

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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Philippines

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Introduction

Advertising of pharmaceutical products in the Philippines is generally governed by guidelines under the Implementing Rules and Regulations of the Food and Drug Administration Act of 2009 (“FDA IRR”), and regulations issued by the Philippine Food and Drug Administration and the Department of Health (“FDA”). The promotion and advertisement of health products are likewise regulated by Codes of Conduct developed by self-regulating organizations, which are intended to apply to member pharmaceutical companies and other members from the health products industry.

The Regulatory Framework

Pursuant to Republic Act No. 9711 or the Food and Drug Administration Act of 2009 (“FDA Act”), the manufacture, importation, sale, offering for sale, promotion, advertising and sponsorship of any health product in the Philippines is regulated by the FDA, an office under the Department of Health (“DOH”). The FDA has the power, among others, to prescribe standards, guidelines and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship and other marketing activities about health products.

The term “health product” includes food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, and household or urban hazardous substances. The terms “advertisement” and “promotion” are not defined in the FDA Act or in the FDA IRR promulgated in 2011. However, various regulations of the FDA¹ define “advertisement” as any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale

¹ See, e.g., Administrative Order 65, Series of 1989 and Regulation No. 5, Series of 1987.

or disposal of any health product, and broadly define “promotion” as the practice of giving temporary additional value to a brand, product or service to achieve specific marketing objectives, and includes the distribution of free products or samples.

Under the FDA IRR, all advertisements, promotions, sponsorship and other marketing activities about a health product must adhere to the standards, guidelines and regulations of the FDA. Advertisements, promotions, sponsorship and other marketing activities on health products refer to those addressed to the general public in any form of media.

Permitted and Prohibited Practices

The FDA IRR provides the following general rules on the advertisement of health products:

- No health product that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities.
- No claim in the advertisement, promotion and sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA.
- No claims, therapeutic, scientific or otherwise, shall be made that has not been duly approved by the FDA.
- All health products that are permitted to be promoted must specifically state the authority or reference number that approved the same promotional, sponsorship or marketing activities.

An approved health product registration is issued a proper authorization by the FDA in the form of a Certificate of Product Registration (“CPR”). An authorization or CPR covering a particular health product shall be *prima facie* evidence of the registrant’s marketing authority for said health product. As a general rule, only



establishments with a valid License to Operate (“LTO”) from the FDA may hold a CPR. Drug manufacturers, traders, distributors, importers, exporters, and wholesalers are required to obtain an LTO from the FDA. An entity applying for an LTO with respect to drug products shall be required to demonstrate its capacity to perform adequately the activities covered by the LTO, and in a manner that satisfactorily assures the safety, efficacy and quality of its drug products.

Regulation of Prescription Drugs

In addition to the requirements under the FDA Act and FDA IRR with respect to the advertisement and promotion of health products, various regulations specifically govern these activities with respect to pharmaceutical products.

Under Administrative Order 65, Series of 1989 (“AO 65”), pharmaceutical products classified by the FDA as a prescription or ethical drug may not be advertised or promoted in any form of mass media, except through medical journals, publications and/or literature solely intended for medical and allied professions. “Prescription or ethical drugs” refer to pharmaceutical products or drug preparations that are to be dispensed only upon written order of a duly licensed physician or dentist for the treatment of a condition or a diagnosed disease.

Furthermore, pursuant to AO 65, all therapeutic claims for drugs, medicines or any pharmaceutical product made in any advertising or promotional materials must be based on adequate scientific pharmacological and clinical evidence, responsible medical opinion or long experience demonstrating their safety, efficacy and therapeutic value. The pharmaceutical company and its medical director shall be responsible and accountable for the content and form of its advertisement and promotional materials.

Under Regulation No. 5, Series of 1987 (“Regulation 5”), giving of sample of a prescription drug directly to the public is strictly prohibited. The distribution of free products or samples during medical missions and within outpatient dispensaries is allowed,

provided that the distribution is under the supervision of a physician. Furthermore, under Regulation 5, raffles, gifts, promises of reward or and other forms of inducement to the prescribers of prescription drugs (i.e., duly licensed physicians or dentists), are prohibited.

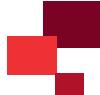
Promotion of Generic Name

Section 6 (c) of the Generics Act of 1988 (“Generics Act”) provides that any organization or company involved in the manufacture, importation, repacking, marketing, and distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

Pursuant to the Generics Act, AO 65 provides that all advertising and promotional materials, whether print, visual or auditory, shall feature prominently the generic name of the drug product designated by the FDA. In the case of branded products, the prominence of the generic name shall be insured in all print, visual or auditory materials that feature the brand name. AO 65 provides for specific requirements on how the generic name shall be presented in a label, and in all promotional and advertising materials (i.e., the generic name shall appear prominently within an outline box, be printed in full and not abbreviated, among others).

In case a product is identified by a brand name together with its generic name, AO 65 also specifically provides how the typeface, font, and color of the generic name and brand name shall be rendered in all promotional and advertising materials, with the end of highlighting the generic name over the brand name of the pharmaceutical product (e.g., the generic name must appear immediately above the brand name, and in a larger point size than the brand name).

The Advertising Board of the Philippines (“AdBoard”) recommended a Supplementary Guideline to AO 65, which was acceptable to the FDA. The AdBoard is a governing body composed of representatives of national organizations involved in advertising practice, which have



banded together to promote the development of the advertising industry through self-regulation. The Supplementary Guideline includes the following:

- Audiovisual advertisements with a duration of 30 seconds or more shall end with an audio: “[Generic Name] is the generic name for [Brand Name]” together with a product shot showing the generic name. Otherwise, the text of the whole statement shall be shown for at least two seconds.
- Auditory advertisements with a duration of 30 seconds or more shall likewise end with the line: “[Generic Name] is the generic name for [Brand Name].”
- For advertisements with a duration of 15 seconds or less, the generic name must be mentioned or shown at least once within the commercial.

