Part D).

**MODEL A**

![Diagram](image)

**Figure 5. Model A.** A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the policy. These associations and other pharmaceutical companies will be mandated to report to FDA all their promotional activities. EPTC acts as an independent watchdog where consumers may file their complaints in case unethical promotion practices are observed among the pharmaceutical companies.
In Model A (Figure 4), the primary involvement of the civil society groups and non-government stakeholders is membership to the Ethical Promotions Transparency Coalition (EPTC). The EPTC is envisioned to be an organized movement of participants from consumer/patient groups, academe and professional societies who will advocate for ethical promotions of medicines and other health products and champion consumer’s rights to correct information. This is seen to be an important role for civil society to take part in, and success has been seen in other countries where sustained effort from civil society has led to significant reforms in regulation. One example is in Australia, where groups such as Healthy Skepticism and the Australian Consumers Association increased public perception in lobbying for stricter controls in pharmaceutical promotion. Another important legislation that is a result of concerted efforts among civil society and other non-government groups advocating for ethical promotion is the Physician Payment Sunshine Act that is now in effect in the US. This act requires full disclosure of all payments and other transfers of value to physicians and teaching hospitals made by pharmaceutical companies. Transparency and accountability of companies with respect to their marketing activities is seen as an important component of implementing the Mexico City Principles. Contexts, assumptions, and risks are identified for this model (Table 6).

**Context**

This model is designed to be most similar to the existing regulatory framework, thus, it has the least need for additional resources. In the absence of a new legislation, this model can still function based on existing laws, regulations, and codes of ethics. It also rests on the context that there are currently self-regulatory mechanisms in place for industry associations such as PHAP and PCPI, the details of which has been discussed previously. It aims to address problems cited previously in the existing regulatory framework, such as limitations in the monitoring capacity of FDA, unfamiliarity of civil society and even healthcare professionals to policies governing pharmaceutical advertisement and the complaints mechanism of FDA. It also aims to take advantage of FDA’s mandate to involve stakeholders in the implementation of its regulations through technical assistance and capacity building, and the current efforts of multiple stakeholders advocating for ethical market practices, which have also been described earlier.
Table 6. Context, Assumptions and Risks for Model A

<table>
<thead>
<tr>
<th>Context</th>
<th>Assumptions</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ There are laws and regulations in place for pharmaceutical promotion, although these are inadequate.</td>
<td>✓ There is the presence of a strong legislative framework.</td>
<td>✓ There is lack of availability and sustainability of resources.</td>
</tr>
<tr>
<td>✓ Self-regulation mechanisms are in place for PHAP/PCPI based on code of ethics.</td>
<td>✓ EPTC can organize themselves and obtain the resources (legal, technical, administrative, human) necessary.</td>
<td>✓ There is lack of a strong legislative framework.</td>
</tr>
<tr>
<td>✓ Some pharmaceutical companies are not members and hence are not subject to PHAP/PCPI Code of Ethics.</td>
<td>✓ There are sufficient resources at the FDA to act on all complaints.</td>
<td>✓ There is potential conflict between the industry and EPTC.</td>
</tr>
<tr>
<td>✓ The FDA needs strengthening with regards to monitoring for violations.</td>
<td></td>
<td>✓ There is potential corruption within organizations.</td>
</tr>
<tr>
<td>✓ There is low generation of complaints due to lack of awareness on policies and perceived complicated mechanisms.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ The FDA is mandated to provide technical assistance, consultative and advisory services to stakeholders in the implementation of regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ There are efforts from multiple stakeholders advocating for ethical promotions.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Assumptions**

For this model to effectively materialize, a strong legislative framework needs to exist describing specific guidelines for implementation of the *Mexico City Principles*. This would allow consistency to be formed among the codes of ethics for industry and healthcare professional associations since currently, different associations have varying levels of detail and leniency in their codes of ethics. This would also create detailed and clearer guidelines for regulation of companies that are not members of industry associations. Consistent with RA 9711, FDA is still mandated as the implementing agency for regulation of pharmaceutical advertisement and promotions, through the EMC and the CDRR. Because of this, the FDA needs to have the capacity to evaluate and impose sanctions on reports of violations in order for this regulatory framework to be effective.
Consumers, healthcare professionals, and other members of civil-society may participate in this model through the formation of the EPTC. Thus, there is a need to form a recognized, consolidated body with solid representation from various stakeholders. Existing groups and individuals who have done advocacy or research work on pharmaceutical marketing may be enjoined to unite efforts.

Below are the resources and requirements foreseen for the EPTC to materialize:

1. **Legal Resources**
   - Official recognition of the EPTC by the FDA as a partner in the regulation of advertisement and promotions through a Memorandum of Agreement
     - The Memorandum of Agreement outlines the functions of the EPTC, and recognition of the FDA of the EPTC’s role in monitoring and forwarding cases of violative marketing practices. FDA will provide technical assistance and capacity building to the EPTC.

