

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



HONG KONG

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Hong Kong

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Introduction

There are no specific laws or regulations in Hong Kong governing the promotion of pharmaceuticals or medical devices (together, “medical products”).

Advertising Legislation

Regulatory Framework

Hong Kong does not have a general advertising law. There is no relevant legislation governing medical devices and the Trade Descriptions Ordinance (Cap. 362) (“TDO”) applies. In relation to drugs, the Public Health and Municipal Services Ordinance (Cap. 132) (“PHMSO”) is specifically applicable.

Trade Descriptions Ordinance

The Trade Descriptions Ordinance (Cap. 362) (“TDO”) provides the overriding principle that all product descriptions must be true and not misleading. The TDO is broadly applicable to all goods.

“Trade description” is broadly defined to cover indications, direct or indirect, and given by whatever means, of various matters with respect to goods or parts of goods, including quantity, composition and fitness for purpose, strength, performance, behavior and accuracy.

The penalty for non-compliance is, on conviction on indictment, a fine of HKD100,000 and imprisonment for five years and, on summary conviction, a fine of HKD200,000 and imprisonment for two years.

Public Health and Municipal Services Ordinance

False labeling and advertisement of drugs is an offense under Hong Kong law. If any person gives with any drug sold by him, or

displays with any drug exposed for sale by him, a label which falsely describes the drug or is calculated to mislead as to its nature, substance or quality, he will be guilty of an offense under section 61(1) of the PHMSO, unless he did not know of or could not with reasonable diligence have ascertained the false character of the label. The maximum penalty for non-compliance is a fine of HKD50,000 and imprisonment for six months.

Undesirable Medical Advertisements Ordinance

Separately, there are statutory stipulations over medical claims under the Undesirable Medical Advertisements Ordinance (Cap. 231) (“UMAO”) that are relevant to medical products. The UMAO is very broad and wide-catching, and prohibits advertisements likely to lead to the use of any medicine, surgical appliance or treatment for the purpose of preventing or treating certain diseases or conditions detailed in Schedules 1 and 2 of the UMAO. The purpose of the legislation is to protect the public from being induced by advertisements to seek improper self-medication or treatment. “Advertisement” includes the labels on product containers but excludes package inserts.

However, the interpretation of the UMAO by the Department of Health (“DOH”) in its Guidelines on the Undesirable Medical Advertisements Ordinance is much narrower than the statutory wording. Under the DOH’s current practice, advertisements will generally only be forbidden if they claim that a product has curative or preventive effects on the specified diseases. The appearance of the name of the product and the name or logo of the pharmaceutical company is generally permissible in advertisements, as long as there is no specific reference to curative or preventive purposes of the product for the specified medical diseases and conditions. While the enforcement risk is apparently manageable given the DOH’s current approach, advertising medical products may still be found to be in breach of the UMAO given its broad application.

Any person who contravenes the UMAO is liable upon first conviction to a fine of HKD10,000 and, upon a second or subsequent conviction, to a fine of HKD25,000 and imprisonment for one year.



However, it is a defense if the advertisement was made only in a publication of a technical character intended for circulation mainly among certain medical professionals.

Television and Radio Codes

Depending on the media used for advertising medical products, further regulations may be applicable. For example, advertisements on broadcast media must also comply with the Generic Code of Practice on Television Advertising Standards (“TV Code”). Advertisements for “unacceptable products or services” (e.g., smoking cessation and pregnancy testing services) cannot be advertised on broadcast media.

The TV Code also strictly controls the design and content of medical product advertisements, and prohibits impressions of professional advice and support from medical professionals, appeals to fear or exploitation of credulity, encouragement of excess, and exaggerated claims using superlative or comparative adjectives such as “the most successful” or “quickest.”

Advertisements over the radio are required to comply with the Radio Code of Practice on Advertising Standards of Ancillary Visual Service.

Permitted and Prohibited Practices – Advertisements

The promotion of off-label use of pharmaceuticals is prohibited in Hong Kong. Under the Pharmacy and Poisons Regulations (Cap. 138A), pharmaceutical products sold in Hong Kong must be registered with the Drug Office of the DOH. The particulars of the product are registered, including its proposed indication, dosage and route of administration. If any of the particulars are changed without approval, the product will not be regarded as registered.

Although the Hong Kong Association of the Pharmaceutical Industry (“HKAPI”) Code of Pharmaceutical Marketing Products (“HKAPI Code”) acknowledges that pharmaceuticals should not be promoted for use until requisite approval for marketing for such use has been

granted, it states that this should not abridge the right of the scientific community and the public to be fully informed concerning scientific and medical progress.