Adoption of the Mexico City Principles

The FDA has also issued FDA Circular No. 2013-0124 on 5 September 2013, which adopts the “Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector” (Mexico City Principles) (“FDA Circular”). The Mexico City Principles Circular provides, among others, that (i) interactions with healthcare professionals (“HCPs”) are to be conducted in a professional and ethical manner, (ii) nothing should be offered or provided by a pharmaceutical company in a manner that inappropriately influences an HCP’s prescribing practices, and (iii) payments in cash or gifts for the personal benefit of HCPs should not be provided or offered to HCPs, among others, and (iv) any sponsorship to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, or promote any medicine. Under the FDA Circular, the FDA, through the Center for Drug Regulation and Research (“CDRR”), shall formulate and issue guidelines for application and approval of promotional, advertisement and/or sponsorship materials for health products, and in particular, pharmaceutical and biological products (“Guidelines”). To

date, the Guidelines have yet to be promulgated. The FDA Circular provides that any violation of the FDA Circular shall be a ground for the filing of administrative charges and imposition of administrative sanctions such as suspension, cancellation or revocation of any license, permit or registration issued by the FDA.

Consequences of Breach

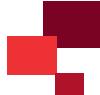
FDA Act and FDA IRR

The printing, broadcasting and dissemination of advertisements, advertising or promotional materials of medical products that do not comply with the guidelines and requirements under the FDA IRR and relevant regulations and issuances of the FDA, may subject the drug establishment to administrative sanctions and penalties. The Licensing, Inspection and Compliance Division of the FDA is tasked with monitoring whether the advertisements and/or promotion of drug products comply with the standards, guidelines, and regulations of the FDA.

The FDA is authorized to receive complaints on violations of FDA rules and regulations. If the FDA finds, based on its own findings or complaints filed, that any of the advertising or promotional material violates the relevant provisions of the FDA IRR, AO 65 or other relevant regulations, it may issue a cease and desist order against the responsible drug establishment to stop the further release, printing, broadcast or dissemination of the advertising or promotional material.

The FDA may also undertake the following punitive and corrective actions in case of repeated and serious violations:

- Seizure and confiscation of products that are subject of violative promotional or advertising materials
- Withdrawal by the FDA of accreditation of the drug establishment's medical director
- Suspension of the LTO of the drug establishment
- Cancellation of the CPR



- Revocation of the LTO of the drug establishment

Additionally, the FDA Act prohibits the advertisement of any health product that is adulterated, unregistered or misbranded (adulterated or misbranded drugs are further discussed below), and imposes the following penalties for the said violation:

- Imprisonment ranging from one year but not more than 10 years
- Fine of not less than PHP50,000 but not more than PHP500,000
- Fine and/or imprisonment, at the discretion of the court.

If the foregoing violation of the FDA Act is committed by a manufacturer, importer or distributor of any health product, the penalty imposable is at least five years imprisonment but not more than 10 years, and a fine of at least PHP500,000 but not more than PHP5,000,000. An additional fine of one percent of the economic value/cost of the violative product or violation, or PHP1,000, whichever is higher, is also imposable for each day of continuing violation.

If the offense is committed by a juridical person, the chairman of the board of directors, the president, general manager, or the partners and/or the persons directly responsible of the erring entity shall suffer the penalties provided by law. If the offense is committed by a foreign national, such violator shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

Generics Act

Any juridical person that violates Section 6 (c) of the Generics Act shall suffer the penalty of a fine of not less than PHP5,000 but not more than PHP10,000, and suspension or revocation of the LTO of such drug establishment or drug outlet at the discretion of the Court, provided that, its officers directly responsible for the violation shall

suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six months but not more than one year, or both fine and imprisonment, at the discretion of the Court. Furthermore, if the guilty party is an alien, he shall be ipso facto deported after service of sentence without need of further proceedings.

Any advertising or promotional material found to violate AO 65 will be identified and the medical company responsible shall be notified. The FDA shall issue a cease and desist order stopping the further release, printing, broadcast or dissemination of the violative advertising or promotional material.

AO 65

For repeated or serious violations of the guidelines under AO 65, the FDA may impose any or all of the following sanctions:

- Withdrawal by the FDA of accreditation of the establishment's medical director
- Suspension of the LTO of the drug establishments
- Cancellation of the CPR
- Revocation of the LTO of the drug establishment

Regulation 5

Any person who violates Regulation 5 may be imposed any or all of the following sanctions by the FDA:

- Issuance of a cease and desist order
- Cancellation of the CPR and withdrawal of the product from the market within 45 days from date of cancellation
- Imposition of administrative fines in the amount of PHP5,000.

AdBoard

As a self-regulatory body, the AdBoard relies on the agreement between member-associations to carry out its rulings. Any violation of its standards or guidelines may cause all media – print and broadcast – to refuse to print or broadcast violative advertising material.

Criminal Liability in Relation to Anti-Bribery and Anti-Corruption Laws

As discussed above, criminal liability may arise from violations of the FDA Act. In addition, in relation to health products, including pharmaceutical products, anti-bribery and anti-corruption laws are also potential basis for criminal sanctions.