2. **Technical Resources**
   - Adequate training on advertisement and promotion through collaboration with the FDA

3. **Administrative Resources**
   - Source of funding for its activities, probably through association fees or income generated from commissioned work and events such as research and continuing professional education (CPEs)
   - A clear mission and vision statement stating the EPTC’s thrust and goals
   - Constitution and bylaws that would guide the functions and decisions of the association, as well as its own code of ethics
   - Infrastructure and facilities for the association to use during meetings, research work, and correspondence with other stakeholders
   - A website, as well as other platforms for communication with its members and the general public

4. **Human Resources**
   - Representation from multiple stakeholders such as: the medical and/or pharmacy academe, patient groups, and practicing doctors/ pharmacists (a core group)
➢ A pool of members such as other interested individuals or groups from the broader community

The basic functions of the EPTC may include:

1. Inform and educate healthcare professionals and the public on ethical pharmaceutical marketing practices, and their role in reducing inappropriate, misleading, or unethical advertisements and promotions
2. Monitor and evaluate drug advertisements and promotions for violative practices, and submit complaints to the FDA
3. Investigate on concerns or complaints from the public regarding pharmaceutical marketing practices
4. Spearhead research on pharmaceutical marketing practices and its regulation
5. Develop initiatives to promote ethical pharmaceutical marketing practices, such as lobbying for regulatory reforms and recognition of ethical practices

*Risks*

Risks that may come up in implementing Model A include the following:

➢ **Lack of access and sustainability of resources which have been described in the assumptions**

The most significant foreseen concern to the institution of the EPTC is the availability and sustainability of financial and human resources. Initial funding for the coalition is expected to come from membership fees, which may be a problem if there are few groups or individuals who are inclined to join. Lack of interest from key stakeholders may also limit the membership of the EPTC, which may translate to insignificant or unsatisfactory output.

➢ **Lack of a strong legislative framework**

Although this model may still function in the absence of new legislation, the lack of specific guidelines to operationalize the *Mexico City Principles* may lead to ambiguity in evaluating unethical marketing practices.

➢ **Conflicts between the civil society and the industry**

Once generation of complaints commences, opposition to the EPTC may come from the industry, especially the concerned company. The authority and credibility of the EPTC to monitor and generate complaints towards the industry may be questioned.
Corruption within organizations, especially the EPTC

Any form of corruption among the members of the EPTC would weaken the credibility of the coalition. Biases may affect the conduct of some of its activities, such as monitoring and research.

MODEL B

Figure 6. A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the policy. These associations and other pharmaceutical companies are mandated to report to FDA all their promotional activities. Should there be complaints of observed unethical practices among pharmaceutical companies, these will be forwarded to the PPSC. The PPSC evaluates the complaints, check for their validity and recommends sanctions. These are then forwarded to FDA who shall impose the sanctions to the erring company. The FDA may also provide incentives/ recognize companies who practice ethical promotions.

Model B is adapted from a regulatory model published in the Health Action International Blog (Reed, 2014). The involvement of civil society and non-government stakeholders is membership to the Pharmaceutical Promotions Standards Committee (PPSC). The PPSC is an unbiased body for receiving and evaluating complaints prior to forwarding to the FDA. As an independent evaluator, the PPSC can reduce the burden on FDA by screening and validating complaints through a standardized process involving expert evaluation. It can also reduce conflicts between and among industry association members in reporting violations against each other. This is seen as a much more cost-effective measure than for the FDA to hire additional personnel to perform these tasks.
This proposed model is similar to the CRP of Australia which is a partnership between government and non-government stakeholders to exercise controls. Its difference however is that the PPSC is envisioned to handle all complaints related to pharmaceutical promotions while CRP only handles complaints about direct-to-consumer advertising. It is also worth noting that the CRP was created as a result of amendments made to the *Therapeutic Goods Act and Regulations*. Contexts, assumptions, and risks are also identified for this model (Table 7).

### Table 7. Context, Assumptions, Risks of Model B

<table>
<thead>
<tr>
<th>Context</th>
<th>Assumptions</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ There are laws and regulations in place for pharmaceutical promotion, although these are inadequate.</td>
<td>✓ There is the presence of a strong legislative framework.</td>
<td>✓ There is lack of availability and sustainability of resources.</td>
</tr>
<tr>
<td>✓ Self-regulation mechanisms are in place for PHAPI/PCPI based on code of ethics.</td>
<td>✓ PPSC will be appointed as a technical working group of FDA.</td>
<td>✓ There is lack of a strong legislative framework.</td>
</tr>
<tr>
<td>✓ Some pharmaceutical companies are not members and hence are not subject to their codes of ethics.</td>
<td>✓ Resources (technical, administrative, human) are available to the PPSC.</td>
<td>✓ There is potential conflict between the industry and PPSC.</td>
</tr>
<tr>
<td>✓ The FDA needs strengthening with regards to monitoring for violations.</td>
<td>✓ FDA has sufficient resources to act on all complaints.</td>
<td>✓ There is potential corruption within organizations</td>
</tr>
<tr>
<td>✓ There is low generation of complaints due to lack of awareness on policies and complicated mechanism.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ The FDA is mandated to provide technical assistance, consultative and advisory services to stakeholders in the implementation of regulations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ There are efforts from multiple stakeholders advocating for ethical promotions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓ Conflict of interest may exist in assessing complaints and appeals of members during self-regulation.</td>
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</tbody>
</table>

***Context***

Apart from the existing context described for Model A, Model B recognizes possible problems that may arise when self-regulation is completely left to industry associations. In receiving and deciding on complaints from its members, conflicts of interest may exist within these associations and may lead to undue influences in decisions regarding complaints or reports of violative marketing practices.
Assumptions

This model operates under the same assumptions - a strong legislative framework needs to exist in order for defined guidelines to be available. The FDA still needs to impose sanctions on reports of violations, but compared to Model A, this model does not necessitate as much technical capacity or manpower from the FDA in evaluating complaints related to pharmaceutical advertisements and promotions. This model, hence, can operate with the current manpower of the EMC and CDRR.

