Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

PHILIPPINES

Philippines

Christina Macasaet-Acaban, Lara Camille Lee

Introduction

Advertising of health products in the Philippines is generally governed by Republic Act No. 9711 or the Food and Drug Administration Act of 2009 ("**FDA Act**"), the Implementing Rules and Regulations of the FDA Act ("**FDA IRR**"), and regulations and guidelines issued by the Philippine Food and Drug Administration ("**FDA**") and the Department of Health ("**DOH**"). 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.

Regulatory framework

Pursuant to the 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 DOH. The FDA has the power 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. Nonetheless, various regulations of the FDA define "advertisement" as any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale 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 pharmaceutical products and medical devices must adhere to the standards, guidelines and regulations of the FDA. Advertisements, promotions, sponsorship and other marketing activities on pharmaceutical products and medical devices 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 pharmaceutical products and medical devices:

- No pharmaceutical products and medical devices that have 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 pharmaceutical products and medical devices, or as duly approved by the FDA.
- No claims, therapeutic, scientific or otherwise, shall be made that have not been duly approved by the FDA.
- All pharmaceutical products and medical devices 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**") as a health product establishment 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.

On the other hand, medical devices must either be notified, registered or subject to a listing requirement with the FDA before they can be manufactured or distributed in the Philippines, depending on the nature of the device and its intended use. Note, however, that implementation of such notification, registration and listing are in the initial/transitory phases and not yet fully implemented. Please refer to our discussion on 'Regulation of Medical Devices' below.

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, certain regulations specifically govern these activities with respect to prescription 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 DOH Administrative Order No. 0053-15 entitled, "Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices," ("**PPPMD Promotion Guidelines**"), giving a sample of a prescription pharmaceutical product or medical device ("**PPPMD**") directly or indirectly to the public is strictly prohibited.

Samples may be provided to a healthcare professional ("**HCP**") and healthcare organization ("**HCO**"), provided that these are duly acknowledged by the HCP and HCO. Manufacturers and distributors are not permitted to give, directly or indirectly, samples of PPPMD to the general public or gifts of any sort to any member of an HCP's immediate family. They are also not allowed to distribute samples of prescription products to anyone other than licensed physicians and dentists. In the case of substantial amounts provided for indigent patients, the recipient HCP and/or HCO must execute a written statement that the samples shall be used for its intended purpose and shall not be used for financial gain.

Under the PPPMD Promotion Guidelines, medical missions must also not be used as a platform for promoting or advertising PPPMD.

Promotion of generic names

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). The PPPMD Promotion Guidelines also provide that any promotional material of pharmaceutical products (in any form of mass media) shall comply with the provisions set forth by AO 65 specifically under Section 3 on the guidelines on advertisement and promotions to implement the Generics Act, including those set forth above.

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 industry in the Philippines is self-regulated. The Ad Standards Council ("**ASC**"), which took over the functions of the Advertising Board of the Philippines, is the self-regulatory agency that screens and regulates the content of advertising materials. Membership in the ASC is voluntary. Members of the ASC agree to voluntarily adopt the rules of the ASC and subject themselves to the restrictions in the ASC rules. In addition, the Consumer Act of the Philippines ("**Consumer Act**"), which regulates advertising and sales promotion, provides that all advertising materials shall conform to the Code of Ethics of the Advertising Board of the Philippines ("**AdBoard**"). The ASC has its own Code of Ethics, which is based on the Code of Ethics of the AdBoard. The ASC has promulgated certain

guidelines to implement the Generics Act. Such guidelines include the following:

- television, cinema and electronic billboard advertisements that run for 30 seconds or more

If the label on the product shot is not reasonably readable, the generic name shall be prominently shown with the first product shot.

All television, cinema and electronic billboard advertisements shall end with the following audio: "(GENERIC NAME) is the generic name for (BRAND NAME)", provided that the audio is voiced together with the product shot prominently showing the generic name.

Otherwise, the text of the whole statement shall be shown for at least two seconds without audio.

- television, cinema and electronic billboard advertisements that run for 15 seconds or less

The generic name should be mentioned or shown at least once within the commercial.

Advertisements featuring two or more products shall mention or show at least once the generic name of each branded product featured.

Regulation of medical devices

Similar to prescription pharmaceutical products, regulation of medical devices is governed by the FDA Act, the FDA Act IRR and issuances of the DOH and FDA.

