

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
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GENERAL
1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.
<p>The advertising and promotion of pharmaceutical products and medical devices in Thailand is primarily governed by the Drug Act B.E. 2510 (1967) (Drug Act) and the Medical Device Act B.E. 2551 (2008) (Medical Device Act). In addition, the Pharmaceutical Research and Manufacturers Association (PReMa) and the Thai Medical Technology Industry Association (THAIMED) have established code of conduct for pharmaceutical products and medical devices, respectively. Members of each association must comply with their code of conduct despite it being non-legally binding. Notably, non-members of these associations tend to follow the same standards as a courtesy.</p>
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>The Drug Act does not specifically define the meaning of both 'advertising' and 'promotion'. However, the Thai Food and Drug Administration (FDA) views advertising as 'any act or activities including promotion initiated for commercial gains or trade purposes through any advertising media.' The Thai FDA's Regulation Re: Requirements on Advertising of Drugs B.E. 2545 (2002) (Regulation 2002), categorises advertising into two categories namely: (1) advertisements targeting the general public; and (2) advertisements targeting healthcare professionals (HCPs).</p> <p>Meanwhile, 'promotion' is often viewed as a marketing or communication aimed at increasing awareness of drug and medical device information.</p> <p>The Medical Device Act explicitly defines the term 'advertising' as an act 'by whatever method, done with a view to causing anyone to see, hear, or know a statement, for the purposes of trade, and shall also include an act of sales promotion' and 'sales promotion' means 'an act of giving information or soliciting or any act by means with securing a sale.'</p> <p>Although advertising is defined differently, the essence of advertising for pharmaceutical products and medical devices remains the same: effectively communicating messages to intended audiences for trade or commercial purposes.</p>
3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?
<p>The Thai FDA, under the Ministry of Public Health, is the primary regulatory authority overseeing the regulations under its power. The Drug Division and the Medical Device Control Division of the Thai FDA are responsible for approving the advertising licence and monitoring and enforcing the advertisement that violates the Drug Act and Medical Device Act in Thailand.</p> <p>Since both the Drug Act and Medical Device Act do not prescribe interactions with HCPs, which forms the crucial part of promotion activities, the pharmaceutical and medical device associations such as PReMa and THAIMED play crucial roles in overseeing their member companies' conduct. The violation of PReMa and THAIMED guidelines may result in sanctions, such as suspension of membership. The pharmaceutical and medical device companies who are not members tend to also apply the codes of conduct of these associations. Conversely, the Drug Division and the Medical Device Control Division of the FDA is responsible for granting advertising licences and for enforcement within the pharmaceutical and medical industries. While these entities have distinct responsibilities, they may collaborate to address issues relating to pharmaceutical products and medical devices, such as sharing information, policy development, and developing corrective action or guidance to address identified concerns. The collaboration between THAIMED, PReMA, and the Drug Division and the Medical Device Control Division of the FDA aims to foster a cooperative relationship promoting public health, ensuring regulatory compliance and ethical conduct within Thailand's pharmaceutical and medical device industry.</p>
4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If

