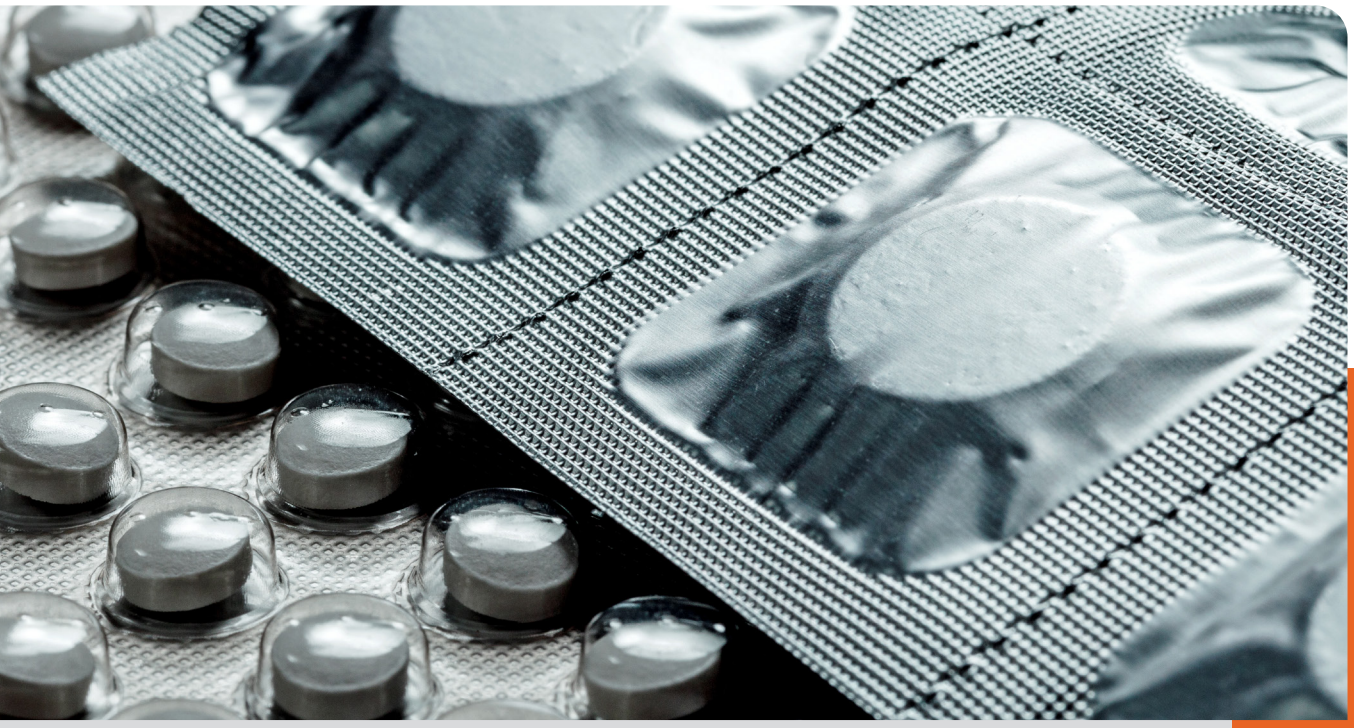
International
Comparative
Legal Guides



# Pharmaceutical Advertising

# 2024

21st Edition

Contributing Editors:
Ian Dodds-Smith & Adela Williams
Arnold & Porter

glg Global Legal Group

# Expert Analysis Chapters



# Q&A Chapters

# Thailand



Dr. Atthachai Homhuan


Alan Adcock


Chanya Veawab


Kunanon Sereesawetrat

Tilleke & Gibbins


## 1 General – Medicinal Products

**1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?**

The advertising of medicinal products in Thailand is primarily governed by the Drug Act B.E. 2510 (1967), and its amendment.