Resources and requirements foreseen for the PPSC are similar to the ones cited in Model A, except for the following:

1. Legal Resources
   - Appointment of the PPSC by the FDA as a Technical Working Group (TWG) in the regulation of pharmaceutical advertisements and promotion. Currently, the FDA has a TWG for Drug Regulation under the CDRR, composed of representatives from industry stakeholders, such as PHAP, PCPI, Drugstores Association of the Philippines (DSAP), and Philippine Association of Pharmacists in the Pharmaceutical Industry (PAPPI). One senior technical officer from CDRR also sits as a member of the TWG. The function of this TWG is primarily centered on discussing issues and concerns of the industry stakeholders, and reviewing the processes and issuances of the FDA. The PPSC can adapt a similar approach in that it can serve a consultative function with the FDA.

2. Administrative Resources
   - Source of funding for its activities, probably through funding from the FDA or processing fees

3. Human Resources
   - Representation from multiple stakeholders such as: the medical and/or pharmacy academe, patient groups, and practicing doctors/pharmacists
   - The representative members of PPSC must have extensive experience or training in the area of pharmaceutical promotions, and must have no unethical record. They must also declare any conflict of interest.
   - Confidentiality on the identity of individuals who serve as representative members of the PPSC
The functions of the PPSC include the following:

1. Receive and evaluate complaints according to the policy on pharmaceutical promotions
2. Provide recommendations on sanctions of the erring pharmaceutical company in accordance to the policy
3. Hear appeals of the pharmaceutical companies
4. Recommend adjustments to the policy
5. Provide regular reports to FDA of all its activities

Should there be a complaint a group from the PPSC will be chosen and tasked to review complaints and/or hear appeals. The PPSC may also meet at specified time periods (i.e. every two weeks) to review and refer complaints. They may also generate their own complaints and actively monitor for transgression of the policy or of violations of codes of ethics/practice.

Compared to the first model, the second model increases the involvement of civil society in the regulatory process. Based on the assumption that members of the PPSC can acquire sufficient technical expertise to decide upon violations to the legislation, this model is cognizant of the existing limitations in the FDA and thus aims to provide additional support to the regulatory workforce. Although lessening the liberties of industry members involved in self-regulation, this model ensures effective and consistent decision-making when it comes to violation of the policy.

**Risks**

Foreseen risks in the implementation of Model B are similar with those identified for Model A. A greater possibility of conflict is seen with this model as compared to the first since this group is taking a more aggressive stance at regulation. This conflict could be reduced by forging a partnership with both the FDA and the industry in promoting transparency and accountability in pharmaceutical marketing activities. The PPSC must sustain an unbiased and credible image that would allow it to gain trust from both the industry and the regulatory body.
MODEL C

Figure 7. Model C. A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the policy. ASC serves as pre-clearing house for advertisements of OTCs and other health products. The framework requires that FDA will be involved in the final approval of these advertisements before these are aired to the general public. The PPRB serves as a pre-clearing house for all CPDs that are sponsored by a pharmaceutical company before these are submitted to PRC. Pharmaceutical companies are required to submit all their promotional activities to the PPRB, which in turn submits reports to FDA on compliant and non-compliant pharmaceutical companies. All complaints are filed with the FDA who in turn is required to provide feedback to the complainant. The FDA likewise shall impose the sanctions to the erring company. The FDA may also provide incentives/recognize companies who practice ethical promotion.

Model C takes a step further from model B, as it encourages transparency and increases the scope of the regulation to non-members of associations, by providing another way of monitoring the events that are commonly used for pharmaceutical promotion if the resources can be provided.

It also tries to address the specific issue of regulating pharmaceutical promotion in CPDs and CMEs through pre-approval of a Pharmaceutical Promotion Regulatory Board (PPRB). Members shall come from consumer/patient groups, academia, health care professional societies and the industry. Members can be individuals who are familiar with the pharmaceutical industry. They must have track record of integrity and service, are genuinely concerned for patient welfare, must know the existing practices in the field, declare any conflict of interest and are expected to undergo training on ethical promotions.
The PPRB which will serve like a Technical Working Group (TWG) of the FDA, shall have the following functions:

1. Pre-approves/provides pre-clearance for conferences, trainings, CPDs, CMEs
2. Accepts reports of pharmaceutical companies regarding their promotional activities
3. Reports to FDA compliant and non-compliant companies

For the regulation of advertisements, this model employs the current system enforced by the ASC which is the only self-regulatory process in this model. Receiving and filing of any complaints are all coursed directly to the FDA.