so, are there any special considerations for the promotion (and advertisement) of such other product types?
<p>No. The Food Act B.E. 2522 (1979) (Food Act) classifies food supplements, special nutritional products, and medical foods as food. According to this definition, these are food means substances intended to be consumed or used as ingredients with no intent to diagnose, treat, or cure human diseases/illnesses.</p> <p>Further clarification is provided by the Notification of the Ministry of Public Health (No 293) B.E. 2548 (2005) Re: Food Supplements (Notification No 293), which defines 'food supplements' as 'products intended for consumption other than regular food, which contain nutrients or other substances in the form of pills, capsules, powder, granules, liquid, or other forms, and do not fall within the normal food category (ie, unconventional foods) for consumers who anticipate health promoting benefits.' Prior approval from the FDA is therefore required for any advertisement promoting the qualities or usefulness of food supplements and special nutritional products. However, if the advertisement does not promote these qualities or usefulness, no advertising licence is required.</p>
CONSUMER MARKETING
5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?
<p>No. In general, over-the-counter pharmaceutical products can directly be advertised to the public. The relevant party must first obtain the advertising licence from the Thai FDA. The advertisement of prescription-only or professional-use products can only be advertised to HCPs and requires an advertising licence from the Thai FDA before the dissemination. Regardless of the restrictions, all advertisements must adhere to the advertisement requirements summarised below.</p> <p>The advertisement of pharmaceutical products must not:</p> <ol style="list-style-type: none">1. Exaggerate therapeutic properties or ingredients as being miraculously or completely capable of treating, mitigating, curing, or preventing a disease or illness.2. Falsely or exaggeratedly depict therapeutic properties.3. Mislead by claiming a particular substance as its chief or component ingredient when it in fact does not contain it or contains a lesser quantity than advertised, which may cause misunderstanding.4. Mislead as to being an abortifacient or a strong emmenagogue.5. Mislead as to being an aphrodisiac or a birth-control drug.6. Show the therapeutic properties of a dangerous or a specially controlled drug.7. Contain certification or laudation of its therapeutic properties by any other person.8. Show a drug's therapeutic properties as being capable of curing, mitigating, treating, or preventing diseases (or symptoms of them) identified by notification from the Minister of Public Health under Section 77 of the Drug Act (eg, cancer, diabetes, paralysis, psychiatric disorders, blood pressure disorders, AIDS, health conditions related to neurological, cardiovascular, lung, kidney, spleen, or liver disorders).9. Contain offensive content, singing and dancing, or show the distress or suffering of a patient.10. Involve a gift or lottery. <p>Advertisements targeting HCPs are permitted to mention (1), (4), (5), (6), (7), and (8).</p> <p>Similar to pharmaceutical product advertisements, all advertisements of medical devices to the general public are subject to obtaining an advertising licence from the FDA before dissemination. However, the Medical Device Act exempts advertisements displaying only the trademark of the medical device, provided the picture of the medical device is not present in the advertisement, and advertisements of medical devices targeting HCPs from obtaining an advertising licence from the FDA. Consequently, only the advertisement of medical devices targeting the public must receive approval from the FDA before dissemination.</p> <p>Additionally, the advertisement of medical devices must comply with the general restriction outlined by the Medical Device Act below.</p> <ol style="list-style-type: none">1. Prohibition of advertising for medical devices banned for manufacture, import, or sale.2. Prohibition of advertising for counterfeit, substandard, poor quality, or unsafe medical devices.

3. Restriction on false or exaggerated advertisements, including the use of boastful or deceptive language.
4. Limitation on providing more details than specified in the product label or documentation unless supported by evidence.
5. Prohibition of endorsements or praise of medical device benefits by any person.
6. Prohibition of advertisements offering prizes through any means.
7. Prohibition of advertisements claiming the ability to prevent, cure, relieve, or treat diseases or symptoms banned by a ministerial notification.
8. Prohibition of boastful, false, deceptive, misleading, or culturally inappropriate names for medical devices.
9. Prohibition of offensive or divisive advertisements.
10. Restriction on discrediting or comparing a medical device to another operator's, except for comparisons to one's own products or academic comparisons, without mentioning the names of other persons' medical devices or product technologies.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

In accordance with our response to Question 2, the advertisement of pharmaceutical products and medical devices includes advertising on the internet and social media platforms. Therefore, online advertisements of pharmaceutical products and medical devices must adhere to the same regulations stipulated in the Drug Act and the Medical Device Act and their implementing subordinate legislation. The same requirements apply regardless of whether promotional activities are conducted online. Please also refer to our response to Question 5 for further details.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Yes, prior approval from the FDA is required to promote and advertise pharmaceutical products and medical devices under the Drug Act and Medical Device Act, respectively. Below is a summary of the procedure for obtaining advertising approval from the FDA.

