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Pharmaceutical Advertising 2022

Thailand: Law & Practice

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THAILAND

Law and Practice

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1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Laws Regulating Advertising on Medicines

In Thailand, the main pieces of legislation governing the advertising of medicines are:

- Drug Act BE 2510 (1967), as amended ("Drug Act") – Sections 88-90; and
- Regulations of the Thai Food and Drug Administration on Advertisements of Drugs for Sale BE. 2545 (2002) ("Advertisement Rules").

Codes Regulating Advertising on Medicine

Although there are no self-regulatory codes on advertising medicines which apply to the entire pharmaceutical industry, pharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers Association ("PReMA") must comply with the PReMA Code of Sales and Marketing Practice. The current version is 12th edition – 2019 ("PReMA Code").

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Pharmaceutical companies that are members of the PReMA must comply with the PReMA Code.

- The PReMA Code provides the standards for the industry's practice of promotional activities, including organising conferences for healthcare professionals (HCPs), interaction with HCPs, etc.
- Many pharmaceutical companies, including non-members of PReMA, tend to follow the same standards as a courtesy and to ensure fair competition within the industry.
- Although the PReMA Code is not considered to be law, and the Thai Food and Drug Association (FDA) does not have the authority to enforce it, a violation of the PReMA Code may be reviewed by the PReMA Committee, which has the power to sanction its members.

2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

2.1 Definition of Advertising

The Drug Act does not provide a specific definition of "advertisement". In the view of the Thai FDA, any activities undertaken, organised or sponsored by a pharmaceutical company with the objective to encourage the prescription, supply or administration or consumption of its pharmaceutical product(s) through all methods of communications (including the internet) are considered an advertisement.

The FDA's Advertisement Rule 2002 explains that advertising may be classified into two main categories:

- advertisements targeted at the general public – permissible for household remedy drugs (similar to over-the-counter (OTC) drugs in other countries); and
- advertisements targeted at healthcare professionals – applicable for both household remedy drugs and non-household remedy drugs (eg, pre-packed drugs, dangerous drugs and specially controlled drugs).

In Thailand, drugs are divided into four categories based on the channel of distribution.

- "Household remedies" which are equivalent to OTC drugs. Products in this category can be sold without a prescription and do not require to be dispensed by a pharmacist.
- "Pre-packed drugs" which are not "dangerous drugs" or "specially controlled drugs" can

be sold without a prescription at a drugstore but must be dispensed by a licensed practitioner (ie, a medical doctor, dentist, nurse, veterinarian or pharmacist).
- "Dangerous drugs" can be sold without a prescription, but must be dispensed by a pharmacist only. The majority of pharmaceutical products in Thailand fall in this category.
- "Specially controlled drugs", which may result in potentially harmful effects if misused, can be dispensed by prescription only. Furthermore, some specially controlled drugs are only available in hospitals.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Information such as on a disease awareness campaign is not considered to be advertising, as long as the materials are unbranded and are not intended to promote the use of a product through advertising. There are no differences based on the target audience (eg, HCPs or the general public).

2.3 Restrictions on Press Releases regarding Medicines

Restrictions on press releases differ depending on the drug category and target audience. As mentioned in **2.1 Definition of Advertising**, only household remedy drugs (or OTC drugs) can be advertised directly to the general public (eg, through mainstream media). Advertisements for non-household remedy drugs are limited to HCPs only.

Restrictions on Press Releases of Household Remedy Drugs

There are no restrictions on press releases or media releases related to household remedy drugs. Nonetheless, the material or media is subject to FDA review and approval before dissemination.

Restrictions on Press Releases of Non-household Remedy Drugs

Press releases or media releases related to non-household remedy drugs wherein the general public (or layperson) is a target audience, are not allowed by the Thai FDA. Advertisements of non-household remedy drugs are limited to HCPs only.

However, the above provision does not prevent pharmaceutical companies from responding to media enquiries or sharing the scientific/technical achievements of their drug products in a current, accurate and balanced manner (Chapter 13.2 on Media Release, PReMA Code).

2.4 Comparative Advertising for Medicines

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 pharmaceuticals. According to the 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. Disparaging references to other products or manufacturers must also be avoided.