Philippine anti-bribery and anti-corruption laws consist of the following:

- the Revised Penal Code;
- Republic Act No. 3019 or The Anti-Graft and Corrupt Practices Act (“RA 3019”);
- PD No. 46 which penalizes giving of gifts on any occasion (“PD 46”); and
- Republic Act No. 6713 or The Code of Conduct and Ethical Standards for Public Officials and Employees (“RA 6713”).

These laws, in many instances, overlap with each other. Notably, while certain gifts/payments may appear to be allowed under certain laws, e.g., exemption for unsolicited gifts or presents of small or insignificant value under RA 3019, the same gifts/payments may technically be covered by the broad language of other laws, e.g., indirect bribery, which penalizes acceptance of any gift given by reason of one’s public position.

Philippine anti-bribery and anti-corruption laws are relevant insofar as transactions between pharmaceutical companies and public officials

are concerned, e.g., with healthcare professionals in government hospitals, officials of the FDA who are involved in the processing or approval of licenses and/or new drugs, public officials involved in procurement of medical supplies, or officials of the Intellectual Property Office involved in the processing or approval of licenses or permits relating to intellectual property.

Notably, the term “public officer” is broadly defined under Philippine anti-bribery and anti-corruption laws. “Public officers” include “any person who, by direct provision of law, popular election or appointment by competent authority, shall take part in the performance of public functions in the Government of the Philippine Islands, or shall perform in said Government or in any of its branches public duties as an employee, agent or subordinate official, of any rank or class.”² They include those employed either on a permanent or temporary basis, whether or not they are in the career or non-career service, including military personnel, and whether or not they receive compensation, regardless of amount.³

“Government”, on the other hand, includes the national government, local governments, government-owned and government-controlled corporations, and all other instrumentalities or agencies of the Republic of the Philippines and their branches.⁴ A “government-owned and controlled corporation” is any agency organized as a stock or non-stock corporation, vested with functions relating to public needs whether governmental or proprietary in nature, and owned by the government directly or indirectly or through its instrumentalities either wholly, or, where applicable as in the case of stock corporations, to the extent of at least 51 percent of its capital stock.⁵

Bribery Under the Revised Penal Code

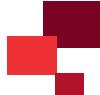
The Revised Penal Code defines two types of bribery, namely, direct bribery and indirect bribery.

² Revised Penal Code, Article 203.

³ See RA 6713, Section 3(b) and RA 3019, Section 2(b).

⁴ See RA 3019, Section 2(a).

⁵ The Administrative Code of 1987, Section 2 (13).



Direct Bribery

Direct bribery is committed by accepting an offer/promise, or receiving a gift/present, in consideration for:

- an act constituting a crime;
- an unjust act (not constituting a crime); or
- refraining from doing something which is the public officer's official duty to do.⁶

The elements of direct bribery are:

- the offender is a public officer;
- the offender accepts an offer or a promise, or receives a gift or present by himself or through another;
- the offer or promise must be accepted or gift received by the public officer with a view to committing some crime, or in consideration of the execution of an act which, although not constituting a crime, is unjust, or to refrain from doing something which is his official duty to do; and
- the act is connected with the performance of the public officer's official duties.

In a case officers of the Land Transportation Office ("LT Office") were convicted of having committed direct bribery for collecting "protection money" from a taxi driver, in exchange for refraining from impounding his vehicle for alleged violations of LT Office rules and regulations.⁷

⁶ Revised Penal Code, Article 210.

⁷ *Balderama vs. People of the Philippines* (G.R. Nos. 147578-85 & 147598-605, 28 January 2009)

Indirect Bribery

Indirect bribery, on the other hand, is committed by a public officer simply by accepting a gift/present given by reason of his office.⁸

The elements of indirect bribery are:

- the offender is a public officer;
- the offender accepts gifts offered; and
- the gift is given by reason of his public office.

Corruption of Public Officials

The crime committed by a public officer who receives an improper payment or a promise thereof may either be direct bribery or indirect bribery. The private person who gives the gift or promise may also be held liable for the crime of “corruption of public officials.”⁹

Special Anti-Corruption Laws

PD 46 (Giving of Gifts on any Occasion)

PD 46 punishes the act of giving, or offering to give, to a public official or employee, a gift, present or other valuable thing on any occasion, including Christmas, when such gift, present or other valuable thing is given by reason of the public official/employee’s position, regardless of whether or not the same is for past favor or the giver hopes or expects to receive a favor or better treatment in the future from the public official or employee concerned in the discharge of his official functions. Included within the prohibition is the throwing of parties or entertainment in honor of the public official or employee or of his immediate relatives.

⁸ Revised Penal Code, Article 211.

⁹ Revised Penal Code, Article 212.

Republic Act No. 6713 (Code of Conduct and Ethical Standards for Public Officials and Employees)

RA 6713 prohibits public officials and employees from soliciting or accepting, directly or indirectly, any gift, gratuity, favor, entertainment, loan or anything of monetary value from any person in the course of their official duties or in connection with any operation being regulated by, or any transaction which may be affected by the functions of their office.

RA 6713 provides that “gift” shall not include an unsolicited gift of nominal or insignificant value not given in anticipation of, or in exchange for, a favor from a public official or employee. The phrase “receiving any gift” includes the act of accepting directly or indirectly, a gift from a person other than a family member or relative, even on the occasion of a family celebration or national festivity like Christmas, if the value of the gift is neither nominal nor insignificant, or if the gift is given in anticipation of, or in exchange for, a favor.

Private individuals who participate in conspiracy as co-principals, accomplices or accessories, with public officials or employees are subject to the same penal liabilities as the public officials or employees, and shall be tried jointly with them.