For drug advertisements:

1. Prepare the advertisement materials and supporting documents in compliance with the Drug Act.
2. Complete and submit the application form.
3. On receipt of the application and supporting documents, the official at the Advertising Supervision Division of the Drug Division will verify the completeness of the application and record the information in the computer system.
4. The pharmacists, head of the advertising division, and director of the advertising division will conduct a substantive examination to evaluate the application and advertisement.
5. If compliant and approved, the authority will forward the application to the Secretary-General of the FDA or authority appointed by the Secretary-General to issue the licence and send it to the official for recording.
6. Once recorded, the applicant may collect the advertisement approval and proceed with the advertising activities.

The advertising approval timeframe varies based on the material. Gimmick/merchandise items, such as pens or flash drives displaying a product trademark, can take three to five business days, while leaflets/product brochures addressing medical product indications require approximately 30 business days to obtain the licence.

For medical device advertisements to the general public:

1. Prepare the advertisement materials and supporting documents in compliance with the Medical Device Act.
2. Complete and submit the application form in person or online.
3. Once received, the official will verify the completeness of the application and have the applicant pay an official fee.
4. The relevant official will examine the application and supporting documents.
5. If the advertisement material is deemed compliant and acceptable, the applicant may proceed to pay the official fee for the issuance of the advertisement approval permit.

<p>The timeframe for obtaining advertising approval can take between seven and 21 business days depending on the complexity of the advertising materials.</p>
<p>8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?</p>
<p>No, the advertisement of pharmaceutical products and medical devices is permissible only on receiving market authorisation/approval from the FDA. Failing which, the advertisement of unauthorised pharmaceutical products and medical devices may violate advertising requirements stipulated in the Drug Act and Medical Device Act. This is because the Drug Act bans the advertisement of false or exaggerated therapeutic properties of pharmaceutical products while advertising an authorised medical device is considered the advertisement of a counterfeit medical device, which is banned by the Medical Device Act.</p> <p>Nevertheless, the Drug Act and Medical Device Act do not prevent companies from sharing or exchanging scientific information on unauthorised pharmaceutical products or unapproved indications, in the form of disease awareness or disease information for educational purposes.</p>
<p>9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?</p>
<p>No. The FDA Regulation broadly states that the advertisement of drug sales in the general media must not compare or disparage other drugs. A comparison of drugs is feasible, provided that the drug's trade name is not mentioned and the information in the advertisement is factual and scientifically based. Similarly, advertising which involves disparagement or comparison of medical devices with those of other businesses should be avoided, unless it involves a comparison with the advertiser's own medical device or is done in an academic context, provided that the names of the medical devices or technologies of others are not disclosed.</p>
<p style="text-align: center;">DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS</p>
<p>10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?</p>
<p>The Drug Act classifies HCPs into three categories: medical practitioners, modern healing practitioners (dentists, pharmacists, midwives, nurses), and traditional healing practitioners. According to the Medical Device Act, HCPs refer to 'medical and public health practitioners', including medical practitioners, physiotherapy practitioners, medical technology practitioners, or other medical and public health practitioners. Considering the somewhat similar definitions of HCPs, it can be interpreted that HCPs are individuals with medical and healthcare-related qualifications, including a wide range of healthcare professionals from those in traditional healing arts to modern healing. Nonetheless, the same restrictions apply when advertising pharmaceutical products and medical devices targeting HCPs. Please refer to our response to Question 5.</p>
<p>11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?</p>
<p>During the pandemic, advertisements of pharmaceutical products directed to HCPs shifted from in-person to online platforms, including virtual meetings or online conferences. In light of this, the FDA issued a Circular Letter No ST1004.4.5/15308, permitting pharmaceutical companies with existing advertising licences to extend the coverage to online promotional activities for the same advertising content. However, it is necessary to obtain an advertising licence, as online promotions of pharmaceutical products are also subject to FDA approval before dissemination.</p> <p>As for medical devices, the Medical Device Act has yet specifically to address advertising of medical devices directed to HCPs via online meetings and conferences. However, advertisements of medical devices to HCPs, as explained in our response to Question 5, are exempted from obtaining an advertising licence. This is provided that there are access restrictions to only HCPs with disclaimers, such as 'advertising to HCPs exempted from advertising licence.'</p>
<p>12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?</p>

