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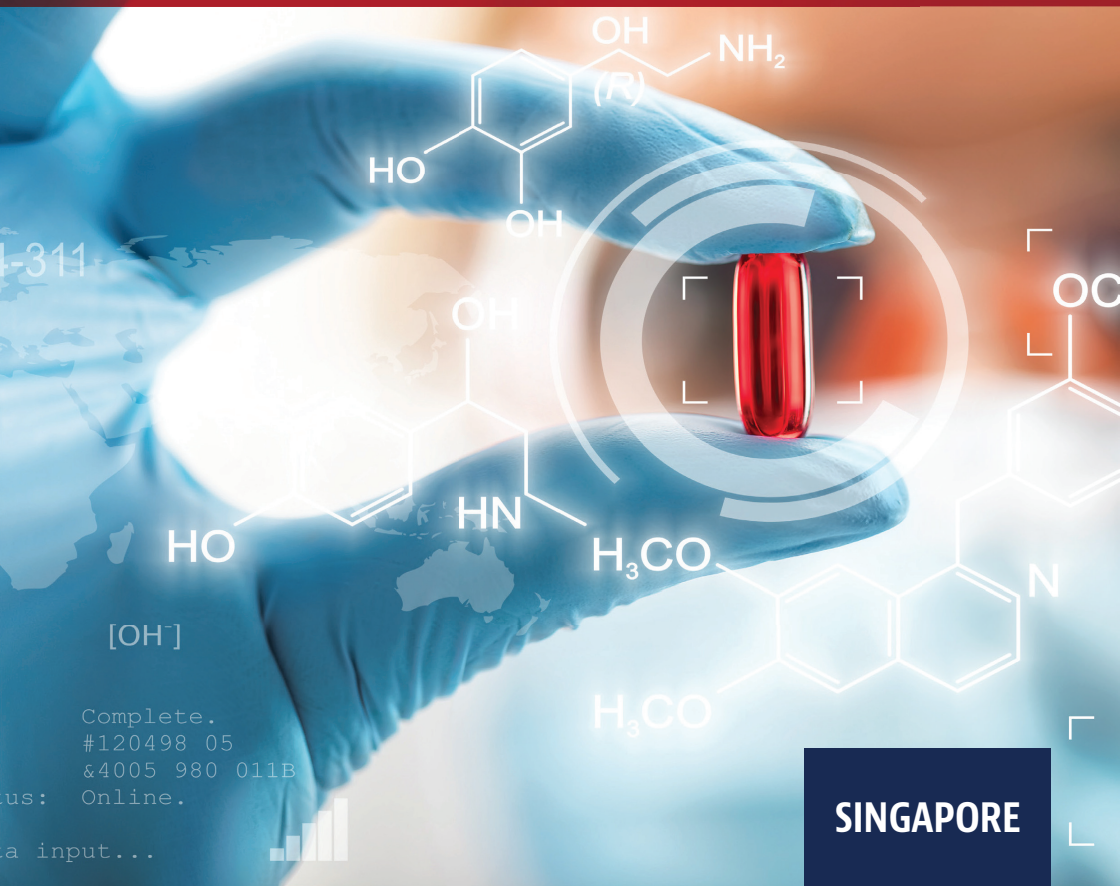
Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



SINGAPORE

Singapore

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Introduction

In Singapore, various legislation, guidelines and industry codes of conduct govern the promotion of therapeutic products and medicinal products. It is important to first identify the types of promotional activities involved, such as 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

The advertising of medicinal products is governed by the Medicines Act ("**MA**") and the Medicines (Medical Advertisements) Regulations ("**MAR**"); and the advertising of therapeutic products is governed by the Health Products Act ("**HPA**") and the Health Products (Advertisement of Therapeutic Products) Regulations 2016 ("**TP Advertising Regulations**").

As a result of the port over of the regulatory controls for therapeutic products to the HPA, the MA and MAR no longer apply to drugs but still regulate Chinese proprietary medicines, traditional medicines, homeopathic medicines, quasi-medicinal products and medicated oil balms.

A "medicinal product" is defined under the MA as any substance or article (not being an instrument, apparatus or appliance) that 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.

The definition excludes therapeutic products, medical devices and any other types of health products as ordered by the minister from time to time.