<table>
<thead>
<tr>
<th>Table 8. Context, Assumptions, Risks for Model C</th>
</tr>
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<tbody>
<tr>
<td><strong>Context</strong></td>
</tr>
<tr>
<td>✓ There are laws and regulations in place for</td>
</tr>
<tr>
<td>pharmaceutical promotion, although these</td>
</tr>
<tr>
<td>are inadequate.</td>
</tr>
<tr>
<td>✓ Self-regulation mechanisms are in place for</td>
</tr>
<tr>
<td>PHAP/ PCPI based on code of ethics.</td>
</tr>
<tr>
<td>✓ Some pharmaceutical companies are not</td>
</tr>
<tr>
<td>members and hence are not subject to their</td>
</tr>
<tr>
<td>codes of ethics.</td>
</tr>
<tr>
<td>✓ The FDA needs strengthening with regards to</td>
</tr>
<tr>
<td>monitoring for violations.</td>
</tr>
<tr>
<td>✓ There is low generation of complaints due to</td>
</tr>
<tr>
<td>lack of awareness on policies and</td>
</tr>
<tr>
<td>complicated mechanism.</td>
</tr>
<tr>
<td>✓ The FDA is mandated to provide technical</td>
</tr>
<tr>
<td>assistance, consultative and advisory</td>
</tr>
<tr>
<td>services to stakeholders in the</td>
</tr>
<tr>
<td>implementation of regulations.</td>
</tr>
<tr>
<td>✓ There are efforts from multiple stakeholders</td>
</tr>
<tr>
<td>advocating for ethical promotions.</td>
</tr>
<tr>
<td>✓ ASC aids in self-regulation of OTC</td>
</tr>
<tr>
<td>advertisements via pre-clearance/ screening</td>
</tr>
<tr>
<td>of advertisements.</td>
</tr>
<tr>
<td>✓ FDA does not sit in ASC in the approval of</td>
</tr>
<tr>
<td>OTC &amp; other health product advertisements.</td>
</tr>
<tr>
<td>✓ FDA recognizes ASC through MOA and</td>
</tr>
<tr>
<td>provides guidelines to ASC.</td>
</tr>
<tr>
<td>✓ PRC regulates CPDs/ CMEs (pre-approval and</td>
</tr>
<tr>
<td>monitoring) but does not cover promotional</td>
</tr>
<tr>
<td>activities within CPD/CME.</td>
</tr>
</tbody>
</table>
**Context**

The context behind this model is characterized by the inadequate laws and regulations in place to clearly define what is and what is not acceptable in pharmaceutical promotion. Self-regulation by industry associations is also not transparent enough. However, the biggest challenge is the non-members of any industry associations. This model includes the current model of the ASC in regulating advertisements and takes advantage of the currently implemented CPD/ CME approval process of the PRC. Through this, the model will also support the FDA’s need for strengthening in monitoring violations, hopefully also addressing the low generation of complaints against violations.

**Assumptions**

The following are required to enable this framework:

- The FDA must have the sufficient capability and resources to help pre-screen advertisements through the ASC, and a well-defined mechanism for efficiently handling complaints involving pharmaceutical promotion.
- The FDA must contribute to the regulation of the approval of advertisements of health products through issuing clear guidelines for the ASC that will ensure that information found in the advertisements are not misleading rather than actively looking for published/ advertised materials which are non-compliant to the policy.
- Since the PPRB will also be working in coordination with the PRC particularly in pre-screening CMEs and CPDs, the PPRB must be recognized not only by the FDA, but also by PRC as a body that helps ensure that both the industry and health professionals practice within their codes of ethics. For the PPRB to be effective in its role, it is necessary that the PRC also provides support by requiring ethical pre-clearance of CPDs through the PPRB.
- Another prerequisite for this model is also the organization of a properly trained expert group/ individuals that could work under the PPRB, which is not much different from the external invitees of the ASC and the Ethics Committee of the PHAP.
Risks

Some of the risks of this model include inadequate technical and financial resources. For the PPRB, this may be reduced through the collection of fees for the processing or pre-clearance. However it will be a greater concern for FDA, as it will be the central receiver of complaints filed. A greater challenge would be the lack of a strong legislative framework as this model involves the formation of the PPRB under the FDA and collaboration with the PRC. Lastly, corruption would still pose a risk here especially within areas that may be vulnerable like the PPRB and the ASC. Therefore, they must be kept free from the influence of the pharmaceutical companies by selection of credible and reliable consultants and screeners, and confidentiality.

MODEL D

Figure 8. Model D. A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the framework. The PPRB serves as a pre-clearing house for all CPDs that are sponsored by a pharmaceutical company before these are submitted to PRC. Pharmaceutical companies are required to submit all their promotional activities to the PPRB, which in turn submits reports to FDA on compliant and non-compliant pharmaceutical companies. The PPRB will also serve as pre-clearing house for advertisements of OTCs and other health products. All complaints are filed with the FDA who in turn is required to provide feedback to the complainant. The FDA likewise shall impose the sanctions to the erring company. The FDA may also provide incentives/recognize companies who practice ethical promotion. EPTC acts as an independent watchdog where consumers may file their complaints to in case unethical promotion practices are observed among the pharmaceutical companies.

Model D includes the function of the ASC into the scope of functions of the PPRB. This tries to address the challenges encountered by ASC in terms of evaluating the technical components of
evaluating pharmaceutical advertisements especially with regard to their therapeutic claims and uses. Another component added to this model is the establishment of an EPTC which will be undertaken by civil society, opening a better opportunity for health care professionals, patient organizations and concerned citizens to channel any observed violations without fear or risk to their privacy and safety. The EPTC can file the complaints on their behalf if these reports from individuals are found to be valid.