Marketing authorization for medical devices

The DOH has recently issued DOH Administrative Order No. 2018-002 on 26 January 2018 entitled: Guidelines Governing the Issuance of an Authorization for a Medical Device based on the Association of Southeast Asian Nations ("**ASEAN**") Harmonized Technical

Requirements ("**Medical Device Guidelines**"), which aims to provide guidelines on the documentary requirements for the registration of medical devices in the Philippines and to align the registration requirements to the Common Submission Dossier Template (as defined in the Medical Device Guidelines) ("**CSDT**") based on the provisions of the ASEAN Medical Device Directive ("**AMDD**").

Under the Medical Device Guidelines, medical devices are classified into four categories based on its risk-rating, as follows:

Class	Risk level
A	Low
B	Low to moderate
C	Moderate to high
D	High

The foregoing classification was based on standards formulated by the relevant standards and quality committee and working group of ASEAN, to which the Philippines belongs.

The FDA will issue guidance documents containing a list of medical devices per classification. Reclassification of certain medical devices may be changed by the FDA if there are incidents relating to the manufacture, distribution, or use of the device, after proper consultation with the advisory committee of the FDA and ASEAN.

If a medical device is not on the list to be issued by the FDA, the medical device company must classify the device based on the intended use and on the classification rules of the AMDD. The FDA will verify the classification made by the applicant and shall reclassify the device if another classification is deemed to be more appropriate.

Under the Medical Device Guidelines, all medical devices under Class A shall apply for notification of the medical device product, while all medical devices under Classes B to D shall apply for registration of the medical device product. Upon successful notification of a Class A medical device, the FDA will issue a Certificate of Medical Device Notification ("**CMDN**") and a Certificate of Medical Device Registration ("**CMDR**") upon successful registration of a Class B/C/D medical device.

Medical devices strictly for research, clinical trial, exhibit and/or donated brand new medical devices are exempted from notification and registration. However, the researcher, institution and/or user of such devices shall apply for a Certificate of Medical Device Listing ("**CMDL**") from the FDA before the medical device can be imported or used in the Philippines.

The Medical Device Guidelines provide for the requirements, process and timeline in relation to applications for notification, registration and listing of medical devices. The procedure and requirements under the Medical Device Guidelines will become effective one year from its publication (i.e., 15 March 2019).

Advertising and promoting medical devices

The FDA has adopted the Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector ("**Mexico City Principles**") through FDA Circular No. 2013-0124 ("**FDA Circular**"). The Mexico City Principles provide, among others, that: (i) interactions with 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; (iii) payments in cash or gifts for the personal benefit of HCPs should not be provided or offered to HCPs; and (iv) any sponsorship to individual HCPs must not be conditional upon an obligation to prescribe, recommend or promote any medicine.

The FDA also issued FDA Circular No. 2014-007 on 25 February 2014, which adopts the "Kuala Lumpur Principles Medical Device Sector Code of Ethics" ("**Kuala Lumpur Principles**"). The Kuala Lumpur Principles aim to promote ethical interactions between medical device and diagnostics companies and HCPs. The Kuala Lumpur Principles provide that medical technology industry codes of ethics should incorporate, but not necessarily be confined to, the following:

- Collaborative interactions between companies and HCPs should preserve independent decision-making by HCPs and public confidence in the integrity of patient care, treatment and product selection.
- Consultancy agreements between companies and HCPs should support research and development to advance medical science, develop new technologies, improve existing products and services and enhance the quality and efficacy of care for patients. Consultancy agreements should not be used as a means of inappropriate inducement.
- Company support of HCPs' education, for example, through support to third-party educational programs and educational grants, should preserve the independence of medical education and should not be used as a means of inappropriate inducement.
- Companies may provide training of HCPs on product-specific device deployment, use and application to facilitate the safe and effective use of medical technologies by HCPs.
- Companies should not provide entertainment and recreation to HCPs as an inappropriate inducement. Any attendance at entertainment events, consenting or agreeing to receive any gift, commission or gratuity shall not be regarded as appropriate for nurturing appropriate business relationships.

- Company donations for charitable or other philanthropic purposes should support bonafide charitable organizations and missions, and should not be a means to privately benefit an HCP.