In addition, the Pharmaceutical Research and Manufacturers Association (PReMA) has established a Code of Conduct (PReMA Code) for the ethical promotion of pharmaceutical products. Members of the association must comply with the PReMA Code, despite it being non-legally binding. Notably, non-members of the association tend to follow the same standards as a courtesy and to ensure fair competition within the industry.

**1.2 How is "advertising" defined?**

The Drug Act does not specially define the meaning of "advertising". The Food and Drug Administration, Thailand (Thai FDA), as a regulatory body, views advertising as "*any activities including the promotion initiated for commercial purposes through any media source*".

**1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?**

An advertisement of a pharmaceutical product must receive the advertising licence from the Thai FDA, who will review the text, sound or picture used in the advertisement proposed by the applicant. There is no signing-off regarding promotional copy requirements under the Drug Act and its bylaws.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There are no legal requirements for companies to have SOPs for governing advertising activities. On the other hand, the PReMA Code stipulates that pharmaceutical companies are responsible for ensuring that an internal compliance procedure exists and complies with all provisions of the PReMA Code. Procedures should be documented and provided to relevant employees, thus to further enhance compliance with the PReMA Code.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Yes. The advertising of pharmaceutical products must obtain prior approval (i.e., advertising licence) from the Thai FDA. The advertiser must submit the advertising application via online submission. The content (e.g., VDO storyboard, brochures and photos of giveaway items), as well as the Marketing Authorisation (MA) licence of the pharmaceutical product, academic references and package insert all must be submitted for evaluation of advertising. The advertising licence is valid for five years from the approval date.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Yes. According to Section 90 *bis* of the Drug Act, the Secretary General of the Thai FDA has the power to issue administrative orders to cease any advertisement deemed to be contrary to such Drug Act.

Following the receipt of complaints, the PReMA Code of Practice Committee (CPC) will review and decide whether to sanction the alleged member found to be in breach under the PReMA Code. Examples of the sanctions include the following:

- Referring the complaint and findings to the head office and regional office of the offending company.
- Suspending the offending company's membership for no more than three years.
- Debarring the offending company from PReMA membership.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The penalties for failing to comply with the rules governing the advertisement of medicines are detailed below.

Administrative sanction: the Secretary General of the Thai FDA can issue a cease order or suspend any advertisement deemed to be contrary to the Drug Act (Section 90 *bis*).

Criminal penalties:

- Whoever advertises the sale of medicines in violation of Sections 88, 88 *bis*, 89 or 90 of the Drug Act shall be liable to a fine not exceeding THB 100,000 (USD 3,200) (Section 124).
- Whoever violates the order suspending the advertisement of medicines by the Secretary General of the Thai FDA under Section 90 *bis* of the Drug Act shall be liable to imprisonment not exceeding three months or a fine not exceeding THB 5,000 (USD 160), or both, and shall be liable to a fine of THB 500 (USD 16) per day until the Secretary General of the Thai FDA's order is complied with (Section 124 *bis*).

The Thai FDA and Public Health Provincial Office are the regulatory authorities responsible for enforcement.

There have been many advertisers of medicines who violate the rules, particularly the advertising of medicines via online platforms. For example, the Thai FDA has sent letters to warn pharmacy stores that the advertising of medicines without a licence is subject to criminal penalty.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Pharmaceutical associations, such as PReMA, have been working closely with the Thai FDA. Nonetheless, the Thai FDA does not typically follow up matters based on an adverse finding of violation of the PReMA Code, because the officials do not have the power to execute for non-compliance of the PReMA Code.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