Permitted and Prohibited Practices – Other Promotional Activities

Prevention of Bribery Ordinance

The Prevention of Bribery Ordinance (Cap. 201) (“PBO”) governs both the public and private sectors, and sets the standards of behavior for agents conducting their principals’ business. In relation to the public sector, the Hospital Authority (“HA”), the statutory body in charge of all public hospitals in Hong Kong, is considered a public body for the purposes of the PBO.

The following are prohibited under the PBO:

- Solicitation or acceptance of an advantage by a prescribed officer or public servant in relation to his official duties without the permission of the Chief Executive of Hong Kong/relevant public body;
- Offering of an advantage to a prescribed officer or public servant in relation to his official duties where the prescribed officer/public servant does not have the permission of the Chief Executive/relevant public body;
- Solicitation or acceptance of an advantage by an agent when conducting his principal’s affairs or business without the permission of his principal (this would cover doctors in private hospitals); and
- Offering of an advantage to an agent in the conduct of his principal’s affairs or business where the agent does not have the permission of his principal.

The definition of “advantage” under the PBO is very wide and would include gifts and free participation in seminars without payment of registration or entry fees.



“Prescribed officers” are members of the civil service (government employees/officials). It is not a defense to claim that any advantage accepted or offered is customary in any profession, trade, vocation or calling. The maximum penalty for breach is a fine of HKD500,000 and imprisonment for seven years.

As stated above, offering and accepting advantages is allowable where permission is obtained. Permission must be sought before the advantage is accepted; or as soon as reasonably possible after such offer or acceptance, provided that all relevant circumstances have been considered. For doctors employed in public hospitals, permission from the HA or the hospitals must be in writing. For doctors in private hospitals, it is advisable but not required for the employer’s permission to be in writing.

Gifts, Seminars, Hospitality, Entertainment

The PBO governs such activities, and as discussed previously, where a healthcare professional seeks to accept an advantage from a pharmaceutical company, permission of the principal must first be obtained.

Under the HA’s Code of Conduct, employees shall avoid obligations to customers or business associates resulting from advantages, gifts or entertainment received in or due to their official capacity which could compromise their position in any way or be perceived by a third party to potentially compromise themselves or the HA.

Gifts

Under section 3 of the PBO, prescribed officers are prohibited from soliciting or accepting any advantage without the general or specific permission of the Chief Executive.

The Acceptance of Advantages (Chief Executive’s Permission) Notice 2010 states that prescribed officers may accept gifts of value under HKD250 from any one person on any one occasion, provided the person has no official dealings with the department or organization in

which the prescribed officer works, and the prescribed officer does not attend the occasion on which the gift is given in his official capacity or by virtue of the official position he holds.

Under the HKAPI Code, no financial benefit or benefit-in-kind may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so.

Promotional Items of Nominal Value

Pursuant to the HKAPI Code, promotional items of nominal value are permissible. However, they must be provided free of charge and only on an infrequent basis, relate to the healthcare professional's work, and/or entail a benefit to patients.

Text, Reference Books, Magazines, Journals, etc.

Pursuant to the HKAPI Code, such items may only be given to hospitals or private group practices when they serve a genuine educational purpose and can only be provided on an infrequent basis. The monetary limit is HKD5,000 per hospital department or group practice per year. Maximum expenditure of these items per company should be of a modest amount per calendar year.

Seminars and Hospitality

The HKAPI Code provides rules on sponsorship of symposia, congresses or other promotional, medical/healthcare or educational programs.

- For events over three hours, a minimum of two-thirds of the time must be devoted to the scientific agenda.
- Hospitality must be reasonably related to the event, reasonable by local standards (maximum of HKD400 for breakfast or lunch and maximum of HKD700 per attendee for dinner), and in any event limited to travel, meals, accommodation and genuine registration fees.



- Entertainment of “modest” nature by reasonable local standards and which is secondary to refreshments and/or meals is allowed.
- No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies at events.
- Payments to compensate healthcare professionals for time spent attending such events are strictly prohibited.

Entertainment

“Entertainment” is defined under the PBO as food and drink provided for consumption on the occasion when it is provided and any other entertainment connected with or provided at the same time.

Entertainment is specifically excluded from the PBO’s definition of “advantage.”

The Civil Service Regulations state that government employees may not, without the permission of the head of his department, accept entertainment that is likely to lead to the embarrassment of the officer in the discharge of his functions, or bring the officer or the public service into disrepute.

Samples

Samples would be considered an “advantage” under the PBO and any healthcare professional that seeks to accept samples can only do so with the permission of his principal.

Under the HKAPI Code:

- the distribution of product samples is permissible as long as the samples are intended for the use of physicians to gain patient experience with a particular drug;
- each sample pack should clearly indicate that it is intended for physician use only;

- the frequency and volume of the provision of samples should be reasonable given the doctor’s experience with the products and in any event limited both in size and face value; and
- samples cannot be included or used as part of any sale and purchase transaction of any products with any healthcare professional.