3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is not possible to advertise information on unauthorised medicines or unauthorised indications (off-label use).

Restrictions on Unauthorised Medicines

No pharmaceutical products or medicines can be promoted for commercial purposes until market authorisation approval of the product has been obtained from the Thai FDA.

Restrictions on Unauthorised Indications (Off-Label Use)

Promoting or advertising a pharmaceutical product for use other than for the purpose approved by the Thai FDA is restricted under the Drug Act and Advertisement Rules. Specifically, the Drug Act states that an advertisement for the sale of a pharmaceutical product may not falsely or exaggeratedly show its therapeutic properties.

However, these provisions do not prevent pharmaceutical companies from sharing or exchanging scientific information on unauthorised medicines or unauthorised indications with HCPs. Materials that contain only scientific information and are scientific or educational in nature (ie, do not include any references to product branding or the company) would not be deemed an "advertisement" under the Drug Act and would therefore not need to obtain pre-approval from the Thai FDA.

3.2 Provision of Information during a Scientific Conference

Information an unauthorised medicine or an unauthorised indication for academic purposes, provided by an academic researcher, is acceptable. On the other hand, provision of the information by the company without a request from HCPs, or at a company-sponsored event, is not allowed.

Such information should be provided or discussed only when there is a request from HCPs. To mitigate risk, it is advisable to:

- present balanced information scientifically relating to the topic, such as giving updates on the treatment of a certain disease, covering all relevant drugs and treatment methods, without the tone of promoting non-approved products or indications;
- use a generic name as opposed to the product's trade name or trade mark; and
- avoid displaying any brandings, logos, banners, slogans or statements that may be construed as promotional in nature.

3.3 Provision of Information to Healthcare Professionals

As for **3.2 Provision of Information during a Scientific Conference**, pharmaceutical companies are not allowed to proactively send information on unauthorised medicines or unauthorised indications to HCPs. Pharmaceutical companies may only respond to unsolicited requests from HCPs or medical associations for scientific information on unauthorised medicines or unauthorised indications.

3.4 Provision of Information to Healthcare Institutions

Information on unauthorised medicines or unauthorised indications should not be presented to healthcare institutions. Pharmaceutical companies may send such information only upon receiving a written request from the healthcare institution.

3.5 Publication of Compassionate Use Programmes

There are no specific restrictions on publication of the availability of a compassionate use programme. Nonetheless, it is advisable to comply with the general rules for advertising a pharmaceutical product through HCPs. This strict and conservative approach will help to reduce legal risk.

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4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

As a general rule, drug advertisements (either directed at the general public or HCPs) must be reviewed and approved by the FDA before dissemination. The main restriction on advertisements targeted at the general public is that these advertisements are only permissible for household remedy drugs.

Non-household remedy drugs (such as dangerous drugs and specially controlled drugs) cannot be advertised to the general public. Direct-to-consumer marketing activity for non-household remedy drugs is limited to activities that help create disease awareness or improve patient education and basic healthcare education.

Summary of Restrictions on Advertisements Directed at the General Public

Sections 88–89 of the Drug Act state that advertisements must not:

1) claim that a medicine can miraculously or absolutely treat, cure, or prevent a disease or illness;

2) exaggerate or falsely declare properties of the medicine;

3) give the impression that the drug has a substance as its main or component ingredient that it either does not have or has in a lower quantity than is believed to be present;

4) give the impression that it is an abortifacient or a strong emmenagogue (promoting menstrual flow);

5) give the impression that it is an aphrodisiac or a birth control drug;

6) present therapeutic claims for a dangerous or a specially controlled drug;

7) contain certification or endorsement of its therapeutic properties by any other person; and

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 disorders, or cardiovascular, lung, kidney, spleen or liver disorders, etc).

Points (1), (4), (5), (6), (7) and (8) above do not apply to advertisements directed at HCPs.