In Thailand, comparative advertising for all types of goods and services is generally not allowed, and this is particularly true of highly regulated goods such as medicinal products. According to the Thai FDA's Advertisement Rules, advertisements that compare or discredit a competing medicine are prohibited. Non-compliance of advertisements of medicinal products is monitored by the Thai FDA. Complaints regarding the violation of advertisement rules can be filed by pharmaceutical companies based on the grounds of unfair competition.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Despite the amendment to the Drug Act's (Drug Act B.E. 2510 (2008)) prohibition of the advertisement of unauthorised pharmaceutical products and unapproved indications unless receiving market authorisation/approval from the Thai FDA, pharmaceutical companies have the freedom to share or exchange scientific information on unauthorised pharmaceutical products or unapproved indications to healthcare professionals (HCPs) on the unsolicited means. The dissemination of unauthorised pharmaceutical products and unapproved indications must be conducted for the purpose of furthering scientific/medical knowledge, where the tradenames of products or references to companies should be avoided. Therefore, it is possible to discuss and make available to the HCPs, at scientific meetings, exhibitions and educational meetings, unauthorised pharmaceutical products.

The provision of information by the sponsored companies is possible, provided that the sponsorship and/or the provision of information is requested by HCPs, healthcare institutions or medical associations for the purpose of enhancing medical and scientific knowledge. The proactive approach of pharmaceutical companies to HCPs on marketing promotion of off-label/unauthorised medicine is not permissible.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Unauthorised pharmaceutical products and unapproved indications can be published and disseminated among HCPs, only in the context of scientific education or exchange of information. The information must be balanced, without direct or indirect promotion of unauthorised pharmaceutical products and unapproved indications and include references to reliable sources that have been publicly published. This includes using a generic name and avoiding displaying any brandings and logos of the products. This is to avoid being deemed as an advertisement, since the Thai FDA's Regulation RE: Requirements on Advertising of Drugs B.E. 2545 (2002) provides the definition of "advertisements targeting healthcare professionals" as "*advertising for sale of drugs targeting the dissemination of advertising messages directly to healthcare professionals through any media, such as medical journals, brochures, flyers, sign[s], posters, or other materials, and internet media*".

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.**

It is permissible for pharmaceutical companies to issue press releases regarding unauthorised pharmaceutical products or unapproved indications, provided that the information is presented with restricted access only to HCPs and for the purposes of disease awareness, unbranded and not for commercial purposes to advertise or sell unauthorised pharmaceutical products. This is because the press release or dissemination of unauthorised pharmaceutical products or unapproved indications accessible to the public through the mainstream public means is not allowed.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Yes. Information on unauthorised pharmaceutical products or unapproved indications may be provided to HCPs and medical associations through educational or scientific events upon their requests. In addition, pharmaceutical companies may provide support for continuing medical education (CME) to HCPs and medical associations for the purpose of providing the latest and most accurate information, provided that the materials and content are fair, balanced and consist of medical or scientific information. This includes responding to the request of HCPs or medical associations on unauthorised pharmaceutical products or unapproved indications.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The ECJ judgment in the *Ludwigs* case is not applicable to Thailand. An MA from the Thai FDA is required prior to selling medicinal products in Thailand. Additionally, only the advertising of approved medicinal products is allowed.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Kindly refer to our response to question 2.4 on the dissemination of information on unauthorised pharmaceutical products or unapproved indications. Sending information on unauthorised pharmaceutical products or unapproved indications for commercial purposes should be avoided, as it can be deemed as an advertisement under the Drug Act. However, it is possible to provide institutions with educational or scientific information upon request from the institutions.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The PReMA Code, addressing market research, which does not prohibit the involvement of HCPs. However, the PReMA Code explicitly states that the research must not contain biased data and must be conducted in a non-promotional context, as well as prevent the conduct of market research in the form of a disguised sale promotion and influencing the opinion of HCPs. The PReMA Code further prescribes the confidentiality of the identity of an informant (HCP).