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

- treating or preventing disease
- diagnosing a disease or ascertaining the existence, degree or extent of a physiological condition
- contraception
- inducing anesthesia
- 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 in any other way

A "therapeutic product" is defined under the HPA as any substance that:

- is intended for use by and in humans for a therapeutic, preventive, palliative or diagnostic purpose
- has as a constituent any of the active ingredients stated in paragraph 3(1)(b) of the First Schedule of the HPA

- exerts an inherent effect either pharmacologically, chemically or by other physiological means, leading to its use for a therapeutic, preventive, palliative or diagnostic purpose

- is not among the exceptions stated in paragraph 3(1)(d) of the First Schedule of the HPA (which include medical devices, products containing human/animal cells, substances administered to humans to manipulate genetic sequences, whole blood/blood components and quasi-medicines).

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 catalog, 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 that health product 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
- offer of trials of the health product to members of the public

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

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

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, publicising or promoting the sale or use of any medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose." Permit fees range from SGD 100 (about USD 70) to SGD 300 (about USD 220). A breach of this permit requirement is an offense punishable with a fine not exceeding SGD 5,000 (about USD 3,700) and/or imprisonment of up to 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 also be held liable and 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 that does not contain any recommendations on product use
- Any medical advertisement issued or published by any public authority or any person authorized by the minister to issue or publish such advertisement

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

- The Consumer Protection (Trade Descriptions and Safety Requirements) Act ("**CPTDA**")
- The Consumer Protection (Fair Trading) Act ("**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 the 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 ("**PCA**"). The PCA may potentially apply to the promotion of medicinal products and therapeutic products.

Permitted and prohibited practices

Generally, the abovementioned legislation does 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, the TP Advertising Regulations, the CPTDA, the CPFTA and the PCA, as well as the consequences of a 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 under any of the following circumstances:

- It falsely describes the medicinal products to which it relates.
- 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 that is distributed only to/intended for circulation among practitioners, pharmacists and nurses, no person shall publish or cause to be published any of the following:

- Any medical advertisement that 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)

- 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 that consists/includes unauthorized recommendations shall be guilty of an offense. The term "unauthorized 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 license" (i.e., recommendations of off-label uses/purposes).

For each of the above MA offenses, the punishment is a fine not exceeding SGD 5,000 (about USD 3,700) 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 ("**HSA**"). A breach of any of these requirements is an offense punishable by a fine not exceeding SGD 5,000 (about USD 3,700) and/or imprisonment of 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/TP advertising regulations

Under the HPA, any person who advertises any health product or causes any health product to be advertised in a false or misleading way shall be guilty of an offense. An advertisement shall be taken to be false or misleading under any of the following circumstances:

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

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

Under the TP Advertising Regulations, advertisements of therapeutic products must not contain any of the matters excluded under Regulation 4, which address issues such as (but not limited to) the following:

- encouraging excessive/inappropriate use of the therapeutic product
- comparing or contrasting the therapeutic product with any other named therapeutic product or a brand thereof (but it is permissible for a company to make a comparison between its own brands)
- any endorsements by healthcare professionals or any person who, because of the person's celebrity, social or professional status, is likely to encourage use of the therapeutic product

For each of the above offenses in the HPA and the TP Advertising Regulations, the punishment is a fine not exceeding SGD 20,000 (about USD 15,000) and/or imprisonment not exceeding 12 months. The fine may be doubled to SGD 40,000 (about USD 30,000) 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 also be held liable and 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 include medicinal products and therapeutic products.

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 oral statements as well.

A "false trade description" is a trade description that is false or likely to mislead in a material respect as regards the goods to 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.

A breach of the CPTDA is punishable by a fine not exceeding SGD 10,000 (about USD 7,300) 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 also be held liable and be punished accordingly.

The CPFTA

The CPFTA prohibits any "unfair practice" which includes any of the following:

- Doing/omitting to do anything (which arguably includes an oral statement) that as a result might reasonably deceived or mislead a consumer.
- 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.
- 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. The CPFTA also includes provisions relating to "lemon laws," which provide consumers with an alternative simplified regime for obtaining redress for goods that do not conform to contract at the time of delivery. These provisions give consumers four additional remedies:

- repair
- replacement

- reduction in price
- rescission

Separately, the Consumer Association of Singapore ("**CASE**"), 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. Under the new CPFTA, which was amended in late 2016, CASE can also refer disputes to the Standards, Productivity and Innovation Board of Singapore ("**SPRING Singapore**") for further action. SPRING Singapore has also been granted investigative and enforcement powers, and is now the overarching administering agency in respect of consumer complaints.

