Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

Singapore

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Singapore

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Introduction

In Singapore, various legislations, guidelines and industry codes of conduct govern the promotion of medicinal products and medical devices. It is important to first identify the types of promotional activities involved, for example sponsorship of meetings and symposia, hospitality and entertainment, gifts and donations. Certain considerations should also be taken into account in relation to public procurement and contracts with healthcare professionals and institutions.

These will be examined below.

The Regulatory Framework

Advertising of medicinal products is governed by the Medicines Act (the MA) and the Medicines (Medical Advertisements) Regulations (the MAR), whereas advertising of medical devices is governed by the Health Products Act (the HPA) and the Health Products (Medical Devices) Regulations 2010 (the MDR).

A "medicinal product" is defined under the MA as any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways:

- use by being administered to one or more human beings or animals for a medicinal purpose;
- use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

A "medicinal purpose" means any one or more of the following purposes:

- treating or preventing disease;
- diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- contraception;
- inducing anaesthesia; or
- otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

On the other hand, a "medical device" is defined under the HPA as any instrument, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information for medical or diagnostic purposes by means of an in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means.

The term “advertisement” is given a very broad meaning under both the MA and the HPA.

The MA essentially regulates “medical advertisements,” which are “advertisement[s] relating or likely to cause any person to believe that it relates to any medicinal product… used or represented to be used for a medicinal purpose.” An “advertisement” includes “every form of advertising, whether in a publication, or by display of any notice or signboard, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents, or by words inscribed on any article, or by the exhibition of a photograph or cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way.” An “advertisement” also includes “words forming part of a sound recording or embodied in a sound-track associated with a cinematograph film” and “words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service.” Although an “advertisement” does not include “spoken words,” the MA separately regulates “representations,” which include any statements or undertakings consisting of spoken words.

Similarly, the HPA defines “advertisement” to mean the publication, dissemination or conveyance of any information for the purpose of promoting, whether directly or indirectly, the sale or use of [a medical device] by any means or in any form, including the following:

- publication in a newspaper, magazine, journal or other periodical,
- display of posters or notices;
- circulars, handbills, brochures, pamphlets, books or other documents;
- letters addressed to individuals or bodies corporate or incorporate;
- photographs or cinematograph films;
- sound broadcasting, television, the internet or other media;
- public demonstration of the use of the health product; and
- offer of trials of the health product to members of the public.

From this broad definition, it appears that the HPA also covers oral advertisements.

The key difference between the MA and the HPA regimes is that permits are required for “medical advertisements” (defined above under the MA) and “sales promotion” of medicinal products (but none are required for medical devices).

Under the MAR, a “sales promotion” means “any sales campaign (including door to door sales), exhibition, competition or any other activity for the purpose of introducing, publicizing or promoting the sale or use of any medicinal product.” Permit fees range from SGD100 (about USD70) to SGD300 (about USD220). Breach of this permit requirement is an offense punishable with a fine not exceeding SGD5,000 (about USD3,700) and/or imprisonment not exceeding 12 months. Furthermore, if the offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

According to the MAR, the following types of medical advertisements do not require a permit:

- Reference advertisements - product information pertaining to the sale and correct use of a medicinal product, published by a person or company with no commercial interest in the product, for dissemination to practitioners and pharmacists
- Trade advertisements - documents for the purpose of a sale by way of wholesale dealing which does not contain any recommendations on product use

Apart from the MA and HPA (which specifically apply to medicinal products and medical devices), the following general consumer/trade legislations may also apply:

- The Consumer Protection (Trade Descriptions and Safety Requirements) Act (the CPTDA)

- The Consumer Protection (Fair Trading) Act (the CPFTA)

The CPFTA only applies to consumer transactions, and aims to protect consumers against unfair practices. The CPTDA may apply to business and consumer transactions, and generally regulates descriptions of goods supplied in the course of trade. Unlike the MA and the HPA, both the CPTDA and the CPFTA do not substantively define "advertisement." Nonetheless (as shown below), their regulated practices are very broadly defined to potentially capture any form of advertisement, written or otherwise.