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The Thai FDA's Regulation RE: Requirements on Advertising of Drugs B.E. 2545 (2002) specifically prescribes required information for advertising drugs to HCPs as follows:

1. The advertisement must display:
   a. Drug name, in accordance with the Thai FDA registration.
   b. Therapeutic claims or indication.
   c. Composition of drug product.
   d. Source of manufacture or distributor.
   e. Indication and usage, including the dosage and precautions statements.
   f. Warning statements, including displaying the statement: "Read warning label prior to usage".
2. The advertisement must display properties, indications, history and other details as specified in the summary of product characteristics (SmPC) and product specification, except such information based on reliable documents or registration that would not cause material misunderstanding of the drug.
3. The advertisement must contain references to reliable sources of information, in alignment with the product specification, e.g., widely published textbooks and journals.
4. The advertisement must contain statements recommending the product with reference to the product specifications or full text of the information leaflet.
5. The advertisement must display the advertising licence number issued by the Thai FDA on the advertisement.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to: (a) studies not mentioned in the SmPC; or (b) studies which have not been published either in peer-reviewed journals or at all ("data on file")?**

Yes. According to the Thai FDA's Regulation RE: Requirements on Advertising of Drugs B.E. 2545 (2002), the advertisement must not:

a. Exaggerate or falsely declare the properties of the medicine.
b. Mislead that it contains substances or components of an ingredient, which in fact it does not have, or does have but less than the quantity as caused to be understood.
c. Impolitely advertise or, by means of singing and dancing, show distress or suffering of the patient, or a gift or lottery drawing.

Furthermore, scientific or research studies/data must be referenced from reliable sources, i.e., textbooks published by the Minister or textbooks, journals or research studies that were publicly published. When referencing the effects or dosage of a drug, such reference must be cited from the evidence-based literature and have statements consistent with the product SmPC. Referring to studies not mentioned in the SmPC is possible; the cited studies/data must not contradict the information approved by the Thai FDA specified in the SmPC. On the other hand, the referencing of unpublished studies is not allowed by the Thai FDA.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Section 88 of the Drug Act explicitly prohibits making representations or endorsements in advertisements of pharmaceutical products' therapeutic properties.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no such requirement for the data from the head-to-head clinical trials. As a general rule, the comparative claims discrediting a competing medicine are prohibited by the law of Thailand (see question 3.5).

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

In Thailand, comparative advertising to discredit or disparage goods and services is generally not allowed, and this is particularly true of highly regulated goods such as pharmaceutical products. According to the Thai FDA's Advertisement Rules, advertisements that compare or discredit a competing medicine are prohibited. Any comparison implying a therapeutic advantage that is not, in fact, justified must be avoided, including disparaging references to other products or manufacturers.

**3.6 What rules apply to environmental "green" claims made in relation to specific products in promotional material?**

The Drug Act is currently silent on environmental "green" claims. Environmental claims are considered advertising claims and, if used in conjunction with promotional materials, it is recommended for pharmaceutical companies to have evidential support for such environmental or "green" claims to avoid being deemed to contain a false or exaggerated statements.

**3.7 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Pharmaceutical companies do not need to obtain prior approval from the regulatory authority on the distribution of scientific papers and/or proceedings of congresses to HCPs, but the advertisement materials to be disseminated at the congresses may be subject to Thai FDA review and approval if the materials fall within the scope of advertisement.

**3.8 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There are no restrictions on the dissemination of teaser advertisements to HCPs under the Drug Act. Therefore, teaser advertisements are permissible as long as they do not violate the advertising requirements stipulated in the Drug Act.

**3.9 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Yes. Referring to studies/indications not mentioned in the SmPC is possible, provided that the cited studies/data do not contradict the information approved by the Thai FDA specified in the SmPC. Therefore, it is possible for the MA of Product A to rely on its indication of use in combination with Product B as specified in Product A's SmPC. On the other hand, the SmPC of Product B lacks the indication to be used in combination with Product A; however, it is possible for the MA of Product B to refer to Product A's indication, as long as such indication does not contradict Product B's approved SmPC. Additionally, in practice, the Thai FDA will consider the advertisements or advertising claims and indications based on the approved declaration in the SmPC. Since there is supportive information in the approved SmPC (indication in another product in this case), it can also be approved and used for advertising.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes. The PReMA Code explicitly states that samples can be provided to HCPs with the appropriate quantity to enhance patient care with no intention to induce prescriptions or personal benefits or to be sold out.