The FDA's Advertisement Rules prescribe that advertisements must not:

- be contrary to tradition, such as local beliefs, norms, and morals;
- persuade patients to consume the product more than necessary or create a misunderstanding that the product should be used regularly;
- make a comparison that would defame other products;
- cause consumers to misunderstand that the drug is equivalent to other products, such as food or cosmetics; or
- encourage acts or activities contrary to law.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Information that Cannot Be Advertised to the General Public or Consumers

- Therapeutic claims of dangerous or specially controlled drugs;
- therapeutic claims related to the drug being an abortifacient or a strong emmenagogue;
- therapeutic claims related to the drug being an aphrodisiac or a form of birth control;
- therapeutic claims related to diseases for which advertisement is prohibited under a notification from the Minister of Public Health (eg, cancer, diabetes, paralysis, psychiatric disorders, blood pressure disorders, AIDS, health conditions related to neurological disorders, or cardiovascular, lung, kidney, spleen or liver disorders, etc); and
- other statements as prescribed in the FDA's Advertisement Rules.

Information that Can Be Advertised to the General Public or Consumers

- Name(s) of the active ingredient(s) – International Non-proprietary Names (INN) and approved generic drug names are acceptable;
- brand name;
- composition of drug product, eg, name or amount of inactive ingredient(s);
- therapeutic claims or indications;
- dosage or treatment regimen;
- name and address of manufacturing site or distributor;
- advertisement approval number granted by the Thai FDA;
- if there is a citation for reference, the required statement must be: "For further information, please see the full version of the reference or the package insert";
- price; and
- other statements as prescribed in the FDA's Advertisement Rules.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The laws and self-regulatory code (PReMA Code) do not restrict interaction between pharmaceutical companies and patients or patient organisations.

Declaration of Involvement

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.

Written Documentation

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.

5. ADVERTISING TO HEALTHCARE PROFESSIONALS

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertisements for dangerous drugs and specially controlled drugs can only be targeted at HCPs. However, only products that are registered in Thailand can be promoted to HCPs. No pharmaceutical products can be promoted until the required marketing authorisation has been obtained.

Information that Cannot Be Advertised to HCPs

- exaggeration or false declaration of the properties of the medicine (including off-label use and unauthorised indications);
- comparisons that would defame other drug products;
- statements that persuade consumers or HCPs to use the drug persistently and unnecessarily, or lead consumers to understand that it is appropriate to take the drug regularly; and
- misleading statements demonstrating that the drug has a substance as a main or component ingredient that it either does not have or has in a lower quantity than believed to be present.

For further information on advertising restrictions, see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**.

The same information can be advertised to HCPs as can be advertised to the general public. For a detailed list, see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

There is no restriction on referring to scientific data that is not included in the summary of product characteristics (SPC). Scientific data includes academic publications (eg, official pharmacopoeias, textbooks, journals, research studies, experimental results, etc). Nonetheless, this scientific data must not be contrary to the information as approved in the SPC.

Presentations of scientific data should follow these general requirements:

- scientific data or references used as proof or support of content in an advertisement must be accurate, reliable and in accordance with international principles;
- advertising content must align with the details in the product leaflet or package insert (eg, dosage, therapeutic properties, indications, etc) and experimental results;
- for statistical studies, the full statistical data must be specified (eg, p-value, sample size, etc);
- the name of the experimental study must be shown, and the name of the sponsor must be disclosed; and
- the statement "For further information, please see the full version of the package insert or relevant technical documents" must be added.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Drug advertisements may refer to combination products or companion diagnostics, as long as the advertising material has received prior approval from the Thai FDA. In order to obtain advertising approval, scientific evidence substantiating the advertising of combination products must be provided to the Thai FDA.

Assuming that the combination product or companion diagnostic is a medical device, the advertisement must be reviewed and approved per the relevant medical device legislation as well.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

There is no restriction specifically on providing HCPs with educational information or reprints of journal articles. However, companies should provide reprints of journal articles only after receiving a request from an HCP. Furthermore, companies should ensure that the journal article is accurate, balanced and does not focus on a particular product or contain unfair comparisons.

5.5 Medical Science Liaisons

Thai law does not restrict discussion or interaction between medical science liaisons (MSLs) and HCPs. Nonetheless, as mentioned earlier, information on unauthorised medicine or indications should not be explicitly presented. Therefore, MSLs should not proactively discuss unauthorised medicines or indications with HCPs. MSLs may discuss such information only upon receiving an unsolicited request from an HCP.