Note, however, that this exception for “unsolicited gifts” under RA 6713, is not recognized in other relevant Philippine laws, e.g., PD 46 discussed above, or the Revised Penal Code.

RA 3019 (Anti-Graft and Corrupt Practices Act)

RA 3019 prohibits a public officer from:

- knowingly inducing or causing a public official to commit an act constituting a violation of official rules and regulations/offense in connection with official duties;
- directly or indirectly receiving a gift, present, share, percentage or benefit, for himself or another, in connection

with a contract or transaction between the government and any other party;

- directly or indirectly receiving a gift, present or any other pecuniary or material benefit, for himself or another, from any person for whom a government permit or license will be or is obtained;
- accepting, or having a member of his family accept, employment in a private enterprise which has pending official business with him, during the pendency of his employment or within one year after his termination;
- in the discharge of his official functions, causing undue injury/giving unwarranted benefit, advantage or preference to any party through manifest partiality/evident bad faith/gross or inexcusable negligence;
- neglecting or refusing, after due demand/request, without sufficient justification, to act within a reasonable time on any matter pending before him for the purpose of obtaining benefit, or favoring his or another party's interest;
- entering into any contract or transaction manifestly and grossly disadvantageous to the government, whether or not the public officer profited or will profit;
- directly or indirectly having financial or pecuniary interest in any business, contract or transaction in which he intervenes or takes part in his official capacity;
- directly or indirectly becoming interested for personal gain, or having material interest in, any transaction or act requiring his approval as part of a board or group, regardless of his vote;
- knowingly approving or granting any license, permit, privilege or benefit in favor of unqualified persons, or dummies of the same; and



- divulging valuable and confidential official information acquired by him or his office, to unauthorized persons.

A private individual hired by a government agency on a contractual basis for a particular project and for a specific period is considered a public officer for the duration of his contract.

By way of exception, unsolicited gifts or presents of small or insignificant value offered or given as a mere ordinary token of gratitude or friendship according to local customs or usage are not covered by RA 3019. RA 3019 defines the phrase “receiving any gift” as “includ(ing) the act of accepting directly or indirectly a gift from a person other than a member of the public officer’s immediate family, in behalf of himself or of any member of his family or relative within the fourth civil degree, either by consanguinity or affinity, even on the occasion of a family celebration or national festivity like Christmas, if the value of the gift is under the circumstances manifestly excessive.” As mentioned above, however, this exception is not recognized in other laws such as PD 46 or the Revised Penal Code.

The private person who gives the gift, present, share, percentage or benefit shall, together with the offending public officer, be punished with imprisonment and be permanently or temporarily disqualified from transacting business in any form with the Government.

The following case-summaries illustrate how the Supreme Court has resolved issues relating to violations of RA 3019.

- In one case, the Supreme Court held that a court sheriff’s act of demanding and collecting money from a complainant and his clients to defray the expenses of the implementation of certain writs issued by the court, was in violation of RA 3019.¹⁰

¹⁰ *Pasok vs. Diaz* (A.M. No. P-07-2300, 29 November 2011)

- In another case decided by the Supreme Court, a municipal mayor was convicted of violating RA 3019 for refusing to release full payment to a private contractor, unless the mayor received her “kickback.”¹¹
- A mayor who approved the acquisition of a dump truck without a public bidding, when a similar truck could have been bought at a much lower price, was found to have violated RA 3019.¹²
- A private contractor was convicted of violating RA 3019 when he, in conspiracy with other municipal officers and employees, caused the approval and release of funds for the construction of a municipal building and public market, where such funds were higher than the actual contract price.¹³
- A private supplier was convicted of violating RA 3019 when she conspired with police officers to have funds released and paid to her purportedly for the purchase of combat, clothing and individual equipment of police personnel when no delivery of such equipment were ever effected.¹⁴

Administrative Issuances

Department of Health Order No. 2007-0043

The DOH prohibits its officials and employees from soliciting directly or indirectly any gift and/or benefit for themselves or for others, regardless of the cost, unless otherwise approved by the Department of Social Welfare and Development; where this may influence, or may reasonably be seen to influence or to have influenced past, present, or future performance of their functions; or if the gift or benefit is from:

- a tobacco or milk company and organizations/interests and related industries;

¹¹ *Cadiao-Palacios vs. People* (G.R. No. 168544, 31 March 2009)

¹² *Ong vs. People* (G.R. No. 176546, 25 September 2009)

¹³ *Santillano vs. People of the Philippines* (G.R. No. 175045, 3 March 2010)

¹⁴ *Luspo vs. People of the Philippines* (G.R. Nos. 188487, 188541, and 188556, 14 February 2011)



- a bidder, supplier, contractor or entity and their agents with contracts with the DOH;
- those applying for DOH authorization;
- parties transacting business with any DOH office/bureau/center/hospital; or
- an individual, counsel, witness, or their agent undergoing investigation conducted by, or involved in a case before the DOH or any government agency or court.

Donations of food, medical supplies, medicines and medical devices from any donor may be allowed, provided that such donations are:

- covered by appropriate Memorandum of Agreement/Understanding, certificate of donation or acknowledgement receipt; and
- given to DOH hospitals for indigent patients or distributed during DOH public health campaigns or DOH health emergency response activities.

DOH officials and employees may receive plaques, awards, certificates or other tokens of gratitude and/or benefits as appropriate to the occasion to which he/she is invited as a guest speaker or lecturer. Transportation and accommodation provided to enable the DOH official/employee to be a speaker or lecturer during the occasion may also be accepted. DOH officials and employees may also receive performance-based cash rewards, scholarship grants and similar benefits granted by appropriate government agencies, non-profit private institutions, and national or international non-profit organizations.