From a compliance angle, the principal anti-bribery legislation is the Prevention of Corruption Act (the PCA). The PCA may potentially apply to the promotion of medicinal products and medical devices.

Permitted and Prohibited Practices

Generally, the abovementioned legislations do not spell out what forms of advertising/marketing practices are permissible. Rather, they only state what acts are prohibited. Nonetheless, as elaborated below, applicable industry codes may be helpful to determine the permissible ambits of advertising/marketing behavior (such as gifts, seminars, hospitality, entertainment and donations/sponsorships).

This section will address the prohibited practices under the MA/MAR, HPA/MDR, CPTDA, the CPFTA and the PCA, as well as the consequences of breach.

The MA/MAR

Any person who issues or causes another person to issue a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offense. Also, any person who makes a false or misleading representation relating to a medicinal product in connection with the sale of that product shall be guilty of an offense.

An advertisement/representation is taken to be false or misleading if:

- it falsely describes the medicinal products to which it relates; or
- it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects.

Except in an advertisement which is distributed only to/intended for circulation among practitioners, pharmacists and nurses, no person shall publish or cause to be published:

- any medical advertisement which directly or indirectly claims, indicates or suggests that the article advertised will prevent, alleviate or cure any of the 19 diseases or conditions specified in the First Schedule (such as cancer, diabetes, tuberculosis and infertility); or
- any advertisement referring to any skill or service relating to the treatment of any disease affecting the human body.

The MA also addresses the issue of "off-label" advertisements. Any person who issues or causes another person to issue an advertisement relating to medicinal products of that description which consists/includes "unauthorised recommendations" shall be guilty of an offense. The term "unauthorised recommendations" is defined as "recommendations whereby medicinal products of a description to which the licence in question is applicable are recommended to be used for purposes other than those specified in the licence" (i.e., recommendations of off-label uses/purposes).

For each of the above MA offenses, the punishment is a fine not exceeding SGD5,000 (about USD3,700) and/or imprisonment not exceeding two years.

Under the MAR, no person shall, in conducting any sales promotion, offer any gift or prize to promote the sale of any medicinal product. Furthermore, no person shall alter or amend any medical advertisement for which a permit has been granted unless prior approval has been obtained from the Health Sciences Authority of Singapore (the HSA). Breach of any of these requirements is an offense punishable by a fine not exceeding SGD5,000 (about USD3,700) and/or imprisonment up to 12 months.

If any MA or MAR offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

The HPA/MDR

Under the HPA, any person who advertises any medical device or causes any medical device to be advertised in a false and misleading way shall be guilty of an offense. An advertisement shall be taken to be false or misleading if:

- it falsely describes the medical device or gives any false information concerning the medical device; or
- it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the medical device.

The HPA also addresses the issue of "off-label" advertisements. No person shall advertise any registered medical device or cause any registered medical device to be advertised in such a way as to represent the registered medical device as being usable for any purpose other than that for which it has been registered.

Under the MDR, comparative advertisements (which differentiate the medical device from any other competing or similar medical device) must be substantiated by facts or evidence. Otherwise, it will be an offense. In this regard, it appears that comparative advertisements may only be written and not oral, since the substantiation must be indicated on the face of the advertisement.

The MDR also sets out the following prohibitions, any breach of which will be an offense:

- If the medical device is intended for direct delivery to the general public or for direct use by the general public, the advertisement shall not contain any statement about the intended use and efficacy of the medical device unless such statement has been verified by objective evidence and such objective evidence has been furnished to the HSA at the time the application to register the medical device was made.
- An advertisement shall not contain any statement which expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the HSA.
- No person shall advertise any registered "professional use only" medical device, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, qualified practitioners.
- An advertisement shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any of the 19 diseases or conditions specified in the Second Schedule (such as cancer, diabetes, tuberculosis and infertility).