6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

6.1 Requirements for Prior Notification/ Authorisation

Competent Authorities

The government agencies responsible for monitoring the advertising of drug products are:

- the Thai FDA; and
- the Public Health Provincial Office (for advertisements in provinces other than Bangkok).

Both regulatory authorities are under the supervision of the Ministry of Public Health (MOPH).

Requirements

Advertising for medicines directed at the general public or HCPs must receive prior authorisation from the Thai FDA or the Public Health Provincial Office (for advertisements in that particular province).

All advertising materials must be submitted for prior authorisation by filing an application together with the advertising materials for the FDA's review and approval before dissemination. The advertising licence is valid for a period of five years and is not renewable.

For more information regarding advertising requirements, see **4. Advertising Pharmaceuticals to the General Public** and **5. Advertising to Healthcare Professionals**.

6.2 Compliance with Rules on Medicinal Advertising

To reduce legal risk, companies should comply with the general rules for advertising a pharmaceutical product found in the following:

- the Drug Act;
- the Regulation of the Food and Drug Administration Re: Requirements on Advertising of Drugs BE 2545 (2002); and
- the PReMA Code.

There is no requirement to adopt SOPs or employ specific personnel to ensure compliance with rules on the advertising of medicines.

The PReMA Code suggests that companies are responsible for ensuring internal compliance with all provisions of the PReMA Code and rules on the advertising of medicines. Specifically, a designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. Alternatively, a senior company employee may also be made responsible on the condition that they receive scientific advice on the promotional materials and communications from adequately qualified scientific personnel (Chapter 14 Company Procedures and Responsibilities, PReMA Code).

7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising on the internet for medicinal products is regulated under the Drug Act, FDA's Advertisement Rules and the PReMA Code (the same provisions as imposed for other advertising media).

Only household remedy drugs can be advertised online directly to the general public. For non-household remedy drugs, all direct-to-consumer marketing activities are prohibited.

For further information, regarding advertising requirements/restrictions, see **4. Advertising Pharmaceuticals to the General Public**.

7.2 Advertising of Medicines on Social Media

As for **7.1 Regulation of Advertising of Medicinal Products on the Internet**, only household remedy drugs are allowed to be advertised through social media. Advertising for medicines classified as non-household remedy drugs is not allowed on social media.

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Websites with advertisements or other information only intended for healthcare professionals must include access restrictions in order to allow only the intended target audience to view the information.

7.4 Provision of Disease Awareness Information to Patients Online

Under the PReMA Code, companies are allowed to provide disease awareness information or materials to patients online, on the condition that the information or materials adhere to the highest standards of accuracy and support the role of healthcare professionals. Furthermore, websites providing general information to the public must be general and cannot include product promotional information or individual medical advice (Chapter 13.4 Telephone Hotline and Website, the PReMA Code).

7.5 Online Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings and congresses. There are no specific criteria for distinguishing international events from national events. In general, an online conference may be considered an international event if the event is organised by multinational organisers and it features speakers from other countries.

To host a scientific meeting or congress, companies do not need to obtain prior approval from the regulatory authority. However, advertising materials to be disseminated at the event may be subject to FDA review and approval if the materials fall within the scope of advertising.

In response to the COVID-19 pandemic forcing meetings to move online, on 21 September 2020 the FDA published a circular that clarified what types of advertising materials were approved for use in virtual meetings. The circular outlines prior authorisation requirements for the display of materials during the online conference, stating that online materials used in teleconferences or virtual meetings must still be submitted to the FDA for approval, regardless of whether the materials were previously approved by the FDA for other publication formats (eg, as printed materials).

The advertisers must also submit the following documents for review by the FDA:

- a pledge that they will follow the conditions for additional media platforms; and
- a copy of their drug advertising licence for the advertising material currently approved by the FDA.

After the FDA has approved the material for use on additional media platforms, the advertising or promotional material must display the approval number of the advertising licence.

Only material that does not contain the trade name or company name and is used only for educational purposes, is free from the requirement for FDA pre-approval.