Note on Commercial Bribery

In the Philippines, there is no law which penalizes bribery between private individuals in the course of their commercial transactions. An

essential element of bribery or any acts penalized under Philippine anti-bribery and anti-corruption laws is the involvement of public officers, who solicit, accept or are offered, gifts or anything of value from any person, or perform any of the prohibited acts discussed above.

Sanctions

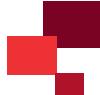
Any public officer or private person convicted of any of the offenses above may be punished with imprisonment or a fine or both, and disqualified to hold public office, by the court's discretion. In addition, the offending public officer or private person shall be civilly liable for damages. The government office to which the public officer belongs may also impose disciplinary sanctions, including suspension or removal from office.

Public Procurement and Fraud

Public Procurement

Republic Act No. 9184 or The Government Procurement Reform Act ("RA 9184") and the Revised Implementing Rules and Regulations of RA 9184 apply to the procurement of infrastructure projects, goods and consulting services regardless of source of funds, whether local or foreign, by all branches and instrumentalities of the Philippine government, its departments, offices and agencies, including government-owned and/or -controlled corporations and local government units. As such, RA 9184 applies to the procurement of government entities of drugs and other pharmaceutical products and services from both local and foreign pharmaceutical corporations.

RA 9184 is anchored on the following principles: transparency; competitiveness; streamlined procurement process; accountability; and public monitoring. Guided by these principles, the procurement of goods and services begins with a pre-procurement conference where specifications of the goods and services to be procured are discussed followed by an invitation to bid, a pre-bid conference, submission of bidding documents, evaluation and announcement of the lowest calculated bid/highest rated bid, or a failure in the bidding process. In the interest of transparency, participants are also required to submit a



disclosure of relations, wherein all bids shall be accompanied by a sworn affidavit of the bidder that it is not related to the head of the procuring entity, members of the Bids and Awards Committee (“BAC”), the technical working group, the BAC Secretariat, the head of the Project Management Office or the end-user unit, and the project consultants, by consanguinity or affinity up to the third civil degree. Existence of a relationship with the aforementioned persons within the third civil degree and failure to disclose the same, shall be a ground for the automatic disqualification of the bid.

As a general rule, all procurement shall be done through competitive bidding subject to a number of exceptions, including: limited source bidding which is allowed for highly specialized goods and services (e.g., sophisticated defense equipment); direct contracting which is allowed for a proprietary source because of the existence of patents, copyrights and trade secrets; repeat order which is allowed in replenishing goods from a previous winning bidder; shopping which is allowed for readily available off-the-shelf goods or ordinary/regular equipment to be procured directly from suppliers of known qualifications; and negotiated biddings which are allowed when there are two failed biddings or emergency situations, among others. Because medical products and services are generally patented or subject to intellectual property rights, it is not uncommon for the procurement of these products and services to be accomplished through limited source bidding or direct contracting.

Fraud

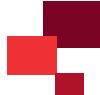
As mentioned above, fraud and other corrupt practices occurring in the bidding process carry penal, civil and administrative sanctions.

In addition to the penal sanctions under the various anti-bribery laws discussed above, RA 9184 penalizes the: opening of any sealed bid prior to the appointed time for the public opening of bids or other documents; delaying, without justifiable cause, the screening for eligibility, opening of bids, evaluation and post evaluation of bids, and awarding of contracts beyond the prescribed periods of bids or other

documents; unduly influencing or exerting undue pressure on any member of the BAC or any officer or employee of the procuring entity to take a particular bidder; splitting of contracts which exceed procedural purchase limits and competitive bidding; and when the head of the agency abuses the exercise of his power to reject any and all bids with manifest preference to any bidder who is closely related to him. When any of the foregoing acts is done in collusion with private individuals, the private individuals shall likewise be liable for the offense.

In addition, RA 9184 also penalizes the commission by private individuals of the following acts: when two or more bidders agree and submit different bids as if they were bona fide bidders, when they knew that one or more of them was so much higher than the other that it could not be honestly accepted and that the contract will surely be awarded to the pre-arranged lowest bid; when a bidder maliciously submits different bids through two or more persons, corporations, partnerships or any other business entity in which he has interest to create the appearance of competition that does not in fact exist so as to be adjudged as the winning bidder; when two or more bidders enter into an agreement which call upon one to refrain from bidding for procurement contracts, or which call for withdrawal of bids already submitted, or which are otherwise intended to secure as undue advantage to any one of them; and when a bidder, by himself or in connivance with others, employ schemes which tend to restrain the natural rivalry of the parties or operates to stifle or suppress competition and thus produce a result disadvantageous to the public.

The penalties under RA 9184 for the foregoing offenses range from six years to 15 years of imprisonment. In addition, a conviction under RA 9184 or RA 3019 shall carry with it civil liability, which may either consist of restitution for the damage done or the forfeiture in favor of the government of any unwarranted benefit derived from the act or acts in question or both, at the discretion of the courts. Lastly, the offender may also be subject to administrative sanctions which include suspension or disqualification from participating in government procurement processes.



Professional Codes of Conduct

Code of Ethics of the Philippine Medical Association

As discussed above, while existing anti-bribery and anti-corruption laws target dealings with government officials and public officers, there are codes of conduct for members of the health and pharmaceutical industries which regulate activities and arrangements among such members.