**4.2 Are there any restrictions on the value of payments or benefits that may be provided to healthcare professionals or healthcare organisations for consultancy services? Is it necessary to obtain advance approval from the authorities for the arrangements?**

Yes. The compensation for consultation services must be reasonable and reflect the fair market value of the services provided by the HCPs. It is recommended that the payment for services provided by HCPs must be agreed in advance of the commencement of the services. However, it is not necessary to obtain approval from the authorities for the arrangements.

**4.3 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Yes. The companies are allowed to provide or offer gifts or giveaway items to HCPs. There are restrictions for HCPs who are also considered government officials, as they are subject to the Organic Act on Anti-Corruption B.E. 2561 (2018) (Anti-Corruption Act), which allows the offering of gifts for customary or traditional occasions. Government officials may receive gifts or any other benefits not exceeding THB 3,000 (around USD 80).

Moreover, the PReMA Code prohibits giving gifts or donations of money for the personal benefit of HCPs; however, corporate images items (e.g., gimmick/giveaway items) with no intention of promotion or linkage to pharmaceutical products are allowed.

**4.4 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Yes. A pharmaceutical company may provide donations of money or equipment to healthcare organisations (such as hospitals). This is not considered a promotional activity, as long as the donations to healthcare organisations are intended to enhance patient care, including donations in relation to the services provided by HCPs or procurement of pharmaceutical products for the patient's treatment.

Additionally, there is no monetary limit applicable on donations to healthcare organisations to enhance patient care.

**4.5 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

No. Providing medical or educational goods and services to HCPs with the aim of inducing changes in their prescribing pattern is prohibited according to the PReMA Code.

**4.6 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Discount arrangements are not in the scope of the advertisement regulation. In practice, pharmaceutical companies can give reasonable and fair-marketed discounts and rebates to HCPs and healthcare institutions in Thailand according to the PReMA Code.

**4.7 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?**

No. Providing or paying for additional medical or technical services, contingent on the purchase of medicinal products, is prohibited according to Section 90 of the Drug Act and PReMA Code.

Commercial arrangements associated with any benefits, like package deals, are also not acceptable if contingent on the purchase of medicinal products.

**4.8 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Yes. Pharmaceutical companies are required to offer a refund or exchange scheme if, for example, the product's shelf-life is too short or the product does not work. This obligation applies to both prescription-only medicine and over-the-counter medicine.

**4.9 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?**

Yes. According to the Ethical Criteria for Medicinal Drug Promotion in Thailand B.E. 2559 (2006), pharmaceutical companies can, upon consideration from themselves and HCPs, offer special financial terms to supply medicinal products to patients who would otherwise be unable to afford said products.

**4.10 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?**

Yes. It is possible for pharmaceutical companies to collaborate with the National Health Security Office, Social Security Funding Office and Comptroller General Department, which are the state agencies regulating the National Health System. Particularly, both pharmaceutical companies and the National Health System work together on the procurement of medicines, distribution and logistics and the Patient Access Scheme. The pharmaceutical companies shall make sure that when collaborating with the state agencies, they comply with the relevant laws and regulations, particularly regarding their interaction with government officials and anti-corruption/anti-bribery related laws (see question 4.12).

**4.11 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes. Pharmaceutical companies are permitted to sponsor scientific meetings and congresses for CME. Such sponsorship must adhere to the ethical guidelines stipulated, following the PReMA Code to ensure that the primary focus is the educational purpose of enhancing medical knowledge, and that the content provided is fair, balanced and objective, rather than promoting specific products or influencing HCPs' use of the products.

**4.12 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and**

**enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The main legislation governing anti-bribery applicable to interactions between pharmaceutical companies and HCPs are the Criminal Code and the Anti-Corruption Act.

The interactions between pharmaceutical companies and HCPs/healthcare organisations are covered predominantly by the Drug Advertising Regulation and procurement of medicinal products. In cases where an interaction involves the inducement of prescription of medicinal drugs, endorsement of the product quality, etc, which may fall within the scope of an offence defined in the Criminal Code and Anti-Corruption Act, both regulatory and criminal liability will arise.