- Free products should not be used as a means of inappropriate inducement. However, companies may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

- To ensure industry codes are effective, they should encourage adherence to the following elements that are relevant to a company's business:

- Companies to appoint a senior executive responsible for oversight of the company's compliance with the industry code.

- Companies to develop or adopt practical, useful, and meaningful policies, guidance and tools on how to implement policies consistent with the industry code.

- Companies to provide effective and ongoing training and education on the industry code and the company's policies consistent with the industry code.

- Companies' senior management and governing body, if applicable, commit to support the industry code.

In line with this, the FDA has issued DOH Administrative Order No. 0053-15 of the PPPMD Promotion Guidelines. Such guidelines were issued in response to the adoption of the Mexico City Principles and the Kuala Lumpur Principles, as implemented by the FDA. Please refer to our discussion on the PPPMD Guidelines for guidelines applicable to PPPMD companies which aims to prescribe standards with respect to information dissemination, advertisements, promotion, sponsorship and other marketing activities and instruments about

PPPMD with the end goal of improving and promoting their rational use, and safeguarding patient rights and welfare.

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 discovers, based on its own findings or on 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 the 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 said violation:

- imprisonment ranging from one to 10 years
- fine of not less than PHP 50,000 but not more than PHP 500,000
- 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 PHP 500,000 but not more than PHP 5 million. An additional fine of 1% of the economic value/cost of the violative product or violation, or PHP 1,000, whichever is higher, is also imposable for each day of continuing violation.

If the offense is committed by a juridical person, the chair 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 PHP 100,000, 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 a fine of at least PHP 40,000 and suspension or revocation of their license to practice their 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/she shall be ipso facto deported after service of sentence without the need for 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

PPPMD Promotion Guidelines

All advertising, promotional or other marketing materials, whether written, audio or visual, for products within the scope of such guidelines, may be subjected to a post-audit by the FDA and if any should be found to violate any FDA provisions, a cease and desist order and/or penalties and/or fines shall be issued by the FDA.

ASC

Any violation of the provision of the ASC Code of Ethics is usually the subject of the complaint that is presented to the ASC for hearing. Decisions may call for a cease and desist order on errant ad materials. Compliance is assured through specific sanctions on violations. An extreme case may cause all media, print and broadcast to refuse to

print/broadcast advertising material found to have violated specific provisions of the code.

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**")
- 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, such as 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 such as 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, such as, 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." 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 the amount.

"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. 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% of its capital stock.

Bribery under the Revised Penal Code

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

Direct bribery

Direct bribery is committed by accepting an offer/promise or receiving a gift/present in consideration for any of the following:

- an act constituting a crime

- an unjust act (not constituting a crime)
- refraining from doing something that is the public officer's official duty

The elements of direct bribery are as follows:

- The offender is a public officer.
- The offender accepts an offer or a promise, or receives a gift or present by him/herself 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 that is his/her official duty to do.
- The act is connected with the performance of the public officer's official duties.

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/her office.

The elements of indirect bribery are as follows:

- The offender is a public officer.
- The offender accepts gifts offered.
- The gift is given by reason of his/her 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."

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 a 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/her official functions. Included within the prohibition is the throwing of parties or entertainment in honor of the public official or employee or of his/her immediate relatives.

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 a "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 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, such as PD 46 discussed above or the Revised Penal Code.

RA 3019 (Anti-Graft and Corrupt Practices Act)

RA 3019 prohibits a public officer from the following:

- 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, or allowing him/herself to be persuaded, induced or influenced to commit such violation or offense.
- Directly or indirectly receiving a gift, present, share, percentage or benefit, for him/herself or another, in connection with a contract or transaction between the government and any other party, wherein the public officer in his/her official capacity has to intervene under the law.
- Directly or indirectly receiving a gift, present or any other pecuniary or material benefit, for him/herself or another, from any person for whom a government permit or license will be or is obtained in consideration for the help given or to be given.
- Accepting, or having a member of his/her family accept, employment in a private enterprise that has pending official business with him/her, during the pendency of his/her employment or within one year after his/her termination.
- In the discharge of his/her 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/her for the purpose of obtaining benefit, or favoring his/her 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/she intervenes or takes part in his/her official capacity.
- Directly or indirectly becoming interested for personal gain, or having material interest in, any transaction or act requiring his/her approval as part of a board or group, regardless of his/her vote.
- Knowingly approving or granting any license, permit, privilege or benefit in favor of unqualified persons, or dummies of the same.
- Divulging valuable and confidential official information acquired by him/her or his/her 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/her 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,

on behalf of him/herself or of any member of his/her 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.