The Code of Ethics of the Philippine Medical Association (“PMA”) (“PMA Code of Ethics”) sets forth certain standards governing physicians and their dealings and relationships with patients, colleagues and other allied professionals, as well as other members of the health products industry. Among its general principles, the PMA Code of Ethics posits that the promotion and advancement of the health of patients should be given the highest priority over the benefits of the physicians and members of such health product industries.¹⁵ The PMA Code of Ethics also provides for certain duties and what are considered as acceptable and ethical behavior of physicians when dealing with promotional, marketing and other related or similar activities involving the health products industry.

Grants and Subsidies

The PMA Code of Ethics recognizes that physicians may accept gifts from a health product company provided the same is of reasonable value, primarily entails benefits to patient care, or relates to the physicians’ work.¹⁶ It is also considered ethical for physicians to request donations for a charitable purpose from pharmaceutical companies for as long as this does not redound to the physician’s personal benefit.¹⁷ Furthermore, physicians may accept reasonable

¹⁵ PMA Code of Ethics, Article 1, Section 7.

¹⁶ *Id* at Article VI, Section 3.

¹⁷ *Id* at Article VI, Section 4.

subsidies from health and other industries to support their participation in Continuing Medical Education (“CME”).¹⁸

CME conferences and professional meetings may be organized by a medical society in cooperation with sponsoring entities.¹⁹ However, during the course of CME activities sponsored by a pharmaceutical company, only generic names of products must be used.²⁰ The sponsoring entity may promote or indicate their branded products only after the lectures.²¹ When commercial exhibits are part of the overall program, information on the product displayed during such exhibits should be limited to relevant information about the product.²²

Funds from commercial sources may be accepted if the same is intended for the benefit of a medical association or society.²³ With respect to grants of scholarships for physicians or to medical students by pharmaceutical companies, these are permissible for as long as the selection of scholars are made by the organizers or the academic institutions concerned.²⁴

Marketing Activities

The PMA Code of Ethics devotes a section on the relationship between physicians and the health products industry, as well as marketing activities involving physicians.

As a rule, physicians are not allowed to commercially endorse any medical or health product.²⁵ They are also prohibited from deriving any form of material gain from product samples.²⁶ To this end, Republic Act No. 5921 or the Pharmacy Law expressly prohibits the sale of any sample of any drug, device or medicine which are intended

¹⁸ *Id* at Article IV, Section 12.

¹⁹ *Id* at Article IV, Section 10.

²⁰ *Id* at Article IV, Section 15.

²¹ *Ibid.*

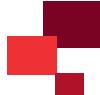
²² *Id* at Article IV, Section 16.

²³ *Id* at Article IV, Section 11.

²⁴ *Id* at Article IV, Section 14.

²⁵ *Id* at Article III, Section 5.

²⁶ *Id* at Article VI, Section 1.



to be given for free to the physician and other qualified person by a manufacturer or distributor of such product.

Pharmaceutical companies may, however, request physicians to participate in post-marketing or similar activities, where physicians are asked to try new products on patients, provided that the patients are properly informed and have given their informed consent.²⁷ Physicians are encouraged to report or share the result of such activities to duly constituted authorities.²⁸

PHAP Code of Pharmaceutical Marketing Practices

The Pharmaceutical and Healthcare Association of the Philippines (“PHAP”) is a non-stock non-profit organization with members consisting of companies engaged in research and development, manufacturing, retail and distribution of pharmaceutical products and medical devices. PHAP membership represents the sector of industry that invest in research and development (R&D) resulting in new therapies.²⁹ Through its members, PHAP’s mission is to produce, enhance, and make accessible quality and life-saving medicines and medical devices and to partner with government, medical professions and non-government organizations in improving the overall healthcare situation in the Philippines.³⁰ PHAP members and local subsidiaries of International Federation of Pharmaceutical Manufacturers & Associations (“IFPMA”) member companies must adhere to the PHAP Code of Practice (“PHAP Code”).³¹

The PHAP Code adopts and aligns with the Expanded Code of Practice of the IFPMA and the Mexico Principles. It sets out standards that apply to the conduct of PHAP members and their agents to ensure that their interactions with stakeholders are appropriate.³²

²⁷ *Id* at Article VI, Section 2.

²⁸ *Ibid.*

²⁹ <http://www.phap.org.ph/index.php?cid=2>

³⁰ <http://www.phap.org.ph/index.php?cid=2&sid=5>

³¹ PHAP Guiding Principles On Ethical Conduct and Promotions.

³² *Ibid.*

Under the PHAP Code, a “healthcare professional” refers to any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply or administer a pharmaceutical product.³³ The terms “promotion and advertisement” mean any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through any medium, including the internet.³⁴

Independence of Healthcare Professionals

Underlying most provisions of the PHAP Code is the importance of upholding the independence of healthcare professionals. Hence, interactions with HCPs should be focused on informing HCPs about medicines, providing scientific and educational information and supporting medical research and education. The PHAP Code provides that no financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would inappropriately influence a healthcare professional’s prescribing practices. Gifts of any kind for the personal benefit of HCPs are not allowed, irrespective of value, kind or occasion.³⁵ The only exception are wreaths given on the occasion of the death of an HCP.³⁶

Medical Information and Promotional Claims

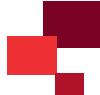
The PHAP Code also highlights the responsibility of pharmaceutical companies for providing accurate, balanced, and scientifically valid data on products. All promotional content (in printed/electronic form,

³³ PHAP Code, 1.2.

³⁴ PHAP Code, 1.2.

³⁵ PHAP Code, 10.0.