For each of the above HPA and MDR offenses, the punishment is a fine not exceeding SGD20,000 (about USD15,000) and/or imprisonment not exceeding 12 months. The fine may be doubled to SGD40,000 (about USD30,000) if the offense is committed by a corporate body. Furthermore, if the offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

The CPTDA

Any person who in the course of a trade or business applies a false trade description to any goods, or supplies any goods to which a false trade description is applied, shall be guilty of an offense.

The definition of "goods" includes "all kinds of movable property" and will likely capture medicinal products and medical devices.

A "trade description" is defined broadly and includes any physical characteristics (such as volume, capacity, weight, method of manufacture, composition, fitness for purpose, strength, performance, behavior and accuracy), results of testing, approval by any person/conformity with an approved type, manufacturer/producer/processor details and any other history. It includes an oral statement.

A "false trade description" is a trade description which is false or likely to mislead in a material respect as regards the goods which it is applied. It includes a false indication that any goods comply with a standard specified by any person, recognized by any person or implied by the approval of any person.

Breach of the CPTDA is punishable by a fine not exceeding SGD10,000 (about USD7,300) and/or imprisonment of up to two years. If the offense is committed by a corporate body and is proved to have been committed with the consent, connivance or neglect of any director, manager, secretary or any other similar officer, the officer may be punished accordingly.

The CPFTA

The CPFTA prohibits any "unfair practice" which includes:

- doing/omitting to do anything (which arguably includes an oral statement) which as a result a consumer might reasonably be deceived or misled;
- making false claims;
- taking advantage of a consumer if the supplier knows or ought to reasonably know that the consumer is not in a position to protect its interests or is not reasonably able to understand the character, nature, language or effect of the transaction; or
- doing anything specified as a "specific unfair practice" in the Second Schedule, which includes representing that goods have approval, components, qualities, uses or benefits that they do not have.

Any affected consumer may sue the supplier, and claim for variation of the contract, orders for repair or replacement of parts for goods, restitution of money or property, damages or an order for specific performance. Separately, the Consumer Association of Singapore which is the relevant regulatory body in charge of consumer protection, may seek a court declaration that the supplier has or is about to be engaged in an unfair practice and/or an injunction against the supplier.

From September 2012 onwards, the CPFTA will include provisions relating to "lemon laws" to provide consumers with an alternative simplified regime for obtaining redress for goods which do not conform to contract at the time of delivery. These provisions give consumers four additional remedies, as follows:

- repair;
- replacement;
- reduction in price; or
- rescission.

The PCA

If any "gratification" is corruptly received/given (or agreed to be received/given) for the doing or preventing the doing of anything in relation to any transaction (actual or proposed), the giver and/or recipient shall be guilty of an offense, even if he acted on behalf of another. The punishment is a fine not exceeding SGD100,000 (about USD73,000) or imprisonment up to five years, or both.

Significantly, the PCA may be enforced against corporate entities.

The definition of "gratification" is broad. It includes:

- money or any gift, loan, fee, reward, commission, valuable security or other property or interest in property of any description, whether movable or immovable;
- any office, employment or contract;
- any payment, release, discharge or liquidation of any loan, obligation, or other liability whatsoever, whether in whole or in part;
- any other service, favor or advantage of any description whatsoever; and
- any offer, undertaking or promise of any gratification within the four items above.

In determining whether any gratification has been given/received "corruptly" the courts adopt a two-stage test:

- whether the transaction is corrupt according to the reasonable man; and
- whether the accused had a corrupt purpose in mind.

In applying this test, the courts usually embark on a multi-factorial consideration of the relevant circumstances of the case (collectively, the PCA Corrupt Test Factors), such as:

- whether justice was perverted;
- whether the transaction took place in secrecy;
- whether there was a pre-existing relationship between the parties;
- the relative cost of the gratification vis-à-vis the receiver;
- the relative cost of the gratification vis-à-vis the transaction;
- the timing of the gratification;
- the degree of personal relationship between the giver and receiver; and
- whether any rules or regulations were breached and the purpose of such rules.

