

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



THAILAND

This publication is copyright. Apart from any fair dealing for the purpose of private study or research permitted under applicable copyright legislation, no part may be reproduced or transmitted by any process or means without prior written permission of Baker McKenzie.

IMPORTANT DISCLAIMER. The material in this publication is of the nature of general comment only. It is not offered as advice on any particular matter and should not be taken as such. The firms involved and the contributing authors expressly disclaim all liability to any person in respect of the consequences of anything done or omitted to be done wholly or partly in reliance upon the whole or any part of the contents of this publication. No reader should act or refrain from acting on the basis of any matter contained in this publication without taking specific professional advice on the particular facts and circumstances in issue.



Thailand

Peerapan Tungsuwan, Prim Uditananda

Introduction

Advertisements and, in many cases, promotional activities for various medical products require an approval from the Food and Drug Administration (FDA). The approval requirements are different from one product to another depending on what category such products are classified in; how dangerous the products may be if the products are taken or used improperly, or whether the products must be prescribed by physicians or can be used directly by patients.

However, there are some basic requirements relating to advertisements and promotional activities that are common to all these products. In this respect, such advertisements must not contain false or exaggerated information. Moreover, the advertisements cannot contain overly aggressive or purely discretionary terms, or information which cannot be proven.

It should be noted that comparative advertisement is not permitted, unless it uses for comparison between the advertiser's own products or comparisons from an academic perspective, provided that the trade names of other persons are not specified.

As far as the process of obtaining an approval is concerned, all applications are required to be accompanied by supporting evidence, as well as scientific and/or academic information and documentation.

As the FDA seeks to improve its processes and other resources, it may be the wish of the medical product industry in Thailand that the relevant processes take them less time and require less documents. Generally speaking, the overall process should be simpler and should be completed more quickly.

Regulatory Framework

Medical Devices

In Thailand, medical devices are governed by the Medical Device Act, B.E. 2551 (A.D. 2008)

(Medical Device Act). The Medical Device Control Division of the FDA enforces the provisions of

the Medical Device Act.

Under the Medical Device Act, medical devices are divided into three categories.

Category 1: Medical devices that require the manufacturer or importer to obtain a license prior to being able to manufacture or import the product, which presently consist of five products, as follows:

- Condoms
- Blood bag
- Rubber gloves for surgical operations
- HIV infection tester kits
- Contact lenses

Category 2: Medical devices that require the manufacturer or importer to provide the specifications of the product prior to being able to manufacture or import the product, which presently consist of six products, as follows:

- Equipments or products used in physical therapy
- Alcohol tester kits



- Implanted silicon breast prosthesis
- Device or equipment for external use in breast enhancement or breast firming
- Ophthalmic Viscosurgical
- Urine test kit for Amphetamine

Category 3: Medical devices which do not fall under Categories 1 and 2.

Notwithstanding the above, kindly note that the above classification of medical devices may be subject to change as the FDA is in the process of re-evaluating each type of medical device in accordance with the risk assessment factors under the ASEAN Harmonization Scheme.

There are also specific regulations, issued under the ambit of the Medical Device Act which may outline certain regulatory requirements, including, but not limited to, the labeling and advertising requirements for medical devices, such as, the Notification on Guidelines, Procedures and Restrictions of Medical Device Advertising, B.E. 2553 (A.D. 2010) (“Notification”).

In addition to the above, there may also be other relevant laws and/or regulations relating to advertisements and promotional activities for medical devices which may not be outlined under the Medical Device Act, as follows:

- Consumer Protection Act, B.E. 2522 (A.D. 1979)
- Direct Sales and Direct Marketing Act, B.E. 2545 (A.D. 2002)
- Medical Facility Act, B.E. 2541 (A.D. 1998)
- Medical Professional Act, B.E. 2525 (A.D. 1982) (or other similar laws which govern other healthcare professionals)

Drugs

Drugs are governed by the Drug Act, B.E. 2510 (A.D. 1967) (“Drug Act”). The Drug Bureau of the FDA enforces the provisions of the Drug Act.