³⁶ PHAP Code 10.2.



or communicated orally) must be accurate, scientifically sound, and objective, reflect the current state of knowledge and must be consistent with FDA approved labeling. All promotional claims must be substantiated and referenced. Data on file may be used as reference and made available upon request.³⁷

In line with the foregoing principles, the PHAP Code provides the following guidelines:

- Promotion should be consistent with locally approved product information.³⁸
- Promotional information should be clear, legible, accurate, balanced, fair and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned.³⁹
- No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.⁴⁰
- Promotional claims should be capable of substantiation either by reference to the approved labeling or by scientific evidence.⁴¹
- The word “new” can be used only to refer to product presentation, or therapeutic indication that has been available and generally promoted for not more than 12 months.⁴²
- No company shall engage any HCP to promote, advertise or endorse any pharmaceutical product in quad media, in print, and visual display.⁴³

³⁷ PHAP Code 2.0.

³⁸ PHAP Code 2.1.

³⁹ PHAP Code 2.2.

⁴⁰ PHAP Code 2.3.

⁴¹ PHAP Code, 2.4.

⁴² PHAP Code 2.5.

- A full disclosure product information must accompany all promotional materials for at least 12 months from the date of product launch.⁴⁴ Beyond 12 months, an abridged product information should accompany all promotional materials.⁴⁵

Promotional Aids

A promotional aid is a brand name reminder. Companies may offer items designed primarily for the education of patients or HCPs if the cost of the item does not exceed PhP1,000 and do not have value to HCPs outside of his or her professional responsibilities. Promotional aids must be related to the work of the recipient HCPs and should be of minimal value and quantity. Possible items include inexpensive pens and notepads. Promotional items intended for the personal benefit of the HCP, such as music CDs, paintings, or food baskets, are not allowed.⁴⁶

Medical Representatives/Professional Service Representatives

Medical Representatives/Professional Service Representatives, whose regular duties comprise or include interacting with or conducting business calls to HCPs, should possess sufficient medical and technical knowledge to present information on the company's products in an accurate, current, and balanced manner. Members have a responsibility to maintain high standards of continuing competency training for representatives and shall be required to conduct the mandatory courses under the Integrity and Proficiency Program in the Pharmaceutical Sector or its equivalent.⁴⁷

Product Samples

Free samples of a pharmaceutical product may be supplied to HCPs, and only with their consent, in order to enhance patient care or to gain clinical experience. Samples should not be sold or otherwise misused

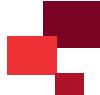
⁴³ PHAP Code 2.6.

⁴⁴ PHAP Code 3.1.

⁴⁵ PHAP Code 3.2.

⁴⁶ PHAP Code 4.6.

⁴⁷ PHAP Code 6.1 and 6.2.



by medical representatives and employees.⁴⁸ Product samples must be accompanied by product inserts and must comply with labeling requirements of the FDA and must be clearly marked “Physician’s Sample - Not for Sale”.⁴⁹ Companies should have adequate systems of control and accountability for samples provided to HCPs including how to look after such samples while they are in possession of medical representatives.⁵⁰

Events and Meetings

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (“Events”) for HCPs organized or sponsored by a company should be to provide scientific or educational information and/or inform HCPs about products.⁵¹ In line with the foregoing principle, the PHAP Code provides the following guidelines:

- All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purposes of the Event. Hotels and establishments that are primarily located at beachfront resorts, as well as those that primarily offer and provide recreational activities such as spas, golf, casinos, etc., are not considered appropriate venues.⁵²
- Exhibit booths must be directed only to HCPs. The display must clearly identify the exhibitor and must comply with all the requirements of the organizer and the provisions of the PHAP Code.⁵³
- Raffle activities will not be allowed.⁵⁴

⁴⁸ PHAP Code 7.0.

⁴⁹ PHAP Code 7.4 and 7.5.

⁵⁰ PHAP Code 7.6.

⁵¹ PHAP Code 8.1.1.

⁵² PHAP Code 8.1.2.

⁵³ 8.2.

⁵⁴ 8.2.1.

- Educational activities maybe conducted in booths provided the tokens are limited to promotional aids.⁵⁵

Continuing Medical Education

Under the PHAP Code, no company may organize or sponsor an event for HCPs that takes place outside of their home country unless it is appropriate or justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are justified and permitted. Travel should be by economy class.⁵⁶

Companies are allowed to sponsor only HCPs' accommodations, meals, transportation and registration fees for participating in CME meetings, except for local meetings where HCPs should shoulder registration fees to encourage attendance. Cash assistance, check vouchers, and payment for accompanying guests are not allowed.⁵⁷

For overseas venues, companies may sponsor 7 HCPs for the Americas, Europe, and Australia. For ASEAN countries, Hong Kong, Taiwan, India, China, Japan, Korea, and Middle East, companies may sponsor up to 12 HCPs.⁵⁸

For CME events in the Philippines, companies may sponsor any number of HCPs, provided the professionals will pay the registration fee. The scientific program must constitute a minimum of 66% of the time in the given location, outside of reasonable travel time, and must be held in business accommodation locations, and not primarily beachfront resorts, as well as those that primarily offer and provide recreational activities such as spas, golf, casinos, etc.⁵⁹

No honorarium or compensation will be given to the HCP for attending the convention, symposium or CME event.⁶⁰

⁵⁵ 8.2.2.

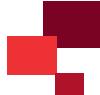
⁵⁶ 8.3.

⁵⁷ 8.4.1.

⁵⁸ 8.4.2.

⁵⁹ 8.4.3.

⁶⁰ 8.4.5.