8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The main anti-bribery laws that apply to interactions between pharmaceutical companies and HCPs are:

- the Penal Code;
- the Organic Act on Counter Corruption BE 2561 (the "OACC"); and
- the Act on Offences Relating to the Submission of Bids to State Agencies BE 2542 (the "Submission of Bids Act").

The bribery addressed in these laws all relates to wrongful payments involving government officials. The Penal Code and OACC criminalise giving bribes to government officials. These laws also criminalise the acceptance of bribes by government officials. The Submission of Bids Act further criminalises bribes related to public procurement. Thailand does not criminalise "private-sector" bribery (ie, 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. The general elements of these laws are as follows.

Giving, Offering, or Agreeing to Give a Bribe

The Penal Code and the OACC prohibit giving, offering or agreeing to give property or any other benefit to induce state officials or assembly members to perform, avoid or delay an act that contradicts their functions. The definition of "state official" in the OACC also includes foreign state officials and international organisation officials.

Under the OACC, a legal entity can be criminally liable for the wrongful activity of its employees, agents and others acting on behalf of the entity (called "associated persons" in the law), even if the associated person gave the bribe without management's authorisation. In such a case, the legal entity can be liable for the bribery if the associated person committed the act for the benefit of the legal entity, and the entity did not have proper internal measures (ie, an anti-corruption compliance programme) to prevent the bribe.

The Submission of Bids Act prohibits offering or agreeing to give property or any other benefit to induce another person to dishonestly participate or not participate in the submission of bids for the benefit of any person.

Demanding or Accepting a Bribe

The Penal Code and the OACC prohibit state officials and assembly members from demanding, accepting or agreeing to accept property or any other benefit that affects his or her duties. The definition of "state official" in the OACC also

includes foreign state officials and international organisation officials.

The Submission of Bids Act extends the prohibition to any person from demanding, accepting or agreeing to accept property or any other benefit. To be guilty under the Submission of Bids Act, the bribe receiver must have the intention of demanding, accepting, or agreeing to accept property or any other benefit to dishonestly participate or not participate in submission of bids for the benefit of any person.

Intermediaries

The Penal Code and the OACC prohibit an intermediary from demanding, accepting, or agreeing to accept property or any other benefit as compensation for influencing a state official and assembly member to perform or not perform his or her duties for an advantage or disadvantage for anyone. The definition of "state official" in the OACC also includes foreign state officials and international organisation officials.

Permitted Gifts/Benefits to State Officials

Under the OACC 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; and
- does not exceed THB3,000 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 social norms in Thailand, and when the gift/benefit is not intended to influence an official (ie, is not a bribe in disguise).

8.2 Legislative or Self-Regulatory Provisions

Under the PReMA Code, gifts and other items provided to HCPs must never constitute an inducement to prescribe, recommend purchase, supply, sell, or administer a pharmaceutical product. Pharmaceutical companies should not provide direct sponsorship for HCPs to attend sporting or other entertainment events, as this can be seen as inducement. Lastly, company representatives and organisations must not employ any inducement or subterfuge to gain a contract from an HCP and must not be paid for that purpose.

9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

9.1 Gifts to Healthcare Professionals

Pharmaceutical companies may only offer gifts to HCPs under certain situations and with monetary limitations. Payment in cash or cash equivalents (such as a gift voucher) must not be offered to HCPs, and gifts for the personal benefit of HCPs are prohibited.

However, gifts to HCPs and institutions for customary and acceptable local occasions are allowed on an infrequent basis. The value of such gifts, the nature and type of which should be related to the particular customary occasion, must not exceed THB3,000 per healthcare professional, per occasion according to the PReMA Code.

Frequency

The restriction under the PReMA Code is that medical representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid for that purpose.

Provision of Hospitality

There are no explicit restrictions on provision of hospitality, but the PReMA Code stipulates that sponsorship of healthcare professionals is limited to payment of legitimate travel, registra-

tion fees, meals and accommodation only for the period and location of the sponsored event. Reimbursement of expenses against official receipts is possible, but no cash advance to an HCP is allowed.

Other Indirect Incentives

Indirect incentives are not allowed to be given to HCPs.