Administrative issuances

DOH 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 any of the following:

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

- 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 an appropriate memorandum of agreement/understanding, certificate of donation or acknowledgement receipt
- 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 that 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 from holding 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 ("**GPRA**") and the Revised Implementing Rules and Regulations of the GPRA 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, the GPRA applies to the procurement of government entities of drugs and other pharmaceutical products and services from both local and foreign pharmaceutical corporations.

The GPRA 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. As 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, GPRA penalizes the following: 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 that exceed procedural

purchase limits and competitive bidding; and when the head of the agency abuses the exercise of his/her power to reject any and all bids with manifest preference to any bidder who is closely related to him/her. 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, GPRA 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/she 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 that calls upon one to refrain from bidding for procurement contracts, or which calls for withdrawal of bids already submitted, or which is otherwise intended to secure an undue advantage to any one of them; and when a bidder, by him/herself or in connivance with others, employ schemes that 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 GPRA for the foregoing offenses range from six years to 15 years of imprisonment. In addition, a conviction under GPRA 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 that 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. 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 physician's work. 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. Furthermore, physicians may accept reasonable subsidies from health and other industries to support their participation in Continuing Medical Education ("**CME**").

CME conferences and professional meetings may be organized by a medical society in cooperation with sponsoring entities. However, during the course of CME activities sponsored by a pharmaceutical

company only generic names of products must be used. The sponsoring entity may promote or indicate their branded products only after the lectures. 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.

Funds from commercial sources may be accepted if the same is intended for the benefit of a medical association or society. 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.

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. Commercial endorsement shall include the advertising or promotion of medical and health products as above defined, whether a physician is paid or not. It includes statements or declarations promoting or advertising medical or health products and the use of the names or the pictures of physicians in the advertisements or promotions. Favorable written or verbal reviews or statements of support for a medical or health product are included as commercial endorsements and are prohibited.

They are also prohibited from deriving any form of material gain from product samples. To this end, Republic Act No. 5921 or the Pharmacy Law expressly prohibits the sale of any sample of any drug, device or medicine that is intended 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. Physicians are encouraged to report or share the result of such activities to duly constituted authorities.

PHAP Code of Pharmaceutical Marketing Practices and the PPPMD Promotion Guidelines

The Pharmaceutical and Healthcare Association of the Philippines ("**PHAP**") is a non-stock, non-profit organization with members consisting of companies engaged in the research and development, manufacturing, retail and distribution of pharmaceutical products and medical devices. PHAP membership represents the sector of industry that invests in research and development resulting in new therapies. Through its members, the 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. 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**").

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

Under the PHAP Code, an "HCP" 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. The terms "promotion and advertisement" mean any activity undertaken, organized or sponsored by a member company that is directed at HCPs to promote the prescription, recommendation,

supply, administration or consumption of its pharmaceutical product(s) through any medium, including the internet.

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. The only exception are wreaths given on the occasion of the death of an HCP.

Medical information and promotional claims

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

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

- Promotion should be consistent with locally approved product information.

- 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.
- No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.
- Promotional claims should be capable of substantiation either by reference to the approved labeling or by scientific evidence.
- 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.
- No PPPMD company shall employ or contract any HCP or health worker to promote, advertise or endorse any pharmaceutical product or medical device in mass media, in print, audio visual display or social media.

Under the PPPMD Promotion Guidelines, information provided by PPPMD manufacturers and distributors to health professionals regarding their products shall be restricted to evidence-based scientific data.

Promotional materials provided by industry to any HCP shall also ensure the following:

- Demonstrate the balance between risks and benefits.
- Comply with existing FDA and other pertinent regulations.
- Substantiate claims with up-to-date scientific evidence.

Informational and educational materials dealing with the use of PPPMDs, whether written, audio or visual, shall include clear information on all the following points: (1) benefits and risks of the

drug or device; (2) pharmacodynamics and pharmacokinetics of the drug; (3) indications and contraindications to use of the drug or device; and (4) adverse effects and drug interactions.

Promotional or marketing materials of PPPMD companies using citations, quotes or statements lifted from medical literature, lectures, presentations or similar sources of information shall not be changed, distorted or taken out of context.