Thailand does not criminalise "private-private" bribery (i.e., when the bribe giver and bribe receiver are both private sector parties). However, an exception to this would be if the private sector bribe-giver and bribe-receiver are involved in bidding for a government project.

Under the Anti-Corruption Act, a state official can receive property or any other benefit from a person who is not a relative of the state official when it is given on an "ethical basis" under the circumstances, does not exceed THB 3,000 in value per occasion, and is meant for the general public. An example of "ethical basis" is when giving or receiving a gift is generally considered proper under normal social norms in Thailand and when the gift/benefit is not intended to induce the official (i.e., is not a bribe in disguise).

This aligns with the industry's code of conduct, the PReMA Code; any benefits provided to HCPs must never constitute an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

The anti-bribery authorities have the power to investigate any matter that might involve corruption or bribery, even if they overlap with ongoing assessments by the Thai FDA. Thus, it is possible for anti-bribery authorities to investigate cases involving pharmaceutical advertising when suspicions of bribery or corruption arise.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Neither the Drug Act, nor its regulations, prescribe the interaction with HCPs, hospitality and related payments. However, the PReMA Code addresses the appropriate offering of hospitality to HCPs. Provision of hospitality should be incidental and conducive to the academic event attended by HCPs. Hospitality offered at a place known for entertainment, at a place unreasonably far from the event's venue, at a time clearly conflicting with or unrelated to the event's schedule, thus potentially impacting each HCP's family members, should be avoided. Expenses for hospitality or meals provided to each HCP should be modest. Luxurious hospitality (e.g., champagne reception, gala dinner) should be avoided.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Yes. According to the PReMA Code, a pharmaceutical company may pay expenses for an HCP regarding travel, accommodation and enrolment fees in connection with attending a scientific meeting. However, if the HCP is not engaged as a consultant/speaker, it is not appropriate to pay him/her expenses for his/her time to attend a scientific meeting.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Generally, pharmaceutical companies are allowed to sponsor scientific meetings, wherein it may provide sponsorship to HCPs to attend. The pharmaceutical company will be responsible for obtaining the advertising licence as discussed in section 1.

Invitations to attend medical and scientific meetings must only be given to HCPs, not to their spouse or family members. Sponsorship must be limited to the payment of travel, meals, accommodation and registration fees. Guests may not be invited, nor expenses of persons accompanying the attendee paid for.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes. The pharmaceutical companies may pay HCPs to provide expert services, such as participating in advisory boards. Kindly refer to our response to question 4.2.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes. Post-marketing surveillance studies should not be conducted in a manner that it is a disguised form of marketing promotion. Kindly refer to our response to question 4.2 for details.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes. Kindly refer to our response to question 2.7 for details.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes. The advertisement of a non-prescription medicine that is classified as an over-the-counter drug under the Drug Act is allowed as long as the advertising licence has first been obtained by the Thai FDA.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The Drug Act prohibits the advertisement of prescription-only medicines (i.e., dangerous drugs and specially controlled drugs following the definition under the Drug Act) to the general public.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are permitted so long as they are carried out without mentioning the brand name of medicines.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Pharmaceutical companies have the freedom to issue a press release in relation to corporate social responsibility, innovation and R&D activities of its pipeline products without mentioning the brand name. However, any press release pertaining to the launch of prescription-only medicines in non-scientific journals is considered the advertising of medicines to the general public, which is not allowed under the Drug Act.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

The advertising rules shall apply in this case. Please see our answer to question 6.4 above.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The Drug Act and the PReMA Code do not restrict interactions between pharmaceutical companies and patients or patient organisations. Companies may financially support a meeting organised by patient organisations with the aim of patient education and disease awareness.