Sponsorship

Pursuant to the Code of Professional Conduct for the Guidance of Registered Medical Practitioners (“Professional Code”), commercial organizations may sponsor healthcare professionals to participate in scientific meetings or for educational and charitable services. The amount sponsored must be reasonable.

According to HA’s internal Guidelines on Acceptance of Donation and Sponsorship (not available to the public), a sponsor should not designate any specific candidate for attending any conference. The hospital should nominate a candidate for the sponsorship and seek prior written consent of the Hospital Chief Executive to accept the sponsorship for conference attendance.

Under the HKAPI Code:

- in relation to symposia and congresses, member companies may sponsor healthcare professionals to attend such events, but sponsorship must not be conditional upon an obligation to prescribe, recommend or promote any medical product;
- companies should not pay any costs associated with individuals accompanying healthcare professionals invited to attend symposia and congresses;
- payments of professional fees in the form of honoraria and reimbursement of out-of-pocket expenses may be provided to healthcare professionals providing genuine services such as chairs, moderators, speakers or presenters on the basis of a written contract with the company; and



- companies should not organize or sponsor an event for healthcare professionals (including sponsoring individuals to attend such an event) that takes place outside their home city, unless it is appropriate and justified to do so from a logistical or security point of view (e.g., international scientific congresses and symposia that derive participants from many countries).

Consequences of Breach

Please see above regarding the consequences of breaching the various legislation which may affect the promotion of medical products.

Professional codes of conduct, as will be discussed below, are non-statutory in nature but often stipulate specified consequences upon breach. For example, although the HKAPI Code is voluntary in nature, it is binding upon members of the HKAPI and breach can result in a monetary fine or suspension or expulsion from HKAPI.

Professional Codes of Conduct

HKAPI Code

The HKAPI Code sets out principles and guidelines for its member pharmaceutical companies and organizations to follow regarding their marketing activities. The 15th edition of the HKAPI Code came into effect in April 2011, and the draft 16th edition is currently undergoing review to be aligned with the latest version of the International Federation of Pharmaceutical Manufacturers & Associations (“IFPMA”) Code of Practice. While the HKAPI Code is not legally enforceable in Hong Kong and is only binding upon its members, it nevertheless serves as a useful reference of acceptable local market practices for non-member companies.

The HKAPI Code operates under the general principle that member companies’ relationships with healthcare professionals are intended to benefit patients and enhance the practice of medicine, and that interactions should be focused on informing healthcare professionals

about products, providing scientific and educational information, and supporting medical research and education.

Code of Professional Conduct for the Guidance of Registered Medical Practitioners

The Professional Code issued by the Medical Council of Hong Kong sets out acceptable professional conduct expected of registered medical practitioners (including doctors working for both private and public hospitals) in Hong Kong. The code embodies two cardinal values of the medical profession – maintaining high standards of proper conduct, and good practice to fulfill doctors’ moral duty of care.

The Professional Code also upholds a robust professional culture to support self-governing through identifying role-specific obligations and virtues of the medical profession. The overriding consideration is whether any act is done in the best interest and benefit of patients. Breach of the Professional Code could lead to disciplinary hearings which may result in de-registration from the registered medical practitioners list or suspension from practice.

HA Code of Conduct

As the statutory body that manages all public hospitals in Hong Kong, the HA plays a very significant role in relation to local healthcare professionals. In Hong Kong, there are currently 39 public hospitals and 12 private hospitals. Public hospitals provide over 85 percent of all hospital beds in Hong Kong.

The code of conduct of the HA includes the philosophies, values and guiding principles that establish a set of benchmark standards of ethical behavior expected of every staff member of the HA.

Compliance with the code is an integral part of its employment terms and conditions.



Code of Professional Conduct and Code of Ethics for Nurses in Hong Kong

The Code of Professional Conduct and Code of Ethics for Nurses in Hong Kong issued by the Nursing Council of Hong Kong aims to make explicit the standards for professional conduct that nurses shall comply with at all times in their course of duty. The code highlights eight aspects of professional conduct that nurses are to comply with in discharging their professional duties.

Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes

The DOH's Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes sets out the standards of good practice for health care institutions to adopt in order to provide quality care to patients. Requirements are set out to be adopted in the management of staff, management of the premises and services, setting out policies and procedures, and setting up a system to deal with complaints. In assessing the suitability for registration and re-registration of health care institutions, compliance with the requirements under the code will be taken into account.