9.2 Limitations on Providing Samples to Healthcare Professionals

The Drug Act does not address the issue of pharmaceutical companies providing free samples to HCPs. However, the PReMA Code provides that samples of products may only be supplied to a healthcare professional upon their consent. The size and quantity of the sample supplied should be appropriate for the following:

- to allow the HCP to become familiar with the presentation and appearance of the product;
- to provide to patients for initiation of therapy; or
- to conduct an agreed-upon clinical evaluation of the product.

All samples delivered by sole distributors or medical representatives, or via mail or courier, should be securely packed and must be signed for by the receiver.

Under the PReMA Code, the term "drug sample" means a unit of a drug that is not intended to be sold and is intended for one of the reasons stated above. No person may sell or trade, or offer to sell or trade, a drug sample.

9.3 Sponsorship of Scientific Meetings

Generally, pharmaceutical companies are allowed to sponsor scientific meetings or congresses and attendance by HCPs at these events. It is also permissible to sponsor healthcare professionals to attend an international congress, and to invite them to a satellite symposium at a congress they are already attending.

However, it is prohibited to run an overseas stand-alone company-sponsored meeting for HCPs where all (or nearly all) of the attendees or speaker(s) are from Thailand.

Furthermore, the PReMA Code contains a guideline that symposiums and congresses (local and international) initiated by a pharmaceutical company (local only), its regional office, or its corporate headquarters, must devote at least 75% of the total time to scientific sessions, outside of reasonable travel time. Any hospitality, entertainment or gimmick provided by drug 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.

Invitations to attend medical and scientific meetings must only be given to HCPs. Sponsorship must be limited to the payment of travel, meals, accommodation and registration fees. Guests may not be invited, and the expenses of persons accompanying the attendee may not be paid.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies should not provide direct sponsorship for HCPs to attend sporting or other entertainment events, as this can be seen as inducement.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide donations directly to a healthcare institution (but not individual HCPs) upon the institution's request to support activities for HCPs, as long as it can be demonstrated that there is a link to scientific

education, patient benefit or the improvement of healthcare services.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies are allowed to give discounts and rebates to HCPs and healthcare institutions in Thailand. Discounts or rebates associated with the sale of pharmaceutical products must be made by account payee cheque, bank transfer to a bank account associated with the respective hospital, or invoice (PReMA Code).

9.7 Payment for Services Provided by Healthcare Professionals

According to the PReMA Code, payment for services provided by HCPs must be agreed prior to their work as consultants and advisers providing services such as speaking at or chairing meetings and events; involvement in medical or scientific studies, clinical trials or training services; participation at advisory board meetings; or participation in market research involving remuneration. The following criteria from the PReMA Code must be satisfied when paid services are provided by HCPs:

- a written contract or agreement of the services must outline the nature of the services and the basis of payment for these services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting HCPs must be directly related to the identified need, and selected professionals must have the expertise necessary to provide the service;
- the number of HCPs providing the service must be only what is reasonably necessary to achieve the identified need;
- the engagement of the HCP(s) for the services must not be an inducement to prescribe, recommend, purchase, supply or administer any medicine; and
- the payment provided for the services must be reasonable and must be at an accepted, fair market rate (Chapter 7.3 Fee for Services, PReMA Code).

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Pharmaceutical companies can offer gifts, sponsorships, donations and payment to HCPs for services provided without prior authorisation or notification involving the regulatory authority.

10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Pharmaceutical companies are not required to disclose details of transfers of value to HCPs or healthcare institutions.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements do not apply to foreign companies or companies that do not yet have products on the market.

11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

11.1 Pharmaceutical Advertising: Enforcement Bodies

Regulatory Authorities

See **6.1 Requirements for Prior Notification/ Authorisation**.

Self-Regulatory Authorities

PReMA has an important role in supervising marketing activities which violate the PReMA Code. The Sales and Marketing Ethics Committee reviews the provisions of the PReMA Code after seeking input from interested parties at least every three years.