Public Procurement

The PCA sets out various presumptions of liability as well as offenses in relation to gratification provided to or received by government officials/employees/public bodies. In this regard, there is a presumption that a gratification is given or received corruptly if the giver or recipient is in the employment of the government, any department of the government, or a "public body" (the PCA Presumption), unless the contrary is proved on a balance of probabilities. This presumption is not conclusive that an offense has been committed, and may be rebutted by the accused.

If the gratification is offered by a person who intends to tender for a contract with the Singapore government or a "public body" to any person who has made a tender for a contract with the Singapore government or a "public body" as an inducement or reward to withdraw that tender, the offeror and/or person who solicits or accepts the business courtesy as such inducement shall be guilty of an offense. The punishment is a fine not exceeding SGD100,000 (about USD73,000) and/or imprisonment for a term not exceeding seven years.

If the gratification is offered to a member of a "public body" as an inducement or reward for the member to procure or prevent the passing of a vote for the grant of a contract in favor of the person offering the gratification, the offeror and/or the member of a "public body" who solicits or accepts the courtesy as such inducement shall be guilty of an offense. The punishment is a fine not exceeding SGD100,000 (about USD73,000) and/or imprisonment for a term not exceeding seven years.

"Public body" is defined to mean "any corporation, board, council, commissioners, or other body which has power to act under and for the purposes of any written law relating to public health or to undertakings or public utility or otherwise to administer money levied or raised by rates or charges in pursuance of any written law."

Apart from the PCA, the Penal Code (the principal criminal legislation in Singapore) also deals with public procurement corruption, as follows:

- If the gratification is given so that the recipient may corruptly influence a "public servant", the recipient shall be guilty of an offense. The punishment is a fine and/or imprisonment not exceeding three years.
- If the gratification is given so that the recipient may exercise personal influence with a "public servant", the recipient shall be guilty of an offense. The punishment is a fine and/or imprisonment not exceeding one year.
- If the gratification is given to a "public servant" as a motive or reward for doing or forbearing to do any official act, or for showing or forbearing to show, in the exercise of his official functions, favor or disfavor to any person, or for rendering or attempting to render any service or disservice with any person, with the government, or with any member of Parliament or the Cabinet, or with any public servant, the public servant shall commit an offense. The punishment is a fine and/or imprisonment not exceeding three years.

"Public servant" is defined broadly, and captures any government official.

Public vs. Private Hospitals/Healthcare Professionals - a Misnomer in Singapore

In light of the above, especially the PCA Presumption, a key issue for medicinal products and medical device companies is whether public/government hospitals and their healthcare professionals are "public bodies", government employees, employees of "public bodies" and/or "public servants."

The terms "public/government hospitals" and "public/government healthcare professionals" appear to be misnomers in Singapore. There is no distinction drawn between private hospitals and non-private hospitals (which should be correctly termed as "restructured hospitals" in Singapore, ultimately owned by the Ministry of Finance but which operate quite independently from the civil service) under the Private Hospitals and Medical Clinics Act (the PHMCA), which regulates the licensing of private and non-private hospitals alike.

A recent case in Singapore has clarified that restructured hospitals are "public bodies" for the purposes of the PCA. Therefore, the PCA presumption will apply to dealings with restructured hospitals.

Professional Codes of Conduct

In addition to the above legislative provisions, there are various industry guidelines and codes of practice which deal with advertisements and marketing practices relating to medicinal products and/or medical devices. These industry guidelines and codes of practice do not have the force of law. The pertinent ones include the following:

- A Guide On Advertisements And Sales Promotion Of Medicinal Products issued by the HSA (the Medicinal Products Advertisement Guide) -- offers guidance on how the HSA applies the MA and the MAR.