<p>Both the Drug Act and the Medical Device Act prohibit HCPs from making representations or endorsements in advertisements of pharmaceutical products' therapeutic properties and/or usefulness of medical devices, respectively. This is because an endorsement by HCPs typically refers to recommendation statements regarding certain pharmaceutical products/medical devices that may leverage credibility and/or create undue influence on the opinions and choices of consumers. However, neither statute bans HCPs from engaging in non-promotional activities, such as acting as consultants, lecturers, or speakers at meetings and events involving medical or scientific studies, provided that there is a written service agreement outlining the nature and payment of their service.</p>
<p>13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.</p>
<p>Yes. Although the Drug Act and Medical Device do not regulate or specifically prohibit companies from providing samples of pharmaceutical products and medical devices to HCPs, PReMa's Code of Conduct explicitly states that samples can be provided to HCPs, provided that the quantity is appropriate to enhance patient care with no intention to induce prescriptions or personal benefits.</p> <p>Regarding gifts and monetary donations to HCPs, HCPs in government or public hospitals are deemed government officials, subject to the Anti-Corruption Act B.E. 2561 (2018). Pharmaceutical and medical device industries are restricted from providing or offering to provide property or benefits to officials, with exceptions for customary or traditional occasions. An official may receive property or any other benefits not exceeding THB 3,000 (Approx. US\$80) per occasion; exceeding this limit could pose a significant risk of bribery.</p>
<p>14. What rules govern the offering of hospitality to healthcare professionals?</p>
<p>While there are no restrictions on providing hospitality to HCPs under the Drug Act and Medical Device Act, the PReMa and the THAIMED code of conduct outline specific restrictions regarding the provision of hospitality to HCPs. This is limited to legitimate travel expenses, meals, and accommodation relating to sponsored events. The PReMa code of conduct also allows reimbursement of expenses if the receipt is presented. Cash advancement to HCPs is not permitted. THAIMED is silent on reimbursements.</p>
<p>15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?</p>
<p>No. Monetary donations provided directly to healthcare institutions or to HCPs through healthcare institutions are not considered promotional activities. This is provided that donations to healthcare institutions or HCPs through healthcare institutions are intended to enhance patient care, including donations in relation to the service provided by the HCPs or the procurement of pharmaceutical products or medical devices to be used by the HCPs.</p>
<p>16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?</p>
<p>Yes. The Drug Act and Medical Device Act do not prohibit the sponsorship of scientific or educational meetings, including providing sponsorship to HCPs to attend exhibitions, events, congresses, meetings, and/or international conferences. However, the PReMa Code of Conduct specifically states that any hospitality, entertainment, or gimmick/merchandise provided by companies, either directly, or through sponsorship, or arrangement with the meeting organisers, must be secondary to the educational purposes of the meeting and not considered extravagant by local standards. Additionally, it is advisable that the invitations to scientific or education meetings only be given to HCPs. With regards to accommodation, please refer to our response to Question 14.</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>Neither the Drug Act, the Medical Device Act, nor the THAIMED specifically address relationships with patient organisations. However, the PReMa code of conduct lays out the following restrictions when associating with patient organisations:</p> <ul style="list-style-type: none"> • Companies can provide financial support to patient organisations only for the purpose of professional, educational, and scientific meetings, as well as to support the patient organisation's mission. It is to be noted that educational meetings for patients should not serve as a substitute for the diagnosis of disease or illness, nor should they provide treatment information from the