When working with patient organisations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. Companies may provide financial support for patient organisation meetings, provided that the primary purpose of the meeting is professional, educational and scientific in nature, or otherwise supports the mission of the patient organisation. If companies provide financial support or in-kind contributions to a patient organisation, it is advisable to have in place written documentation setting out the nature of the support, including the purpose and funding of any activity.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Yes. If any such item is given to patients as a giveaway or gimmick item attached with the product brand or trademark, it is considered as advertising and, as such, an advertising licence must be obtained from the Thai FDA.

**6.8 What are the rules governing company funding of patient support programmes?**

The Drug Act does not govern company funding of patient support programmes. Please see our answer to question 6.6 above.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

No. Under the PReMA Code, companies are committed to the transparency of any clinical trials that they sponsor. It is recognised that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, patients and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property related laws and contract rights, as well as under the Personal Data Protection Act.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

No. It is not mandatory to disclose Transfers of Value provided by companies to HCPs.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

No. There is no self-regulatory code for companies to make publicly available information pertaining to Transfers of Value provided by them to HCPs.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

This is not applicable in Thailand.

## 8 Digital Advertising and Social Media

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Apart from the Drug Act and its regulations, Internet advertising is also regulated under the Computer Crime Act BE 2550 (2007).

Only non-prescription medicines that are classified as over-the-counter drugs under the Drug Act are allowed to be advertised via the Internet (including social media). Nonetheless, the advertising licence is a mandatory requirement (kindly refer to our response to question 6.1 above).

**8.2 What, if any, level of security is required to ensure that members of the general public do not have access to websites or digital platforms intended for healthcare professionals?**

Websites or digital platforms intended for HCPs must include access restrictions. The application of the advertising licence with the Thai FDA must provide information on how the advertising is restricted to HCPs only. For example, HCPs may be required to register a username and password provided by the advertiser following identification of the HCPs.

**8.3 What rules apply to the content of independent websites or digital platforms that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent sites to a company's website or platform? Will the company be held responsible for the content of the independent site in either case?**

If there is a link of an independent website from the company-sponsored site and the content is considered as the advertising of medicines, then the advertising regulation is applied, i.e., the company-sponsored site must first obtain an advertising licence from the Thai FDA. The regulatory officials also routinely monitor the content linked via the company's website/platform, including reviewing information following the scanning of the QR code as displayed on the company's website/platform.

The Computer Crime Act shall apply only if the company's website or its linked website displays or contains false, distorted or forged information or dates in such a way that is likely to cause damage to the public. As such, the company shall be responsible for the content of the independent site.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

The website of a pharmaceutical company may provide corporate information, such as the company's history and value, Good Manufacturing Practice (GMP) and quality standard achievement, development of product pipelines/R&D, press releases, unbranded disease awareness campaigns and contact information without mentioning the product tradename.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no specific rules or any guidance to control the use of social media by companies. However, it is the responsibility of companies to control the use of social media by its employees in order to prevent violation of the Drug Act and Computer Crime Act.

**8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?**

No. There are no restrictions on social media activity by company employees using their personal accounts.

**8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?**

Yes. During the COVID-19 pandemic, there was an increase of virtual online meetings among HCPs. Consequently, the advertisement of medicinal products directed to HCPs changed to advertising directed to HCPs during the virtual meeting/online conferences. Considering this, the Thai FDA has issued a circular letter, stating that it allows pharmaceutical companies with existing advertising licences to extend the promotional marketing activities for the same advertising content in virtual meetings of the HCPs.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

In July 2023, the Thai FDA developed an online system for the submission of advertising applications. Some advertising applications shall be granted automatically, such as giveaway or gimmick items attached with the trademark or brand name of medicinal products.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

No, there are no significant developments expected in this field over the next year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Yes. The enforcement of the Thai FDA has become more apparent in Thailand over the last few years, particularly the monitoring of online advertising. Upon discovering or receiving reports of a violating advertisement, the Thai FDA will investigate and collect evidence of the alleged violation. Subsequently, the Thai FDA will issue warning letters to the advertiser to remove the advertisement from the online platform and a warning of the penalties of violation of advertising regulations.