- Guidance On Medical Devices Advertisements And Sales Promotion issued by the HSA (the Medical Devices Advertisements Guide) -- offers guidance on how the HSA applies the HPA and the MDR.
- The Singapore Code of Advertising Practice (the SCAP) -- a set of guidelines regulating advertising activities in Singapore. It is administered by the Advertising Standards Authority of Singapore (ASAS).
- The Singapore Association of Pharmaceutical Industries Code of Marketing Practice (the SAPI Code) -- an industry code which addresses marketing practices vis-à-vis pharmaceutical, medicinal and biological products only, and not medical devices, between SAPI members and healthcare professionals.
- The Singapore Manufacturing Federation (the SMF) Medical Technology Industry Group's Code of Ethical Conduct for Interactions with Healthcare Professionals (the SMF Code) – an industry code which seeks to facilitate ethical interactions between the medical device industry and healthcare professionals in Singapore.
- The Singapore Medical Council's Ethical Code And Ethical Guidelines (the SMC Code) - sets out what the SMC regards as minimum standards of registered medical practitioners discharging their professional duties, including conduct in respect of financial interests, sponsorships and gifts. The SMC usually relies on the SMC Code for guidance in disciplinary proceedings against errant registered medical practitioners.

Medicinal Products Advertisement Guide

The following sales promotion activities are expressly allowed:

- Giving discounts
- Banding of different pack sizes of the same medicinal product or medicinal product within the same range, with or without a discount; and
- Distribution of samples of vitamin and mineral products, medicated plasters, antiseptic preparations, medicated soaps (subject to approval)

The following sales promotion activities are expressly prohibited (apart from those prohibited under the MAR):

- Use of the word "free" or "complimentary"
- Use of money-back guarantee
- Offer of medicine free-of-charge with the purchase of a non-medicinal product; and
- Distribution of samples of medicinal products to the general public.

The following types of advertisements relating to a medicinal product do not require a permit from the HSA (apart from those spelt out in the MAR):

- Package inserts accompanying the product
- Announcements and warnings on imitation of medicinal products with no intent to advertise the product
- Announcements on the name and address of a new distributor
- Display cards on product shelves printed with only the name of the medicinal product and the price (not the special or discounted price)
- Packaging with a protruding display flap, containing a single unit of medicinal product; and
- Promotional advertisements for dissemination to healthcare professionals only; it should be stated clearly on the materials that they are for healthcare professionals only and not for general circulation.

The following types of sales promotion activities do not require a permit from the HSA:

- Distribution of samples or bonus offers to drug stores, pharmacies, wholesalers and clinics, provided that there is no sales promotion to the general public; and
- Storewide sales promotion that is not specific to any product by named basis.

The Medicinal Products Advertisement Guide also sets out various general principles (collectively, the Medical Advertisement Guide General Principles) in relation to medical advertisements and sales promotion. The pertinent ones include the following:

- Advertisements should truthfully state the nature, quality and properties of the medicinal product. They should not mislead in any way by ambiguity, exaggeration, omission or otherwise.
- All claims must be substantiated. The literature should be of established sources.
- Recommendations relating to the use of medicinal products should be accurately stated in moderate terms and should be relevant to their properties.
- Advertisements should not contain comparisons with other medicinal products or related products unless scientifically proven.
- Advertisements should not misuse research results or make unnecessary quotations from technical and scientific publications.
- Advertisements should not suggest trial use of medicinal products.
- Advertisements should not give the impression of advice or support from healthcare professionals.
- Testimonials from non-professionals are generally prohibited unless they can be substantiated.
- The names and logos of the HSA and any of its professional groups cannot be used.
- There should not be any words, phrases or illustrations which claim or imply the cure of any ailment, illness or disease other than the relief of its symptoms.
- There should not be direct or indirect suggestion that a medicinal product can prevent, retard or reverse the physiological changes and degenerative conditions brought about by or associated with ageing.
- Advertisements should not discourage the public from seeking professional medical advice.
- Advertisements must comply with the SCAP.

The following terms and claims are not allowed in advertising:

- Superlatives, such as, “miraculously,” “100% safe” or “no side effects”
- Exaggerated claims, such as, “guaranteed,” “instant cure” or “complete cures”; and
- Misleading claims, such as, “anti-ageing”.