Table 9. Context, Assumptions and Risks for Model D

<table>
<thead>
<tr>
<th>Context</th>
<th>Assumptions</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ There are laws and regulations in place for pharmaceutical promotion, although these are inadequate. ✓ There are self regulation mechanisms in place for PHAP/ PCPI based on code of ethics. ✓ Some pharmaceutical companies are not members and hence are not subject to their codes of ethics. ✓ The FDA needs strengthening with regards to monitoring for violations. ✓ There is low generation of complaints due to lack of awareness on policies and complicated mechanism and risk to individuals who want to report violations. ✓ The FDA is mandated to provide technical assistance, consultative and advisory services to stakeholders in the implementation of regulations. ✓ There are efforts from multiple stakeholders advocating for ethical promotions but these are loosely organized. ✓ ASC is recognized by the FDA through a MOA and is provided with guidelines to enforce in the pre-approval of advertisements as a component of self-regulation of pharmaceutical companies. ✓ PRC regulates CPDs/ CMEs (pre-approval and monitoring) but does not cover promotional activities held within CPD/CME.</td>
<td>✓ There is a presence of a strong legislative framework. ✓ PPRB serves as a TWG under FDA with clearly written functions, confidential and credible members and available resources (legal, technical, administrative, human) necessary, and an efficient process that enables them to screen and pre-clear both advertisements and CME/ CPD activities on time. ✓ There are sufficient resources at the FDA to act on all complaints filed directly to them and monitor other promotional activities aside from advertisements and CPDs/ CMEs. ✓ PRC collaborates in improving regulation of pharmaceutical promotion in CPDs/ CMEs by recognizing pre-clearance of CPDs through PPRB. ✓ Civil society initiates the EPTC ✓ ASC agrees that ads for OTCs and health products will not be under their jurisdiction.</td>
<td>✓ There is lack of availability and sustainability of resources. ✓ There is lack of a strong legislative framework ✓ There is potential corruption within organizations (ie. PPB). ✓ Civil society is not willing to start and sustain the EPTC.</td>
</tr>
</tbody>
</table>
**Context**
Model D operates under the same context as Model C except that it will also address the loosely organized efforts of multiple stakeholders and low filing of complaints by encouraging individuals like health care professionals, patients or concerned citizens to report to the EPCW. Another important existing issue addressed will be the relative inadequacy of expertise from the current ASC screening process to evaluate the technical components of the advertisements for health products that may lead to beliefs of unsubstantiated claims and the irrational use of products.

**Assumptions**
Like the context, assumptions for this model are also similar to Model C other than the need for the PPRB to have a very efficient process that allows them to do all pre-screenings of both advertisements and promotional activities on time once ASC accedes to giving the responsibility to screen advertisements for health products to them. To, have an efficient process, it is expected that PPRB in this model will require more resources for operations than that of Model C.

Another important assumption here for the development of the EPTC is that civil society is willing to lead in this undertaking. It is important that the EPTC be independent as it must be completely free from any influence to ensure its integrity in filing and following up complaints on behalf of individual reporters.

**Risks**
Like all the other models, a primary risk would be the unavailability of sufficient resources for FDA, the PPRB and also the EPTC, which may stem from the lack of a strongly supportive legislative framework. Corruption may still be a problem particularly with the PPRB which is now given greater responsibility. Lastly a challenge for the formation of the EPTC may be the lack of incentive for civil society to initiate and sustain the operations of the EPTC, other than their natural interest in ensuring safety and optimized treatment of consumers.
F. Ensuring Solid Involvement of Civil Society and Non-Government Stakeholders in the Regulation of Pharmaceutical Promotions

The need for a strong regulatory framework was extensively discussed along with the recommendations on how to improve the function of stakeholders in the preceding sections of this report. It should be considered however that these initiatives will be more effective with the institution of a more clearly defined set of policies on pharmaceutical promotion that can be used as reference for implementation.

In this section, we present suggestions for necessary steps that will enable solid participation of the civil society and non-government stakeholders in the regulatory processes, possibly through the leadership of groups like MeTA Philippines, ETHIKOS movement, or GIFTS. Such groups can definitely help facilitate the collaboration between consumer/patient groups, academe and professional societies whose interest or professional obligations include rational use of medicines and other health products to achieve optimum patient outcomes. They are expected to champion consumer’s rights to correct information, advocate for ethical promotional practices, and hold institutions and organizations accountable to act on unethical promotion and advertising. However, there is a need to raise further their awareness and capacity to effectively fulfil these roles, with financial and technical support from their own members, the government and other development partners.