Under the Drug Act, drugs are divided into the following categories;

Category 1: Specially-controlled drugs

Category 2: Dangerous drugs

Category 3: Modern drugs

Category 4: Modern-packaged drugs other than those categorized as dangerous or specially-controlled drugs

Category 5: Veterinary drugs

Category 6: Household drugs

Category 7: Traditional drugs

There are also specific regulations issued within the ambit of the Drug Act which may outline certain regulatory requirements, including, but not limited to, the labeling and advertising requirements for drugs, such as the various ministerial notifications relating to a specific drug category. Additionally, the FDA has also issued its internal guidelines which may be used to consider drug advertisements, namely, the Guidelines on Drug Advertising, B.E. 2551 (A.D. 2008) (“Guidelines”).

In addition to the above and similar to the issue of medical device advertisements which are outlined above, there may also be other relevant laws and/or regulations relating to advertisements and promotional activities of drugs which may not be outlined under the Drug Act, as follows:

- Consumer Protection Act, B.E. 2522 (A.D. 1979)



- Direct Sales and Direct Marketing Act, B.E. 2545 (A.D. 2002)
- Medical Facility Act, B.E. 2541 (A.D. 1998)
- Medical Professional Act, B.E. 2525 (A.D. 1982) (or other similar laws which govern other healthcare professionals)

Permitted and Prohibited Practices

Advertising of Medical Devices

Under the Medical Device Act, “advertising” means any form of action taken in order for the public to see, hear or know of any statement, for commercial purposes, including for sales promotional purposes. “Sales promotion” means the provision of information, persuasion, or any actions taken in order to promote sales.

Persons wishing to advertise medical devices must first obtain a license from the FDA. Medical devices which fall under Category 1 and some medical devices under Category 2 can only be advertised to healthcare professionals. The term “healthcare professional” means medical and public health practitioners of pharmacy, dentistry, first-class veterinary sciences, physical therapy, medical technology, or other medical and public health practices as prescribed in the relevant ministerial notification.

Other types of medical devices can be advertised to end consumers or patients.

Under the Medical Device Act, advertisement of any medical device must not:

- show the properties, qualities, volumes, standards, components or origin of the medical device which are false or exaggerated;
- show a guarantee of, or praise for, the properties of the medical device by any particular person;

- provide a reward by means of gambling in any form;
- show properties which indicate the capabilities to prevent, heal, relieve or remedy a disease or symptom which is forbidden to be advertised as stipulated in the relevant ministerial notification; and
- show any wording which causes a material misunderstanding in relation to the medical device.

Moreover, the Notification also outlines more specific requirements in relation to the advertising of medical devices. For example, the advertising of the following types of medical devices is prohibited:

- Fake medical devices
- Substandard medical devices
- Deteriorated medical devices
- Medical devices that are unsafe to use
- Medical devices which are not produced or imported in accordance with the issued license or notified specification
- Medical devices whereby the licenses or specification certificates which have been issued in relation to such medical devices have been revoked

Furthermore, the Notification also prohibits persons from carrying out comparative advertising, except where the comparisons are made between the advertiser's own products or comparisons are based on an academic perspective, provided that the trade names of the other persons are not specified.

The use of academic references, study results, statistics, certification from any institution and any confirmation to support the advertising must follow international principles. Academic references must be well-accepted and be reliable in the following manner:



- A citation to prove or support details used in the advertising must follow academic principles and such references must state the authors and sponsors (if available).
- References are:
 - o academic documents, such as articles, research papers, test results, and medical device quality inspections that are issued in well-accepted and reliable journals; or
 - o certificates which are issued by government authorities or government certified private institutions.

Advertising of Drugs

Under the Drug Act, the manufacturers, importers or sellers of drugs are required to follow the requirements regarding labels and packaging inserts.

Additionally, the Drug Act requires any person wishing to advertise modern-packaged drugs that are not specially controlled drugs or dangerous drugs through audio, visual or printed media to first submit the advertising materials for the FDA's review and approval, obtain a license from the FDA prior to being able to use and release the advertisement to the general public, and follow the conditions set by the FDA.

Among other stipulations, the strongest section of the Drug Act requires that drug advertisements must not:

- boast that a drug or its ingredients are capable of miraculous cures or total treatment; nor state that a drug can relieve, cure or prevent diseases or illnesses; nor use other words with a similar meaning;
- exaggerate or falsely declare the properties of the drug; and

- create an understanding that the drug contains any medicinal substance or ingredient it does not actually contain, or, if it contains a particular medicinal substance or ingredient, create an understanding that it is in a quantity other than that which it actually contains.