SPRING Singapore's broad investigative and enforcement powers under the CPFTA, include the following:

- Conducting an investigation into any alleged unfair practices in which a supplier has reasonably been suspected to have engaged.
- Requiring the person under investigation to provide SPRING Singapore with specified information, documents or articles that are relevant to the investigations.
- Entering premises reasonably suspected of being used by the person under investigation in connection with an unfair practice without a warrant, and doing any of the following:
    - inspecting and searching such premises
    - taking photographs or audio/video recordings relevant to the investigation
    - seizing and detaining any goods found on such premises relevant to the investigation

- taking copies of, or extracts from, any document produced during the inspection of the premises
- taking any step that appears necessary to preserve or prevent interference with any document relevant to the investigation
- interviewing any person who appears to be acquainted with the facts/circumstances relevant to the investigation, and ordering relevant witnesses to appear before the officer

Where there are reasonable grounds to suspect that any of SPRING Singapore's orders have not been complied with, SPRING Singapore may also apply to the court for a warrant to enter and search identified premises. The actions that an investigation officer may take in relation to such premises searched under a warrant are similar to those listed above in relation to premises searched without a warrant.

The CPFTA also provides for a post-seizure procedure in respect of goods, documents, or information seized from any such investigation.

Non-compliance with the requirements imposed in the course of investigations or obstructing investigations may constitute an offense punishable by a fine not exceeding SGD 10,000 (about USD 7,300) and/or imprisonment of up to one year. 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 also be held liable and be punished accordingly.

SPRING Singapore may also apply to court to obtain any of the following additional court remedies:

- a declaration that the practice engaged by the supplier is an unfair practice

- an injunction restraining the supplier from engaging in the unfair practice
- an order that the supplier must periodically publish the details of such declaration/injunction granted against it
- an order that the supplier must, before any consumer transacts with it, notify the consumer of such declaration/injunction granted against it and obtain the consumer's written acknowledgment of such notice
- an order that the supplier must include in every invoice/receipt it issues details of such declaration/injunction granted against it
- an order that the supplier must inform SPRING Singapore of any changes to its circumstances relating to its business (e.g., change of premises, change of online address)

Failure to comply with any of the above court sanctions will allow SPRING Singapore to apply to court to extend the duration of the sanctions imposed, up to a maximum of 10 years.

This action must be commenced by SPRING Singapore within two years from the occurrence of the last material event relating to any alleged unfair practice, or from the date on which the consumer had knowledge of the unfair practice (whichever is later).

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 SGD 100,000 (about USD 73,000) or imprisonment up to five years, or both.

Significantly, the PCA may be enforced against corporate entities.

The definition of "gratification" is broad and includes the following:

- 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
- 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 person
- 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 ("**PCA Corrupt Test Factors**"), such as the following:

- 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
- 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 under the employ of the government, any department of the government, or a public body ("**PCA Presumption**"), unless the contrary is proved on a balance of probabilities. This presumption is not conclusive 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 SGD 100,000 (about USD 73,000) 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 SGD

100,000 (about USD 73,000) 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 over 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/her 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 includes 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 pharmaceutical 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 ("**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 that deal with advertisements and marketing practices relating to medicinal products. These industry guidelines and codes of practice do not have the force of law. The pertinent ones include the following:

- The Guide on Advertisements and Sales Promotion of Medicinal Products issued by the HSA ("**Medicinal Products Advertisement Guide**") – offers guidance on how the HSA applies the MA and the MAR.
- Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016 ("**TP Advertisement Guide**") and the FAQ on Advertisement

Controls for Therapeutic Products – offer guidance on how the HSA applies the TP Advertising Regulations.

- The Singapore Code of Advertising Practice ("**SCAP**") – a set of guidelines regulating advertising activities in Singapore, which also addresses advertising on social media; administered by the Advertising Standards Authority of Singapore ("**ASAS**").

- The Singapore Association of Pharmaceutical Industries Code of Marketing Practice ("**SAPI Code**") – an industry code that addresses marketing practices vis-à-vis pharmaceutical, medicinal, therapeutic and biological products only between SAPI members and healthcare professionals.

- The Singapore Medical Council's Ethical Code and Ethical Guidelines ("**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; within the same range, with or without discount

- 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"
- offer of prizes through lucky draw, contest or membership with purchase of the product
- use of money-back guarantee
- offer of medicine free-of-charge with the purchase of a non-medicinal product
- distribution of free samples of medicinal products to the general public

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

- 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 that 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 should not offer to refund money to users of the product.
- In certain instances, additional advisories may be required for identified groups of products, such as weight management products and medicinal products containing melatonin, among others.
- Advertisements must comply with the SCAP.