In creating any structure that would involve them, be it the EPTC, PPSC, PPRB, there is a need for a multisectoral gathering of stakeholders to discuss and agree on the goals and conceptualize the structure and specific functions of the organization. It is important that memberships and commitments be formalized as well as registration of the group to make it a legal entity. Another important starting activity is the strategic planning to clearly define targets and how they are going to be achieved. Other preliminary but critical steps include creation of constitution and by-laws, and code of ethics. From the beginning, there must also be an available platform for regular communication between members and partners to ensure continuity of discussions and updates on activities being implemented.
In any advocacy and policy-related lobbying, concrete evidences are necessary. Civil society can add to these by spearheading research on unethical pharmaceutical promotions in the Philippines to describe and analyze its scope and impact. Funding from appropriate agencies may be utilized for this purpose. The results may be used not only in lobbying for policies but also for raising awareness on the impact of pharmaceutical promotion. This can be done through information, education and communication programs. Further research may be done to monitor the impact and effectiveness of existing and future policies in reducing the incidence of unethical practices.

The civil society’s involvement is also necessary for pharmaceutical companies and the government to have a platform that is neutral and free from any notion of complicity. Specific steps that can be taken to initiate this include facilitating the development of a universal code of ethics for industry and professionals by means of a workshop that will aim to come up with the minimum ethical standards that must be implemented by all involved stakeholders. The same can be done for the formulation of recommendations for policy particularly for the Implementing Rules and Regulations of the Mexico City Principles which has already been adopted by the Philippines.

Other than research, advocacy and awareness campaigns, suggested continuing functions include active surveillance of violations to the codes and policies, conduct of CPE for both industry and professionals together with the FDA, and lobbying for policies until they are instituted and implemented. For the conduct of CPEs for health professionals, it will however require that they become accredited CPE provider with sufficient financial and technical resources.

**Conclusion and Recommendations**

Medicines account for a majority (46%) of the total out-of-pocket expenditure of Filipino households hence it is critical that the intended health outcomes are achieved. Medicines must be used rationally so that it will provide the expected outcomes and the greatest benefit. Literature have documented that unethical promotional practices result to undue influences on
prescribing and dispensing decisions of health care professionals, reducing the weight of evidence-based decisions that are supposed to consider product quality, efficacy and cost-effectiveness.

Unethical business practices do not only affect patients. These are costly and a significant market access barrier especially for the SMEs in the health products sector which can ultimately translate to higher costs of medicines thereby again affecting patients.

Effective regulation of pharmaceutical promotion is seen as a way to ensure that patients will be informed and provided the most appropriate treatment options and at the same time to promote growth of the biopharmaceutical sector. This study also highlights the value of civil society’s involvement in many aspects as a way to ensure that the best interest of patients, which in this case is synonymous to civil society, will always be upheld during policy development, implementation and monitoring.

This study proposes four models based on review of models of other countries and primary data collected from various stakeholders. These models operate on various contexts, assumptions and risks that may occur. The model that will be most appropriate to implement depends on the situation and conditions surrounding the regulation of pharmaceutical promotion that prevail.

Model A is nearly identical to the current regulatory framework that we have except for enhancements in the implementation of the various stakeholders and the greater involvement of civil society groups and non-government stakeholders through the EPTC. The creation of this body empowers individuals to report violations to codes of practice and policies related to pharmaceutical promotion by filing complaints and close follow-up until they are resolved. Model B is considered a more cost-effective measure that involves civil society and non-government organizations through the PPSC, an unbiased, independent body for receiving and evaluating complaints prior to forwarding to the FDA, reducing the burden on FDA. It can also reduce conflicts between and among industry association members in reporting violations against each other. Model C encourages transparency and increases the scope of the regulation to non-members of associations, through requiring an ethical clearance issued by the PPRB for the accreditation of CME/CPD activities by the PRC. Consisting of credible, service-oriented
members free from any conflict of interest, the PPRB will serve like a Technical Working Group of the FDA. And lastly, Model D expands the role of the PPRB by including the function of the ASC in evaluating the technical components of pharmaceutical advertisements especially with regard to their therapeutic claims and uses. Another key component added to this model is the establishment of the EPTC which is quite similar in function to the EPTC in Model A.

Several recommendations have also been described at length in the description of the proposed models. These may be summarized into the following:

- A policy that promotes transparency which explicitly states or puts in operational form the government’s adoption of the Mexico City principles is warranted. A unified code of ethics that specifically details responsibilities is an ultimate necessity. The industry associations and companies that already subscribe to ethical standards are willing to support and work on this, as it levels the playing field for them against those who do not currently follow the same ethical standards as they do.
- FDA’s capability to perform its mandate must be strengthened by supporting it with technical, financial and human resources.
- Advocacy on awareness of ethical promotions among the civil society is encouraged. They should also be vigilant for areas in the framework that are vulnerable to corruption, such as in areas that need more transparency. Such efforts must be organized and sustained.
- To prevent any suspicion of collusion, civil society may also provide a neutral platform to enable stakeholders (ie. Industry, government, professionals) to have public discussions such as multi-stakeholder discussions on policies for pharmaceutical promotion. The presence of civil society also ensures that the interest of the most important group in the discussions, that is the patients, are upheld. To begin with, civil society must play a role in the development of the unified code of ethics for the industry and health care professionals.
- Holding seminars for health professionals in practice as an effort to influence their decision-making skills in terms of pharmaceutical promotions may be insufficient. Awareness on unethical pharmaceutical promotion may be further enhanced by integrating it early and continuously in the educational curriculum for health care professionals. Teaching students about the problems associated with unethical
promotions early on and repeatedly during their education may be more effective in helping students acquire ethical behaviors and provide them with the skills on how to respond to these practices.