Moreover, drug advertisements cannot be impolite, contain singing or dancing, or show the suffering or distress of patients. The prohibition relating to advertising drugs also extends to advertising via the provision of gifts or lucky draws.

In practice, the FDA may have specific requirements for the advertisement of certain types of drugs which may not be outlined under the Drug Act.

Promotion Activities Conducted with Healthcare Professionals

Promotion activities which are undertaken with healthcare professionals who are deemed to be “officials” should be considered with care. Such promotion activities may include, but should not be limited to, the provision of gifts, entertainment, other forms of hospitality, and sponsorship of the healthcare professional to attend local or overseas events such as medical congresses, symposiums or onsite visits. (Such sponsorship may cover accommodation, travel, meal and registration expenses.) In light of the foregoing, the following matters may be considered:

Bribery Offenses

Under Section 144 of Thailand’s Penal Code, a person may be guilty of a bribery offense if he or she gives, offers or agrees to give property or any other benefit to an official in order to induce the official to do or refrain from doing any act, or to delay the performance of any act, which is contrary to the official’s functions or duties.

Based on the above, an offense constituting bribery requires the existence of dishonest intent, and benefits are given to make the official perform or not perform his or her duty on a *quid pro quo* basis.



Section 144 does not provide any exceptions with regards to facilitation payments, nor are there any express exceptions in relation to *bona fide* business expenses. Nevertheless, despite the lack of the foregoing exceptions, payments made to government officials will only violate Section 144 if the payments are made with the dishonest intent to influence the government official (as discussed above).

The term “official” is not defined anywhere in the Penal Code. However, according to Supreme Court rulings, an “official” is any person who performs governmental duties, who receives a salary from the central governmental budget, and is appointed in accordance with the law. It should be noted that doctors or physicians working in state or government hospitals would be deemed to be government officials under the Penal Code. Moreover, non-government officials may also be deemed to be government officials under the Penal Code if they are appointed to certain positions on government boards or committees which have certain authorities given to them by the law.

Receipt of Properties or Benefits by Officials

In addition to the above, under the Act Supplementing the Constitution Relating to the Prevention and Suppression of Corruption, B.E. 2542 (A.D. 1999) and its subordinate notification, no official may receive property or any other benefits from any person, other than legitimate property or benefits derived under the law, rules, or regulations issued by virtue of the provisions of law, with the exception of the receipt of property or any other benefits on an “ethical basis.”

“Ethical basis” means that an official may receive property or any other benefits from any relative or from any person on a traditional, customary or cultural occasion, or on an occasion in which societal practice requires the giving of such items. Regardless, no official may receive any property or other benefits on a single occasion, from a person who is not related to the official, with a value in excess of THB3,000 (approximately USD90). The receipt of an asset or other

benefit that is given to others as a matter of general practice is acceptable.

Consequences of Breach

Professional Codes of Conduct

Medical Devices

The Thai Medical Device Technology Industry Association has issued its Code of Sales and Marketing Practices (“THAIMED Code”) for its members to adopt on a voluntary basis.

The matters which are outlined under the THAIMED Code include, but are not limited to:

- hosting of educational events or training on products;
- co-hosting educational conferences;
- meeting with healthcare professionals for sales promotion;
- the hiring of consultants;
- the provision of gifts and hospitalities; and
- the provision of subsidies and charity donations.

Notwithstanding the above, the THAIMED Code does not appear to stipulate any sanctions for the members of THAIMED who violate the THAIMED Code.

Drugs

Pharmaceutical companies in Thailand who are members of the Pharmaceutical Research & Manufacturers Association (“PReMA”) may adopt PReMA’s Code of Sales and Marketing Practices (“PReMA Code”) on a voluntary basis.

The PReMA Code outlines certain requirements and/or prohibitions in relation to the sales, marketing and promotion of the member’s



products in order to ensure that such practices are conducted in an ethical manner.

The matters which are controlled under the PReMA Code include, but are not limited to:

- advertising through journals;
- promotional activities undertaken by sales representatives and the materials used by such sales representatives;
- the use of trade displays and audio-visual materials;
- the provision of samples;
- the provision of gifts or entertainment; and
- sponsorship of healthcare professionals to attend symposia or medical congresses.