The following claims and/or comments shall be prohibited:

- one-sided information and any decisive statement based on inadequate or truncated evidence
- superlatives, exaggerations and lines with hanging comparatives, without supporting data, such as, "This product is better (e.g., safety, efficacy, quality and price) because . . ."
- unsupported comments about competitors and their products
- unspecified, unreferenced claims about side effects, safety and efficacy

Other prohibited words and phrases are as follows:

- the word "new," unless the product or indication has been available and generally promoted for less than 12 months
- "Non-toxic" and "no side effects"
- unspecified, unreferenced claims about safety and efficacy without proper qualification

Promotional aids

A promotional aid means a non-monetary item given to HCPs or an organization for a promotional purpose with minimum value, which must be relevant to the HCP's work and not for personal benefit. The PHAP Code provides that educational activities maybe conducted in

booths provided the tokens are limited to promotional aids as defined in the PPPMD Promotion Guidelines.

According to the Guidelines, PPPMD companies may provide promotional aids to HCPs, provided these are: (a) of modest value; and (b) relevant to the practice of the healthcare professions or education of the patients.

Any item that does not have any direct patient benefit or is not related to the work of the HCP shall not be permitted.

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.

Under the PPPMD Guidelines, when presenting product information, PPPMD company representatives must provide scientific information of educational value to the HCP.

Product samples

Free samples of a pharmaceutical product may be supplied to HCPs, and only with their consent, to enhance patient care or to gain clinical experience. Samples should not be sold or otherwise misused by medical representatives and employees. Product samples must be accompanied by product inserts and must comply with labeling requirements of the FDA and be clearly marked "Physician's Sample - Not for Sale." 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.

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. 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.
- 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.
- Raffle activities are not allowed.
- Educational activities maybe conducted in booths provided that the tokens are limited to promotional aids as defined in the PPPMD Promotion Guidelines.

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 a logistical or security point of view. Industry sponsorship of HCPs to events involving foreign/local travel shall be allowed but subject to the following conditions:

- The purpose of the event is to provide scientific or educational information.
- The travel is justified because:
    - the events is held outside of the sponsored HCP's place/country of practice, and/or it makes greater logistical or security sense to hold the event in another location/country
    - the relevant resource or expertise that is the object or subject matter of the event is located outside of the sponsored HCP's place/country of practice
- The venue for such event is appropriate and conducive to the educational or scientific objectives of the conference.
- The selection of the HCPs should be unrelated to the prescribing and sale of the PPPMD company's products.
- The sponsorship for travel of HCPs attending events as legitimate participants shall only be for economy class. This particular restriction on the travel arrangement, however, shall not apply to HCPs who are traveling under a specific and legitimate service agreement with the PPPMD company. The foregoing provisions in the PHAP Code mirrors and was adapted from the PPPMD Promotion Guidelines.

A pharmaceutical company is allowed to sponsor only the HCP's accommodations, meals, transportation and registration fees for participating in programs of scientific meetings for recognized medical societies ("**CME meetings**"), except for local meetings where HCPs should shoulder registration fees to encourage attendance. Cash assistance or check vouchers are not acceptable under any circumstances, neither is payment of expenses for accompanying guests.

The foregoing provisions in the PHAP Code mirrors and was adapted from the PPPMD Promotion Guidelines.

Entertainment and recreation

To ensure appropriate focus on education and informational exchange and to avoid the appearance of impropriety, PPPMD companies shall not provide any form of entertainment that would incur expenses for recreational items, such as tickets to the theater or sporting events, sporting equipment or leisure or vacation trips, to any healthcare professional.

Entertainment or recreational benefits shall not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

No stand-alone entertainment or other leisure or social activities shall be provided or paid for by companies during scientific meetings.

PPPMD companies are prohibited from paying any travel sponsorship, meals, or other expenses of accompanying guests or family.

The foregoing provisions in the PHAP Code mirrors and was adapted from the PPPMD Promotion Guidelines.

International and regional conventions held in the Philippines

To allow more local delegates to participate in international and regional conventions, all international or regional CMEs conducted in the Philippines shall be treated as local events, and hence the following provisions shall apply:

Companies can send more than 12 delegates to conventions but sponsorship will be limited to meals and accommodation.

Delegates must pay their own registration fees.