✓ The government and civil society groups may initiate or support the academe or any non-government stakeholder who can make this information available to both the public and health professionals.

✓ Complaint system for unethical practices of pharmaceutical promotions must be in place which should have a clearly defined and user-friendly reporting and feedback mechanism.
References


47. Republic Act 9711. *An Act Strengthening and rationalizing the regulatory capacity of the bureau of food and drugs (BFAD) by establishing adequate testing laboratories and field offices, upgrading its equipment, augmenting its human resource complement, giving authority to retain its income, renaming it to the food and drug administration (FDA), amending certain section of republic act 3720, as amended and appropriating funds thereof*. 


ENSURING ETHICAL PROMOTION OF MEDICINES TO PROMOTE RATIONAL USE

Drugs and medicines, account for a majority (46%) of the total medical out-of-pocket expenditure of the Filipino households (PHAP, 2008 cited Reyes et al., 2011). While there is no published local data to support whether these medicines are used rationally, globally it is estimated that half of all medicines are prescribed, dispensed or sold inappropriately and half of all patients fail to take them accurately. Inappropriate use of medicines results in wastage of scarce resources and health hazards.

A crucial component to promote rational use of medicines is accurate information on medicines to healthcare professionals and the general public. One of the usual sources of information on medicines is the pharmaceutical industry, which are also the primary developers and producers of medicines. However because it is also a business, it is highly dependent on marketing to expand product sales which may sometimes be unethical at the expense of the public health priority of rational use. Literature documents that reliance on information provided by the pharmaceutical industry through promotions may result to undue influences on prescribing and dispensing decisions of health care professionals.

Unethical business practices hampers growth of SMEs

Unethical promotion or business practices also impose a significant market access barrier and high costs especially for the small and medium enterprises (SMEs) in the health products sector which can ultimately translate to higher costs of medicines at the expense of the patients (APEC, 2014). In order to promote growth of SMEs, the Asia-Pacific Economic Cooperation (APEC) endorsed principles for codes of business ethics for players in the medical device and biopharmaceutical sectors, namely the Kuala Lumpur Principles and Mexico City Principles, respectively. The Philippines, as an APEC member, signed both documents and issued FDA Circulars 2013-024 and 2014-007 adopting both Codes for local application.

Gaps in the current regulatory framework on pharmaceutical promotions need to be resolved

The Philippines has several laws and policies governing pharmaceutical promotions which clearly implicate the State’s policy to protect consumers from misleading advertisement and fraudulent sales and promotion practices. These policies also have clearly defined FDA’s role and responsibilities in the regulation of pharmaceutical promotion. However these also lack transparency and specific provisions to guide both industry and health care professionals in their interactions with each other. The FDA also lacks resources and capable personnel to efficiently carry out its jurisdiction over medicines promotion. While self-regulation exists for PHAP and
PCPI\textsuperscript{10}, with their Codes of Conduct/ ethics governing them, some companies may still engage in unethical practices to expand their market sales because of the absence of a national policy or code of ethics to govern their practices.

The FDA’s issuance of Memorandum Circular 2013-024 on the country’s decision to adopt the Mexico City Principles is clearly a step forward to address some of the gaps indicated in the present system of regulation of pharmaceutical promotions. However, the government needs to operationalize this to properly guide all relevant stakeholders. The government needs to explicitly state what it wants to be done rather than leaving to the public how it wants to translate the said circular. Among the areas that need clarification are interactions with healthcare professionals, sponsorships to local or foreign travels, distribution of free medicine samples, promotional content of materials, advertisements, interaction with patient/ consumer groups, monitoring and sanctions.

**Civil society and other non-government stakeholders must be involved in the regulation of pharmaceutical promotions**

A system for pharmaceutical promotion which involves the civil society and other non-state actors as partners in the oversight and conduct of promotional activities will be significant especially considering the limited resources allotted for the regulation of pharmaceutical promotions, the lack of transparency of the current regulatory framework, and the vulnerability of industry self-regulation. Four models are described which operate on various assumptions and risk. The choice of a model will be dependent on which assumptions are satisfied. The level of involvement of civil society and other non-government stakeholders also vary in each model.

\textsuperscript{10} PHAP (Pharmaceutical Healthcare Association of the Philippines) and PCPI (Philippine Chamber of the Pharmaceutical Industry Inc.) are industry organizations in the Philippines. PHAP represents research-based pharmaceutical companies while PHAP is composed of Filipino pharmaceutical manufacturers and traders/ distributors)
Figure 1. Model A. A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the policy. These associations and other pharmaceutical companies will be mandated to report to FDA all their promotional activities. EPTC acts as an independent watchdog where consumers may file their complaints in case unethical promotion practices are observed among the pharmaceutical companies.