The above guidelines are helpful in assessing whether advertising claims are false and misleading under the MA.

Medical Devices Advertisement Guide

Like the Medicinal Products Advertisement Guide, the Medical Devices Advertisement Guide contains various general principles in relation to advertisements of medical devices. These principles largely mirror the Medical Advertisement Guide General Principles, and are helpful in assessing whether advertising claims are false and misleading under the HPA.

SCAP

The basic premise of the SCAP is that all advertisements should be legal, decent, honest and truthful. In this regard, its general and specific principles applicable to medicinal products and medical devices are similar to the Medical Advertisement Guide General Principles.

The ASAS may ask an advertiser or an advertising agency to amend or withdraw any advertisement in breach of the SCAP.

SAPI Code

The SAPI Code is an industry code which addresses marketing practices vis-à-vis pharmaceutical, medicinal and biological products only, and not medical devices, between SAPI members and healthcare professionals. Marketing practices include:

- sponsorship of meetings and symposia;
- hospitality and entertainment provided at sponsored meetings and symposia;
- gifts and promotional items; and
- donations and grants.

The SAPI Code does not have the force of law. Nonetheless, as highlighted above, one of the PCA Corrupt Test Factors (in ascertaining whether a gratification has been given/received "corruptly") is whether any rules or regulations were breached and the purpose of such rules.

Therefore, the SAPI Code may be relevant insofar as compliance with it will help show that the promotional/marketing activity in question was not conducted "corruptly" under the PCA. For this reason, it may be helpful to comply with the SAPI Code even for the medical device industry. However, it bears noting that such compliance (whether for the medicinal product or medical device industries) is not a safe harbor defense. The SAPI Code is merely a useful guideline.

The following sections will touch on the key ambits of various marketing activities set out in the SAPI Code.

Sponsorship of Meetings/Symposia

Under the SAPI Code, when a pharmaceutical company sponsors a symposium, congress or other medical/healthcare or educational program for both local and overseas meetings, the following should be observed:

- Sponsorship of healthcare professionals should be limited to travel, meals, accommodation and registration fees.
- No payment should be made to compensate healthcare professionals for time spent attending the event.
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any medicinal product.
- Compensation may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the event.
- All companies should only provide economy class tickets for air travel of less than six hours. This should apply to all faculty members, such as speakers, members of advisory boards as well as attendees.
- Companies should not pay any cost for persons accompanying invited healthcare professionals.
- When the event is to be held in an overseas location, the majority of the attendees should be from the country in which the event is held.
- A minimum of 75 percent of time should be spent on core activities of the event and a maximum of 25 percent of time may be devoted to recreational activities, such as cultural dance and sight-seeing tour of modest fees.
- Any activities that have an element of chance should not be part of the event.

Hospitality/Entertainment Provided at Sponsored Meetings/Symposia

The key principle is that scientific objectives should be the principal focus in arranging such events, and entertainment/hospitality is inconsistent with such objectives. In this regard, the SAPI Code sets out the following:

- Meetings should be held in an appropriate venue that is conducive to the scientific or educational objectives of the event. Companies should avoid using renowned or extravagant venues. Venues associated with activities such as gambling, gaming and entertainment are deemed inappropriate.
- Refreshments and/or meals incidental to the main purpose of the event should not extend beyond participants to the event.
- Providing hospitality in relation to food and drinks as per social/cultural norms in a local setting to members of the medical and allied professions should be limited to less than SGD100 (about USD70) per person (excluding taxes). However, this should be accompanied with dissemination of scientific or educational information.
- No stand-alone entertainment or other leisure or social activities should be provided or paid for by companies. However, entertainment of modest nature which is secondary to refreshments and/or meals is allowed during meetings.