Symposia and congresses

Under the PPPMD Promotion Guidelines, companies may support seminars, scientific meetings and third-party conferences under the following conditions:

- The meals provided are modest.
- No entertainment that would incur expenses is provided during the entire duration of the activity.
- Conference organizers shall make a written request to the PPPMD company containing relevant information, such as scientific content, attendees, duration and cost.
- The support provided is consistent with relevant guidelines set by this Order.
- The venue is appropriate and conducive to the scientific/educational objectives of the event. No extravagant venues are allowed, unless there is no other suitable venue in the locality where the event is to be held.
- All forms of support and activities are well documented.
- Attendees to such conference are legitimate or authorized.
- Speakers shall disclose any potential or actual conflict of interest prior to topic presentation during the event.

PPPMD companies shall inform the FDA of any activities/events undertaken by the said company, whether or not the activities are in conjunction with any medical society/association, at least one month prior to holding of the said activity, if the activity involves more than 100 HCP participants. This is to enable the FDA to observe and monitor compliance with these guidelines.

The FDA-designated or -authorized officer and/or staff shall be allowed to do unannounced monitoring visits at conventions, symposia and conferences that use FDA funds.

Sanctions

Members that violate the PHAP Code of Practice will be subject to the following:

- a fine of PHP 200,000 for the first offense
- a fine of PHP 750,000 per offense for succeeding offenses of the same nature (e.g., interfering with HCP independence) or within the same section of the Code within a 12-month period
- a clean slate if no violations of the same offense are committed within a 12-month period; the reckoning date for all violations is the date the decision was issued by the PHAP Ethics Committee.

A summary of the cases on PHAP Code of Practice violations will be published on the PHAP website. The information disclosed will include a brief summary of the key facts and the results of the EC ruling and/or the appeals committee. The respondent company, the complainant and product(s) shall not be named.

However, for companies with multiple violations involving any provision of the PHAP Code, the information on the identity of the company in breach, the name of any product and other relevant information, shall be disclosed. Moreover, the headquarters of the company in breach shall be notified of the violation. A copy of the material to be published is provided to the respondent company for information only.

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. Any remuneration paid for such research activities should be reasonable and should not constitute an enticement.

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.

The PPPMD Promotion Guidelines provide that the engagement of consultant/s in medical conferences or scientific studies may be allowed, provided there is a written contract that specifies the nature of services rendered and payment for such:

- The criteria for consultant selection is based on identified needs and expertise.
- The contracting PPPMD company keeps a record of all transactions.
- The compensation for said services is reasonable and reflects the fair market value for said services.
- The consultant or speaker must disclose any potential or actual conflict of interest.
- Information is to be made public, if and when requested for legitimate purposes.

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 an LTO 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, such as 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 remuneration to HCPs that reflects 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.

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.

The PPPMD Promotion Guidelines also provide for the following:

Any industry-funded research shall comply with the policies and general guidelines stipulated in the pertinent DOH, FDA and Philippine National Health Research System issuances and any future revisions. Once the research protocols are approved by the institutional review board/ethical review boards duly accredited by the FDA, these shall be forwarded to the FDA for their record and information. The FDA may conduct random inspections of the various institutions engaged in clinical trials to ensure compliance.

Researchers shall disclose that the activity is funded by a particular PPPMD company in their publication, and any potential or actual conflict of interest in the conduct of the study shall likewise be stated.

For clinical studies wherein the Philippines is one of the trial sites, the industry may fund members of the research team to attend an international meeting/presentation of the study results and/or undergo training prior to the conduct of the study, subject to the rules on the symposia and congresses provided herein.

Moreover, PPPMD companies must respect the integrity of research activities and not fund, conduct or use such activities as a means to disguise product promotion or prescription. All outcomes or results of researches conducted shall be forwarded to the FDA, regardless of whether the outcomes are favorable or not.

Recommendations

With respect to advertising and promotional activities targeted towards consumers and the general public, PPPMD 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 ASC, may also be undertaken by PPPMD companies to ensure compliance with the minimum advertising requirements and standards set by the relevant regulating agency.

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

PPPMD 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 HCPs. Activities targeted toward 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, PPPMD companies are encouraged to comply with the limits set forth in the PHAP Code and the PPPMD Promotion Guidelines on what would be considered reasonable expenditure when its comes to sponsoring healthcare events and 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.

www.bakermckenzie.com