Limits of Hospitality/Entertainment

Refreshments and/or meals incidental to the main purpose of the Event can only be provided: exclusively to participants of the Event, and if they are moderate and reasonable as judged by local standards. Under no circumstances is a company allowed to pay expenses of accompanying guests.⁶¹

No entertainment or other leisure or social activities should be provided or paid by member companies. Competitions and raffles in congresses and conventions are not allowed. Only educational activities with tokens in the form of promotional aids will be allowed in exhibit booths.⁶²

Events Involving Travel

A company can only organize events involving travel if it is justified, i.e.:

- A significant proportion of the invited HCPs are from outside of the HCP's place/country of practice, and it makes greater logistical or security sense to hold the event in another location/country; or
- The relevant resource or expertise that is the object of the subject matter of the event is located outside of the HCP's place/country of practice.⁶³

Sponsorship of the HCP must be limited to travel to and from the venue and meals and accommodations for the duration of the Event with possibility of extending one day before and one day after the Event if warranted by logistical considerations., Sponsorship of

⁶¹ 8.5.

⁶² 8.5.1.

⁶³ 8.6

entertainment or side trips of the HCP within or outside of the duration of the Event is not allowed.⁶⁴

Sanctions

Sanctions against a subject company may be applied where breaches of the PHAP Code have been established. Sanctions may take the form of one or more of the following:

- the requirement that the subject company takes immediate action to discontinue or modify any practice that is determined to constitute a breach of the Code. Written notification of this action must be provided to the Ethics Committee within ten (10) working days of the receipt of the decision of the Committee.
- at the very least, the company will be asked to confirm that the activity or use of the material/program will cease immediately if not already discontinued, and that all possible steps will be taken to avoid a similar breach of the Code in the future.

the imposition of a fine on the subject company amounting to PHP200,000.00 for the first offense. Succeeding offenses of the same nature or within the same section of the CPMP within a twelve month period shall be punished with a fine of PHP750,000.00 per offense.⁶⁵

Contracts with Healthcare Professionals and Medical Institutions

Research Activities

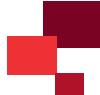
Under the PMA Code of Ethics, sponsored research activities should be ethically defensible, socially responsible and scientifically valid.⁶⁶ Any remuneration paid for such research activities should be reasonable and should not constitute an enticement.⁶⁷

⁶⁴ 8.6.

⁶⁵ 16.8

⁶⁶ PMA Code of Ethics, Article VI, Section 5.

⁶⁷ *Ibid.*



Speaking/Consultant Engagements

The PMA Code of the Ethics also provides that speakers or consultants of conferences or meetings are allowed to accept from health industries honoraria and reimbursement for reasonable transportation, lodging and meal expenses.⁶⁸

Sponsorship of Clinical Trials

Under the PHAP Code, clinical trials, which are defined as scientific investigations using valid study designs conducted according to protocols or study descriptions approved by the FDA and a duly established independent review board or ethics committee, are subject to the following guidelines:

- A sponsor of a clinical trial or a contract research organization must obtain a License to Operate from the FDA;
- Any clinical study or research program involving humans must be conducted in compliance with the principles of Good Clinical Practice as laid down in the Declaration of Helsinki;
- All such studies must address meaningful medical or scientific topics, e.g., the clinical profile of a product such as safety, efficacy, modes of action or performance related to other treatments;
- The well being, personal integrity and privacy of participants must always be of highest priority. The informed consent document must appropriately convey all relevant aspects of the study to potential subjects.
- Studies in humans must not have the promotion of products as their purpose.
- The details of conducting and financing studies must be set out in a written contract, The company will only pay for

⁶⁸ PMA Code of Ethics, Article IV, Section 13.

remuneration to HCPs, which reflect fair market value for study-related activities.

- All clinical trials, once approved for implementation by the FDA, shall be uploaded into the Philippine Clinical Trial Registry as required under local regulations.
- All study data must be statistically evaluated.⁶⁹

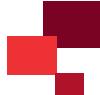
Furthermore, under the PMA Code of Ethics, such research trials conducted by physicians for an industry should be done in accordance with the national or institutional guidelines for the protection of human subjects.

Recommendations

With respect to advertising and promotional activities targeted towards consumers and the general public, pharmaceutical companies must ensure that all materials used for any form of promotion or sale activities, whenever permitted under the law, must consistently contain accurate, balanced and complete relevant product information. For this purpose, it is recommended that such promotional materials be cleared with the company's medical director at all times. In addition to obtaining the approvals required under the relevant laws and regulations, consultations and pre-clearances with the relevant agencies, such as the FDA or the Adboard, may also be undertaken by pharmaceutical companies to ensure compliance with the minimum advertising requirements and standards set by the relevant regulating agency.

Pharmaceutical companies dealing with or intending to enter into transactions with public officials must strictly comply with Philippine anti-bribery and anti-corruption laws. In this regard, pharmaceutical companies may want to avoid giving any gift, gratuity, favor, entertainment, loan or anything of monetary value, to any public official. Pharmaceutical companies intending to provide products or

⁶⁹ 11.1



services to government entities must also strictly comply with public procurement laws.

Pharmaceutical companies intending to engage in promotional and marketing activities in the Philippines are encouraged to exercise restraint in expenditures with respect to dealings with independent healthcare professionals. Activities targeted towards healthcare professionals must always be evaluated with a view to ensuring that these professionals' independence is not compromised and public health and welfare are given foremost consideration. To this end, pharmaceutical companies are encouraged to comply with the limits set forth in the PHAP Code on what would be considered as reasonable expenditure when it comes to sponsoring healthcare events and in providing benefits to healthcare professionals. Industry practice may also be considered, but in case of doubt, pharmaceutical companies are encouraged to err on the side of restraint.



This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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