<p>appropriate HCPs. Instead, these meetings should direct patients to seek further information or explanation from relevant HCPs.</p> <ul style="list-style-type: none"> • The provision of financial funds by companies must be documented in writing, setting out the nature of the support, the purpose, and the funding of activities. • Companies may also provide appropriate hospitality, such as appropriate venues and refreshments or meals.
<p>18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?</p>
<p>Yes, it is possible to engage third parties through a service agreement, as they are not explicitly prohibited by law or regulated in the Drug Act and Medical Device Act. However, the advertising material is still subject to the advertising requirements stipulated in the Drug Act and Medical Device Act.</p> <p>The industry often carries out co-promotion activities between pharmaceuticals, medical devices, food supplements and medical facilities (eg, clinics/ hospitals). The co-promotion activities are regulated by relevant laws. For example, the co-promotion of clinics and pharmaceutical products shall be governed by the Medical Facility Act and the Drug Act. To ensure compliance with legal requirements, it is advisable to establish and implement mechanisms that oversee and verify adherence to relevant laws. Accordingly, we recommend having an internal review and approval process of the advertising material before its dissemination.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>No, it is not mandatory to report the provision of monetary and non-monetary benefits to HCPs to the regulatory authority, as the Drug Act and Medical Device Act do not specify any reporting requirements for such benefits. However, if the monetary and non-monetary benefits provided to HCPs who are deemed government official on a customary/traditional occasion exceed THB3,000 (approximately US\$80), the HCP is required to report the receipt of such property or benefit to their superior immediately, in order to determine whether the receipt is deemed a necessity or appropriate. If it is not deemed appropriate, the official shall return the property or benefit to the donor immediately.</p>
<p>ENFORCEMENT</p>
<p>20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?</p>
<p>Violation of the Drug Act's advertisement requirements may result in a fine not exceeding THB100,000 (approximately US\$2,700). As for the violation of the Medical Device Act's advertisement requirements, the penalties vary depending on the circumstances, summarised as follows: (1) advertisement without obtaining approval – imprisonment for a term of up to six months, a fine not exceeding THB50,000 (approximately US\$1,355), or both; (2) advertisement of medical devices not in compliance with the stipulated conditions – up to a year's imprisonment, a fine not exceeding THB100,000 (approximately US\$2,700), or both.</p> <p>The supervisory authorities actively monitor the advertisement of pharmaceutical products and medical devices, including conducting investigations for any potential violation and imposing penalties on the advertising mediums which violate regulations. The Thai FDA may also impose the administrative order/ sanctions by ordering the advertiser to suspend their advertising, or to revoke the advertising from any media.</p>
<p>21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?</p>
<p>The Drug Division and the Medical Device Control Division of the FDA are the relevant authorities responsible for reviewing advertising material, approving the advertising licence, monitoring and enforcing the advertisement of pharmaceutical products and medical devices that violates the Drug Act and Medical Device Act. Based on our experience, the authorities will constantly monitor and review the legality of advertisements, ensuring compliance with the relevant laws related to drug and medical device advertising. The Drug Act and Medical Device Act will also empower the Secretary-General of the FDA, or an authority appointed by the Secretary-General to change, ban, or suspend violating advertisements.</p>

The Drug Act and Medical Device Act violations are considered state offences where the government is responsible for prosecuting individuals or entities which break these laws. While the private sector may not have the legal authority to prosecute or take legal action as plaintiffs in cases of violations of the Drug Act or Medical Device Act, the private sector can serve as watchdogs, reporting any potential violations, irregularities, or non-compliance with the Drug Act or Medical Device Act to the FDA. It is therefore not possible for the private sector to take direct action through court for the violation of advertisement requirements relating to the Drug Act or the Medical Device Act.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

With the advancement of technologies, pharmaceutical and medical device industries have increasingly used online advertising as a means of promoting pharmaceutical products and medical devices. As online advertising continues to grow, the FDA authorities monitor for potential violations through their own efforts, as well as anonymous reports from third parties.

On discovering or receiving reports of a violating advertisement, the FDA would conduct a thorough review, collecting evidence of the alleged violation. Subsequently, the FDA will issue letters mandating change, cessation, or suspension of the violating advertisements. In addition to the official orders, it is important to note that fines are more likely to be imposed than imprisonment for such violations under the Drug Act or Medical Device Act.