Gifts/Promotional Items

The general rule is that inappropriate financial or material benefits should not be offered to healthcare professionals to influence them in the prescribing of pharmaceutical products. In this regard, the SAPI Code states the following:

- Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals either directly or indirectly.
- Promotional items of insignificant value of no more than SGD20 (about USD15) provided free of charge are permissible as long as they are related to the healthcare professional's work and/or entail a benefit to patients. Gifts as a token of appreciation for services rendered by healthcare professionals should be limited to SGD50 (about USD40) or less.
- Inexpensive food items and drinks as per social/cultural norm may be distributed to healthcare professionals during the course of day-to-day promotional activities only and should be limited to less than or equal to SGD20 (about USD15) per healthcare professional.
- Congratulatory flowers limited to promotions, conferment of awards or clinic/hospital opening should be limited to SGD150 (about USD110) per occasion.
- Congratulatory messages in any form of media on behalf of a healthcare professional or a hospital/clinic are strictly prohibited.
- Exceptional gifts such as cakes, cookies and mandarin oranges during various festive seasons should be symbolic and modest, with a value of up to SGD50 (about USD40). Each healthcare professional should only be offered a maximum of two such gifts per year.
- Items of medical utility may be offered or given free of charge provided such items are of modest value and are beneficial to the provision of medical services and for patient care. The value of such items should be limited to les than or equal to SGD200 (about USD150).

Donations/Grants

Companies may provide donations by request, strictly for charitable purposes and charitable organizations. In addition, companies can provide grants towards financial support strictly for educational programs, (including but not limited to requests to fund accredited CME programs, non-accredited educational programs, fellowships, advocacy organizations, societies, medical conferences, congresses or independent meetings) if they are:

- unsolicited;

- from an institution or organization, not an individual healthcare practitioner;
- unrelated to the prescribing, purchasing, registration of any products;
- substantiated by written documentation of the program details; and
- able to withstand public scrutiny.

Interaction Between SAPI Code and PCA - Tips

The following tips may be helpful in respect of the interaction between the SAPI Code and the PCA:

- The PCA prohibits any gratification that is corruptly given/received "for the doing or preventing the doing of anything in relation to any transaction." It would therefore be prudent to avoid providing any sponsorships, hospitality, entertainment and gifts/promotional items "for the doing or preventing the doing of anything in relation to any transaction" (actual or proposed).
- In cases of promotional/marketing activities that have been addressed by the SAPI Code, medicinal product companies (whether SAPI members or not) should comply with these ambits. This will help militate against liability under the PCA.
- There are naturally several types of promotional/marketing activities that are not addressed by the SAPI Code. These include entertainment/hospitality per se (not provided for sponsored congresses/symposia), gifts for personal occasions like birthdays, and travel arrangements (not provided for sponsored congresses/symposia). In this regard, the PCA is deliberately drafted broadly and does not identify any specific safe harbors in relation to various forms of gratification. A common sense approach should therefore be adopted in light of all the circumstances, including close adherence to the PCA Corrupt Test Factors.

By way of illustration:

- If a local hospital is organizing a tender for medical products, then any approach for a friendly round of golf by the company's business development personnel to healthcare professionals working at the hospital (especially those in a position to potentially influence the award of the bid) around the time of evaluation of the bids would be open to question, and is not recommended. Conversely, if the company's local chief executive officer organizes and pays for a party where one or more of the guests are from the hospital but happen to be mutual friends of the person for whom the party is being held, this may be less of a concern.
- If an expensive birthday gift is given to a healthcare professional (who is in a position to influence the award of tenders) close to the time of evaluation of a tender bid, this may be subject to closer scrutiny than an inexpensive birthday gift where there is no pending award.
- Insofar as it makes "business sense" for travel to other countries (e.g., to visit corporate headquarters in the US to talk about products and opportunities face-to-face) as opposed to it being an excuse for travel to an exotic holiday destination, then payment for travel may be acceptable. The costs should nonetheless be reasonable, and proper receipts should be procured and kept. Where possible, payment should be made direct to the service providers rather than made in cash (or by way of per diem) to the traveler.