**Dr. Atthachai Homhuan** is the director of the regulatory affairs group at Tilleke & Gibbins. He assists biotechnology, chemical, life sciences and pharmaceutical companies to draft and review patent claims and specifications and advises patent agents on amending claims and providing responses to office actions. Atthachai frequently drafts counterstatements against opposing parties in trademark and patent applications and his practice also includes advising on pre-litigation and litigation matters involving life sciences, medical devices and pharmaceuticals. He has presented before the IP&IT Court as a witness in chemistry and life sciences patent litigation.

**Tilleke & Gibbins**
Supalai Grand Tower, 26th Floor
1011 Rama 3 Road, Chongnonsi, Yannawa
Bangkok 10120
Thailand

Tel: +66 2056 5610
Email: atthachai.h@tilleke.com
LinkedIn: th.linkedin.com/in/atthachai-homhuan-06018199

**Alan Adcock** is a partner in the Tilleke & Gibbins intellectual property and regulatory affairs groups, helping to oversee the firm's client work in these areas across ASEAN. He is recognised as a leading intellectual property lawyer based on his handling of corporate IP matters, including licensing and acquisitions, and his knowledge in life sciences, fluency in Mandarin and outstanding client service. Since 2005, Alan has received recognition by *Asialaw Leading Lawyers* as one of Asia's leading business lawyers in the area of intellectual property, and he has been named a top IP lawyer in Thailand by *The Legal 500 Asia Pacific* and *WTR 1000*.

**Tilleke & Gibbins**
Supalai Grand Tower, 26th Floor
1011 Rama 3 Road, Chongnonsi, Yannawa
Bangkok 10120
Thailand

Tel: +66 2056 5871
Email: alan.a@tilleke.com
LinkedIn: th.linkedin.com/in/alan-adcock-82b102a

**Chanya Veawab** is an associate in Tilleke & Gibbins' intellectual property and regulatory affairs department in Bangkok. She ensures that domestic and international clients receive maximum protection for their trademarks under Thai law by handling trademark searches and assisting with new applications, registrations, oppositions, analysis of objections, licensing agreements and other trademark-related matters across multiple jurisdictions.

**Tilleke & Gibbins**
Supalai Grand Tower, 26th Floor
1011 Rama 3 Road, Chongnonsi, Yannawa
Bangkok 10120
Thailand

Tel: +66 2056 5880
Email: chanya.v@tilleke.com
URL: www.tilleke.com/professionals/chanya

**Kunanon Sereesawetrat** is a consultant in Tilleke & Gibbins' regulatory affairs team in Bangkok, where he assists clients with matters related to medicinal products, medical devices and healthcare-related innovations. He has extensive experience in product registration with the Thai Food and Drug Administration and advises clients about Good Manufacturing Practice (GMP) guidelines, Good Storage and Distribution Practices (GSDP), and Good Clinical Practice (GCP) guidelines for clinical trials.

**Tilleke & Gibbins**
Supalai Grand Tower, 26th Floor
1011 Rama 3 Road, Chongnonsi, Yannawa
Bangkok 10120
Thailand

Tel: +66 2056 5672
Email: kunanon.s@tilleke.com
LinkedIn: th.linkedin.com/in/k-sereesawetrat

# International Comparative Legal Guides

The **International Comparative Legal Guide** (ICLG) series brings key cross-border insights to legal practitioners worldwide, covering 58 practice areas.

**Pharmaceutical Advertising 2024** features two expert analysis chapters and 23 Q&A jurisdiction chapters covering key issues, including:

- Providing Information Prior to Authorisation of Medicinal Product
- Advertisements to Healthcare Professionals
- Gifts and Financial Incentives
- Hospitality and Related Payments
- Advertising to the General Public
- Transparency and Disclosure
- Digital Advertising and Social Media
- Developments in Pharmaceutical Advertising

The International Comparative Legal Guides are published by: glg Global Legal Group