In Model A (Figure 1), the primary involvement of the civil society groups and non-government stakeholders is membership to the Ethical Promotions Transparency Coalition (EPTC). The EPTC is envisioned to be an organized movement of participants from consumer/patient groups, academe and professional societies who will advocate for ethical promotions of medicines and other health products and champion consumer’s rights to correct information. The EPTC may also perform active surveillance on promotional activities, spearhead research on pharmaceutical marketing practices and its regulation and forward complaints to the FDA.
In Model B, the involvement of civil society and non-government stakeholders is membership to the Pharmaceutical Promotions Standards Committee (PPSC). The PPSC is an unbiased body for receiving and evaluating complaints from industry, health professionals and the civil society prior to forwarding to the FDA. Aside from acting as a decision-maker, the PPSC aims to reduce the burden on FDA as an implementing agency by screening and validating complaints through a standardized process involving expert evaluation. It also aims to reduce conflicts between and among industry association members in reporting violations against each other.
A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the policy. ASC serves as pre-clearing house for advertisements of OTCs and other health products. The framework requires that FDA will be involved in the final approval of these advertisements before these are aired to the general public. The PPRB serves as a pre-clearing house for all CPDs that are sponsored by a pharmaceutical company before these are submitted to PRC. Pharmaceutical companies are required to submit all their promotional activities to the PPRB, which in turn submits reports to FDA on compliant and non-compliant pharmaceutical companies. All complaints are filed with the FDA who in turn is required to provide feedback to the complainant. The FDA likewise shall impose the sanctions to the erring company. The FDA may also provide incentives/recognize companies who practice ethical promotion.

In Model C (Figure 3), the national policy on pharmaceutical promotions shall require that FDA must be involved in the approval of advertisements of health related products. This will ensure that information found in the advertisements is deemed compliant by the FDA prior to release rather than having FDA to actively search for published/advertised materials which are non-compliant to the policy. The policy shall also create the Pharmaceutical Promotion Regulatory Board (PPRB) which will be tasked to serve as monitoring arm of the FDA. This is a step further from model B, which encourages transparency and increases the scope of the regulation to non-members of associations, in that it provides another way of monitoring the events that are commonly used for pharmaceutical promotion if the resources can be provided.
A clear legislative framework on regulation of promotion and marketing of pharmaceuticals and medical products is in place. This mandates all pharmaceutical companies to create their codes of ethics that are compliant to the legislative framework. PHAP, PCPI or other associations of pharmaceutical companies are recognized and expected by FDA to self-regulate in accordance to the framework. The PPRB serves as a pre-clearing house for all CPDs that are sponsored by a pharmaceutical company before these are submitted to PRC. Pharmaceutical companies are required to submit all their promotional activities to the PPRB, which in turn submits reports to FDA on compliant and non-compliant pharmaceutical companies. The PPRB will also serve as pre-clearing house for advertisements of OTCs and other health products. All complaints are filed with the FDA who in turn is required to provide feedback to the complainant. The FDA likewise shall impose the sanctions to the erring company. The FDA may also provide incentives/ recognize companies who practice ethical promotion. EPTC acts as an independent watchdog where consumers may file their complaints to in case unethical promotion practices are observed among the pharmaceutical companies.

Model D (Figure 4) includes the function of the ASC into the scope of functions of the PPRB. This tries to address the challenges encountered by ASC in terms of evaluating the technical components of evaluating pharmaceutical advertisements especially with regard to their therapeutic claims and uses. Another component added to this model is the establishment of an EPTC which will be undertaken by civil society, opening a better opportunity for health care professionals, patient organizations and concerned citizens to channel any observed violations without fear or risk to their privacy and safety. The EPTC can file the complaints on their behalf if these reports from individuals are found to be valid upon verification.

Clear policies benefit both consumers of medicines and the pharmaceutical industry
The institution of clear policies relating to ethical pharmaceutical promotions is not only meant to benefit the public, the primary consumers of medicines, but the pharmaceutical industry as well. Rational use of medicines is ensured and the growth of SMEs in the health care sector is promoted.

Some identified policy and program directions are:
A policy that promotes transparency which explicitly states or puts in operational form the government’s adoption of the Mexico City principles is warranted. A unified code of ethics that specifically details responsibilities is an ultimate necessity. The industry associations and companies that already subscribe to ethical standards are willing to support and work on this, as it levels the playing field for them against those who do not currently follow the same ethical standards as they do.

FDA’s capability to perform its mandate must be strengthened by supporting it with technical, financial and human resources.

Advocacy on awareness of ethical promotions among the civil society is encouraged. They should also be vigilant for areas in the framework that are vulnerable to corruption, such as in areas that need more transparency. Such efforts must be organized and sustained.

To prevent any suspicion of collusion, civil society may also provide a neutral platform to enable stakeholders (ie. Industry, government, professionals) to have public discussions such as multi-stakeholder discussions on policies for pharmaceutical promotion. The presence of civil society also ensures that the interest of the most important group in the discussions, that is the patients, are upheld. To begin with, civil society must play a role in the development of the unified code of ethics for the industry and health care professionals.

Holding seminars for health professionals in practice as an effort to influence their decision-making skills in terms of pharmaceutical promotions may be insufficient. Awareness on unethical pharmaceutical promotion may be further enhanced by integrating it early and continuously in the educational curriculum for health care professionals. Teaching students about the problems associated with unethical promotions early on and repeatedly during their education may be more effective in helping students acquire ethical behaviors and provide them with the skills on how to respond to these practices.

The government and civil society groups may initiate or support the academe or any non-government stakeholder who can make this information available to both the public and health professionals.
✓ Complaint system for unethical practices of pharmaceutical promotions must be in place which should have a clearly defined and user-friendly reporting and feedback mechanism.

References