If a complaint regarding a breach of the PReMA Code is filed by another PReMA member, the complaint will be administered by the PReMA chief executive officer and the Code of Conduct Committee (CCC). When the allegedly breaching company or complainant disagrees with the decision of the CCC, they may request a second-instance ruling. The resubmission must be made in writing, along with any new evidence, within ten days of receiving the notification from the PReMA CEO. If new evidence or arguments are put forward, the other party will be invited to provide comments within 30 days. The decision of the CCC at this stage will be final.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In most cases, Thai law views violations of advertising requirements as a harm against the general public or an individual consumer. Harm against the general public is enforced by the state, as represented by the Thai FDA and most likely the responsible division of the Royal Thai Police. One or both of these would undertake the enforcement either by summary fines or by referring a criminal action to the court through the public prosecutor. If the violation also injures a consumer, then the consumer may bring a civil case against the advertiser, typically through consumer proceedings, which are more streamlined than general civil and commercial proceedings.

An advertising violation may also be a competitor's cause of litigation if the competitor itself is injured by the advertising, such as comparative advertising (which is generally prohibited) that is also libellous against the competitor.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The Drug Act sets out penalties or measures that regulators can impose for the violation of advertising rules for medicines and rules on inducement. The secretary-general of the Thai FDA can issue a written order to cease any advertisement deemed to be contrary to the Drug Act. If it is determined that the advertisement misled the public, the Thai FDA can order the violator to issue a corrective advertisement.

Violation of the Drug Act's marketing provisions is subject to a fine of up to THB100,000. Calculation of the fine depends on the amount of time it takes the advertiser to act after receiving a warning or notice of violation, and the number of occurrences of other wrongdoings. For example, if a promotional booth uses three posters and two gimmick gifts that have never been submitted for FDA approval, the violator could be fined for a combination of the five offences.

For PReMA members, if a complaint regarding a breach of the PReMA Code is filed by another PReMA member, the complaint will be administered by the PReMA chief executive officer and the organisation's CCC, which may sanction PReMA members.

Upon the decision of the CCC, the PReMA CEO may order one or more of the following actions:

- referring the complaint to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA);
- referring the complaint and the CCC's findings to the head office and regional office of the offending company;
- suspending the offending company's membership of PReMA for up to three years;
- debarring the offending company from membership of PReMA;
- requiring a written undertaking that the practice complained about will be discontinued on or before a date to be determined by the CCC; and
- requiring retraction statements, including corrective letters and advertising, to be issued by the company, subject to the approval of the CCC prior to release.

It is the company's responsibility to ensure that the requirements of the CCC are met and to immediately inform and provide evidence to PReMA of their fulfilment.

PReMA may also fine the company up to THB100,000 (EUR2,480) for a first offence or up to THB500,000 (EUR12,395) for a second offence within a 12-month period. The imposed fine is to be paid within 30 days of being issued, subject to any appeal that may be lodged.

11.4 Relationship between Regulatory Authorities and Courts

Procedures before the self-regulatory authority are considered internal undertakings of a private entity (ie, an association). As such, the measures taken by the self-regulatory authority are, unlike an arbitral award, not enforceable by the court without a trial.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

While enforcement actions against pharmaceutical advertising in Thailand are taken regularly, there has not been any recent trend pointing to a change of policy, organisational structure, or the market landscape.

Contributed by: *Alan Adcock, Atthachai Homhuan, San Chaithiraphant and Kittiya Nopparatrungroj,* ***Tilleke & Gibbins***

Tilleke & Gibbins is a South-East Asian regional law firm with over 200 lawyers and consultants practising in Cambodia, Indonesia, Laos, Myanmar, Thailand and Vietnam. The firm provides full-service legal assistance to investors and companies that drive economic expansion in Asia. Established in Bangkok in 1890, today Tilleke & Gibbins is a major international firm with offices in six countries that prioritises understanding its clients' businesses and working with them towards their commercial goals. The firm is known for its deep local knowledge and commitment to this fast-developing part of the world, which is especially valuable to global companies needing to navigate unfamiliar markets and regulatory environments in South-East Asia. Clients who engage Tilleke & Gibbins are given a team of advisers who provide clear, practical advice; who are responsive in communications; who represent them with integrity; and who guide their clients through the available options to arrive at the most effective course of action, whether this means following well-established procedures or applying an innovative approach.

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