Violation of the PReMA Code by members of PReMA may lead to sanctions under the PReMA Code, which includes suspension of membership and fines.

Criminal and Civil Liability

Violations of the advertising laws outlined under the Medical Device Act and the Drug Act, as well as the relevant anti-bribery laws, may lead to criminal liability (imprisonment and/or fines) for the violator.

Furthermore, the managing director, manager or any person responsible for the business operation of a juristic person which commits a criminal offense may also be jointly liable for the said offense which was committed by the juristic entity.

Lastly, the FDA itself has the authority to order advertisements which violate the relevant requirements to be amended, or to prohibit the use of certain statements, or to suspend the advertisements.

Public Procurement and Fraud

The Act Concerning Offenses Relating to the Submission of Bids to Government Agencies, B.E. 2542 (A.D. 1999) (“Bidding Act”) seeks to prohibit acts of collusion undertaken by and between bidders in a government-held bidding process. The prohibitions include, but are not limited to, acts of collusion in setting a predetermined price in order for one party to win the bid, and the provision of benefits to another party in order for such party to collude in the bidding process.

Parties which collude in the submission of bids in violation of the Bid Rigging Act may also violate and be liable for an offense under the Trade Competition Act, B.E. 2542 (A.D. 1999), as such an act may be deemed to limit or eliminate fair competition.

Contracts with Healthcare Professionals and Medical Institutions

There are no laws or regulations that expressly govern contracts with healthcare professionals and medical institutions.

Notwithstanding the above, the following factors should be considered when any contracts are entered into with healthcare professionals or medical institutions, specifically contracts with government officials or agencies:

- The contract should be of fair market value.
- In the event that the healthcare professional or medical institution is receiving any compensation for services which the healthcare professional or medical institution renders to the business operator, then the compensation which the healthcare professional or medical institution receives should be commensurate with the actual services which are performed by the healthcare professional.
- The contract should only be entered into if there is a legitimate purpose.



- The contract must not be entered into in order for the business operator to gain any improper or illegitimate advantage or benefit from the healthcare professional or medical institution.

Recommendations

We provide below our general recommendations for conducting advertising and promotional activities in relation to medical products in Thailand:

- The business operator should fully understand the relevant laws and regulations which are outlined above as there may be various laws and regulations which may apply to a specific advertising or sales promotion activity.
- Any advertising or sales promotion activity which the business operator may conduct should be planned by also taking into account the relevant laws and regulations, in order to ensure that the advertising or sales promotion activity will comply with the said laws and regulations, as well as to ensure approval may ultimately be obtained from the FDA.
- As noted above, there are various laws and regulations which govern advertising and sales promotion activities. Such laws and regulations may be ambiguous on what statements may be used in an advertisement or what type of sales promotion activities may be conducted. Thus, the business operator should consider utilizing services of persons who have experience in reviewing and analyzing the adequacy and appropriateness of the advertising or promotional activity, in order to obtain clear guidance and input into the business operator's planning process in relation to its advertisements and sales promotion activities.
- As the FDA may also have its own internal regulations, the business operator should work closely with the FDA in preparing advertisements or promotional activities.

- The business operator should ensure that any sales promotion activities which are conducted with healthcare professionals who are government officials, specifically where the business operator may provide properties or benefits to the government official, must not violate any relevant anti-bribery laws.
- The business operator should ensure that any persons who are acting on its behalf, such as employees, agents, representatives and contractors, must also understand and comply with the relevant laws and regulations which apply to advertisements or promotional activities.

Note:

Baker McKenzie's Bangkok office now has the Regulatory Affairs Department to provide services in relation to FDA-related matters, including, but not limited to, assistance in reviewing and revising medical product advertisements and promotional materials, in order to ensure that such advertisements and/or materials are in compliance with the relevant laws and regulation.



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

www.bakermckenzie.com

©2018 Baker McKenzie. All rights reserved. Baker & McKenzie International is a global law firm with member law firms around the world. In accordance with the common terminology used in professional service organizations, reference to a "partner" means a person who is a partner or equivalent in such a law firm. Similarly, reference to an "office" means an office of any such law firm. This may qualify as "Attorney Advertising" requiring notice in some jurisdictions. Prior results do not guarantee similar outcomes.