SMF Code

The SMF Code is an industry code which addresses interactions vis-à-vis medical devices, between SMF members and healthcare professionals. These interactions include:

- sponsorship of training and education meetings;
- hospitality and travel arrangements;
- gifts and entertainment; and
- donations and grants.

The SMF Code's provisions are highly similar to those of the SAPI Code.

SMC Code

While the SMC Code only applies to registered medical practitioners in Singapore (and therefore will not subject the relevant medicinal product/medical device company to sanctions from the SMC), it may be useful for medicinal product/medical device companies to comply with its guidelines governing financial relationships with these companies.

The reasons are two-fold. Firstly, compliance may help show that such relationships are not entered into corruptly for the purposes of the PCA. Secondly, the risk of doctors being censured is reduced. This consequently mitigates the risk of the company being exposed to negative publicity.

Financial/Commercial Interests

Under the SMC Code, a doctor must refrain from improperly prescribing drugs or devices in which he has a financial interest, and sharing fees or obtaining commissions from referrals of patients.

Additionally, a doctor shall not exert undue influence upon a patient in relation to transactions in which he has an interest.

If a doctor has a financial interest in an organization or service to which he intends to refer patients for admission, treatment or, investigation, or for the purchase of any drugs, medicine or service in the course of treatment, he shall always disclose his interest to the patient before making a referral.

A doctor shall not let financial considerations imposed by his own practice, investments or financial arrangements influence the objectivity of his clinical judgement in the treatment of his patients.

Sponsored Educational Events and Research

A doctor may be invited to participate in medical events, conferences, talks, publications or educational websites sponsored by companies marketing pharmaceutical products/medical devices. The doctor should ensure that his participation is not seen as an endorsement of such products, neither is it meant to persuade patients or members of the public to use the products.

Apart from identification and establishment of credentials, no details of services provided by the doctor or service details shall appear in any way in relation to such participation.

A doctor who is sponsored by a company to participate in an educational event or who reports research sponsored by a company must declare all such potential conflicts of interest to the audience.

Gifts/Hospitality

A doctor shall not ask for gifts, hospitality or other inducements that may affect or be seen to affect his judgement in making decisions about patients' treatment. A doctor can receive small, insubstantial gifts which cannot be regarded as inducement.

Contracts with Healthcare Professionals and Medical Institutions

Medicinal product and medical device companies will invariably enter into various contracts with healthcare professionals and medical institutions. These contracts include research contracts, consultancy contracts and speakership contracts. The following points may be helpful:

- There could be corruption issues wherever such agreements are executed. The PCA Corrupt Test Factors, the SAPI Code, the SMF Code and the SMC Code should be complied with.
- The scope of performance and consideration should be defined precisely in the contracts.
- Any consideration must be reasonable and defensible according to market rate.

- Suitable anti-corruption clauses should be included. The contracting party should warrant and confirm that the execution and performance of the contract does not violate any applicable anti-corruption laws, regulations or codes of conduct, as well as any internal compliance policies.
- If contracts are entered into with the healthcare professionals directly, they should warrant and confirm that the execution and performance of the contract does not breach their employment agreements. Furthermore, they should also warrant and confirm that written consent has been sought from their employer. For prudence, request for a copy of such written consent.

Recommendations

The promotion and advertisement of medicinal products and medical devices are snared with various legal risks. In some cases, severe criminal punishment may be meted out. To mitigate these risks, the following points are recommended:

- Check whether permits are required for medical advertisements/sales promotion of medicinal products.
- Check whether the claims in medicinal product/medical device advertisements pass regulatory muster.
- Conduct regular training for the business/marketing team on permissible sales promotion/advertisement claims.
- Create a corporate compliance policy that is in line with the PCA Corrupt Test Factors, the SAPI Code, the SMF Code and the SMC Code and ensure that all employees are bound by this policy.
- Conduct regular training for the business/marketing team on permissible marketing activities from an anti-corruption viewpoint.
- Ensure that contracts with healthcare professionals and medical institutions are appropriately drafted (as highlighted in the previous section).

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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.