Integrity in Practice: A Practical Guide for Medical Practitioners on Corruption Prevention

The Independent Commission Against Corruption ("ICAC") has published a document entitled Integrity in Practice: A Practical Guide for Medical Practitioners on Corruption Prevention ("Integrity in Practice"). Despite not being a professional code of conduct as such, it remains relevant to medical professionals in light of the fact that the ICAC enforces the PBO. Integrity in Practice discusses legal and integrity issues faced by medical practitioners and suggests action plans for corruption prevention.

Codes for Media Providers and Advertising Agencies

As discussed previously, there are further codes of conduct issued by the Communications Authority of Hong Kong that may be applicable depending on the media used in advertising.

In addition, the Association of Accredited Advertising Agencies of Hong Kong (“AAAA”) has issued a voluntary Code of Practice (“4As Code”). The 4As Code is intended to reassure advertisers of the business ethics of agencies, ensure the continuation of the advertising agency as a professional and profitable enterprise, and provide a basis for standards and business practices such as remuneration, import duties, statutory charges and taxation that are common to both Hong Kong and the PRC. Although compliance with the 4As Code is voluntary, such may be considered “best practice” in Hong Kong.

Criminal and Civil Liability

Please refer to “Permitted and Prohibited Practices – Other Promotional Activities” above, regarding the PBO.

Public Procurement and Fraud

The spirit of the PBO is to maintain fair play in the procurement of contracts with public bodies. Section 5 of the PBO makes it an offense for a public servant, without permission of the public body, to solicit or accept an advantage for giving assistance in securing contracts from the public body. Any person who offers such an advantage commits an offense of corruption. The maximum penalty for non-compliance is a fine of HKD500,000 and imprisonment for 10 years.

Furthermore, it is an offense under section 9(3) of the PBO for an agent, with intent to deceive his principal, to use any receipt, account or other document in respect of which the principal is interested, which contains any statement which is false or erroneous or defective in any material way, and which to his knowledge is intended to mislead the principal. This offense carries a maximum penalty of a fine of HKD500,000 and imprisonment for seven years.



The more general anti-bribery provisions discussed in “Permitted and prohibited practices – Advertisements” above may also be relevant in the context of public procurement fraud, depending on the circumstances.

Contracts with Healthcare Professionals and Medical Institutions

There is no specific prohibition against a pharmaceutical company signing a service contract with healthcare professionals, for example, for speaking and chairing at meetings, translating medical documents, writing medical articles or giving medical training. However, the PBO should be observed since a service contract may be considered an “advantage” under the PBO. Due authorization from the employer/principal should be acquired to minimize the risk of violating the PBO.

Public vs. Private

It is important to distinguish between doctors in public hospitals and doctors in private hospitals, as different provisions of the PBO may apply. Moreover, as discussed above, healthcare professionals in public hospitals will require further determination as to whether they are “prescribed officers” (holding an office of emolument under the government) or “public servants” (any prescribed officer and any employee of a public body).

Financial or Other Inducements

The Professional Code states that doctors should not accept any financial or other inducement from healthcare organizations which may compromise, or may be regarded by others as likely to compromise, the independent exercise of their professional judgment. Doctors who have any kind of financial or professional relationship with, use the facilities of, or accept patients referred by, health care and health product organizations must exercise due diligence to ensure that the organization does not advertise in contravention of the principles and rules applicable to individual doctors.

Although the Professional Code acknowledges that the medical professional and the pharmaceutical industry have close ties as they both have common interests in the research and development of new therapies, drugs and the like, doctors must choose drugs or appliances which, in their independent professional judgment and having due regard to cost effectiveness, will serve the medical interests of their patients.

Recommendations

It is key for pharmaceutical companies to avoid contravening the PBO. Companies must therefore ensure that the permission of the public body or principal has been obtained in relation to any “advantage” offered to healthcare professionals.

Advertising:

- Drugs cannot be labeled or advertised in a manner that falsely describes the drug or is calculated to mislead as to its nature, substance or quality.
- Product descriptions for medical products must be true and not misleading.
- Advertisements that claim a product has curative or preventive effects on diseases and conditions specified under the UMAO are prohibited.
- Off-label use of pharmaceuticals cannot be promoted, although the HKAPI Code states that this should not affect the right of the scientific community and public to be informed about scientific and medical progress.

Other promotional activities:

- Public servants and agents should obtain permission from their principal before accepting any “advantage.”



- Gifts should not be offered to healthcare professionals to influence them in the purchase, supply or prescription of medical products.
- Promotional items of nominal value and educational items such as texts and reference books may only be given on an infrequent basis.
- Prescribed officers may only accept gifts of value under HKD250.
- For symposia and congresses, hospitality must be reasonable, any entertainment must be “modest,” and compensation for participation is prohibited.
- Samples can only be distributed in reasonable quantities, and only if it will allow the physician to gain patient experience with a particular drug.



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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