The following terms and claims are not allowed in advertising:

- superlatives, and words such as “miraculously,” “100% safe” or “no side effects”

- exaggerated claims, such as “guaranteed,” “instant cure” or “complete cures”
- Misleading claims, such as “anti-ageing”

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

TP Advertisement Guide

Generally, only registered therapeutic products may be advertised as such and must be aligned with the intended uses (indications) as registered with the HSA. Advertisements of unregistered therapeutic products or unapproved uses of a registered therapeutic product (unregistered indications) are not allowed.

The TP Advertisement Guide also contains various general principles in relation to advertisements of therapeutic products, which mirror the Medical Advertisement Guide General Principles and are helpful in assessing whether advertising claims are false and misleading under the HPA.

Specific issues addressed in the TP Advertising Regulations and the TP Advertisement Guide that are not found in the Medicinal Products Advertisement Guide include the following:

- prohibition against advertisements that are directed exclusively/principally at children below the age of 14
- requirement to display advisories for advertisements of pharmacy-only medicines
- prohibition against prescription-only medicines
- permitted uses of informational statements on corporate websites, press releases and closed-door product launch events

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 therapeutic products are similar to the Medical Advertisement Guide General Principles.

The SCAP also contains guidelines for social media advertising, which requires advertisers to disclose commercial relationships with sponsors and distinguish marketing communication from editorial content.

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 that addresses marketing practices vis-à-vis pharmaceutical, medicinal and biological products only between SAPI members and healthcare professionals. Marketing practices include the following:

- sponsorship of meetings and symposia
- hospitality and entertainment provided at sponsored meetings and symposia
- gifts and promotional items
- 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. However, it bears noting that 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 and 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% of time should be spent on core activities of the event and a maximum of 25% of time may be devoted to recreational activities such as cultural dance and sight-seeing tours 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 SGD 120 (about USD 80) per person per meal (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 that 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 certificates) must not be offered to healthcare professionals either directly or indirectly.
- Promotional items of insignificant value of no more than SGD 20 (about USD 15) 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 SGD 50 (about USD 40) 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 SGD 20 (about USD 15) per healthcare professional.
- Congratulatory flowers limited to promotions, conferment of awards or clinic/hospital openings should be limited to SGD 150 (about USD 110) 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 SGD 50 (about USD 40). Each

healthcare professional should only be offered a maximum of two such gifts per year.

- Educational materials may be given to healthcare professionals and clinical departments if they serve a genuine educational function based on the following limits: less than SGD 1,000 (about USD 730) per healthcare professional per year for private specialists, GPs and public hospital doctors; and less than SGD 1,000 (about USD 730) per clinical department per year (note that the only permissible materials for departments are healthcare/biomedical journals).

- 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 less than or equal to SGD 200 (about USD 150).

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 any of the following:

- 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

- able to withstand public scrutiny

Interaction between the 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 mitigate 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.

SMC Code

While the SMC Code only applies to registered medical practitioners in Singapore (and therefore will not subject the relevant pharmaceutical company to sanctions from the SMC), it may be useful for pharmaceutical 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 in which he/she has a financial interest, and sharing fees or obtaining commissions from referrals of patients. The SMC Code also expressly prohibits payments to third parties that are based on a percentage of consultation fees, and any such financial arrangements with third parties that are continuing after 1 July 2017 will constitute a breach of the SMC Code.

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

If a doctor has a financial interest in an organization or service to which he/she 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/she shall always disclose his/her interest to the patient before making a referral.

A doctor shall not let financial considerations imposed by his/her own practice, investments or financial arrangements influence the objectivity of his/her clinical judgment in the treatment of his/her 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. The doctor should ensure that his/her 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. Financial reimbursements/honoraria given to expert participants at educational events must be fair, reasonable and commensurate with the doctor's time and expertise provided.

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 disclose all such potential conflicts of interest to the audience.

Any unrelated activities, additional stay or the costs of any accompanying persons must be paid for personally by the doctor.

Gifts/hospitality

A doctor shall not ask for gifts, hospitality or other inducements that may affect or be seen to affect his/her judgment in making decisions about patients' treatment. Accepting educational materials and items of medical utility are allowed if they improve patient care. A doctor can receive small, insubstantial gifts that cannot be regarded as inducement.

Contracts with healthcare professionals and medical institutions

Pharmaceutical companies will invariably enter into various contracts with healthcare professionals and medical institutions. These include research, consultancy 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 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 a copy of such written consent.

Recommendations

The promotion and advertisement of pharmaceutical products 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/therapeutic product advertisements pass regulatory muster.
- Check whether statements on corporate websites/press releases are compliant with advertising regulations.
- 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 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).

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

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