Thailand

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A. DISTRIBUTION

1. PRECONDITIONS FOR DISTRIBUTION

1.1 What are the legal preconditions for a drug to be distributed within the jurisdiction? Does the drug need to be licensed (authorised) for distribution? Are there exceptions or different categories such as compassionate use?

Prior to distributing modern and traditional drugs into Thailand, a pharmaceutical company or its distributor has to apply for an import license or a manufacturing license.

A modern drug is a 'drug intended for use in the practice of modern medicine or the cure of an animal disease', whereas a traditional drug means a

> *'drug intended for use in the practice of the traditional medicine or the cure of an animal disease which appears in a pharmacopoeia of traditional drug notified by the Minister of the Ministry of Public Health (Minister), or a drug notified by the Minister as a traditional drug, or a drug of which formula has been registered as that of a traditional drug.'*

The importer or a manufacturer has to comply with the following requirements:

be the owner of the business, and have sufficient assets and structure to be able to establish and operate the business;

- be at least 20 years of age;
- be resident in Thailand;
- have not been convicted for an offense against certain laws, such as laws concerning narcotics and psychotropic substances;
- have the premises to produce, sell, import, or store drugs and equipment for use in the production, sale, or storage of drugs, and the control or maintenance of drug quality and quantity as prescribed in ministerial regulations; and
- use a trade name for the drug business that is not a repetition of, or similar to, the trade name used by another active licensee or a licensee whose license has been suspended or revoked for less than a full year.

After the manufacturing license or import license is obtained, modern and traditional drugs are required to be registered with the Thai Food and Drug Administration (FDA) in order to be distributed in Thailand.

There are some rare exceptions under which some drugs do not require product registration. A doctor may sell drugs directly to his or her patients without having applied for a license to sell. Additionally, according to section 79(4) of the Drug Act B.E. 2510 (A.D. 1967), a drug imported

for research, analysis, exhibition, or charitable purposes does not require registration if it complies with the requirements set up by the Notification of the Ministry of Public Health No.14 (B.E. 2532 (A.D. 1989)) Regarding Bases, Procedures, and Conditions Respecting Importation of Medicines with No Need to Apply for Pharmacopeia Registration, as amended in 2009.

1.2 Are any kinds of named patient and/or compassionate use programmes in place? If so, what are the requirements for pre-launch access? (For EU countries only: has Article 5 (1) of Directive 2001/83/EC been transposed by your national legislator?)

Section 13(3) of the Drug Act states that drugs sold by medical practitioners to their patients only are not required to obtain a license from the regulator (ie, the FDA). However, a doctor would still be required to apply for an import license. Only ministries, sub-ministries (in their official disease prevention and treatment duties), the Thai Red Cross Society, and the Government Pharmaceutical Organisation may be allowed to import drug products without applying for an import license or product license (section 13(5)).

In addition, section 79(4) of the Drug Act states that medicines may be granted permission to be imported into Thailand based on the procedures and conditions prescribed by the Minister, with the approval of the Drug Board, a governmental body consisting, among others, the Permanent Secretary of the Ministry of Public Health as Chairman, the Directors–General of the Departments of Medical Services, Communicable Disease Control, Medical Sciences, and Health, and not less than five but not more than nine qualified members appointed by the Minister of which at least two must be practitioners of traditional medicine.

The Notification of the Ministry of Public Health No.14 (B.E. 2532 (A.D. 1989)) Regarding Bases, Procedures, and Conditions in Respect to Importation of Medicines with No Need to Apply for Pharmacopeia Registration, as amended in 2009, states that medicines imported into Thailand may be exempted from product registration with the FDA if they are used for research, analysis, exhibition, or charitable purposes. However, the right to import is limited to certain entities. For example, importation for research and analysis is limited to a manufacturer, importer, Ministry, Department with duties of prevention and treatment of diseases, the Thai Red Cross Society, and the Government Pharmaceutical Organisation.

Additionally, the importer must submit the relevant application and supportive documents proving that it falls into the scope of the exception.

A drug which is imported into Thailand for clinical research purposes must have the following relevant supporting documentation:

labels for all containers;

- investigator brochure;
- patient information sheet in the Thai language;
- synopsis of the clinical research in the Thai language;
- complete information relating to the clinical research;
- manufacturing and quality control of the drug; and
- approval as reported by the Institutional Review Board (IRB) or the

Independent Ethics Committee (IEC) in Thailand. This process is quite burdensome, as it requires complying with lengthy administrative steps. The relevant documents which are required when applying for importation of a drug for donation purposes are as follows: (i) labels of all of the containers; (ii) package inserts; and (iii) certificate of free sale.

1.3 What is the structure of the procedure regarding licensing a drug for distribution? Which national body (agency) is responsible for licensing?

Companies and individuals wishing to place a drug on the market must:

- Obtain a license from the FDA to manufacture, sell, or import drugs in Thailand. An import license must be renewed every year and is valid from 1 January to 31 December.
- After obtaining the import license, they must obtain an authorisation to manufacture and/or import drug samples.
- Finally, they must submit a full marketing approval application, together with samples, to the FDA for review and registration. Registration requirements differ for general drugs (which include generics, new medicines, and new generics) and traditional drugs. A drug product license does not require any renewal.

The regulation of drugs in Thailand is overseen by the Ministry of Public Health (MOPH). The Drug Control Division of the FDA, under the supervision of the MOPH, handles the four main aspects of drug regulation:

- pre-marketing control (including licensing and registration);
- post-marketing monitoring and surveillance;
- consumer education and dissemination of information;
- promotion of technological development and research for export.

1.4 Is there a simplified licence procedure or are there relaxed licensing conditions for drugs which have already been licensed for distribution in another jurisdiction?

No. Even if a company has already obtained a market authorisation issued in a foreign jurisdiction, it would not be able to benefit from a simplified or relaxed licensing and registration process. However, the application requires the applicant to inform the FDA of any approved and pending marketing authorisations for the product granted in other countries.

If the foreign marketing authorisation has been obtained in a country where the regulatory practice is credible and globally accepted, it would support the registration process, and could be used as evidence to support the application for marketing approval.

Additionally, following the ASEAN Harmonisation on Pharmaceutical Product Registration of 1 January 2009, the FDA implemented the ASEAN Common Technical Requirements and Dossier (ACTR/ACTD) on Quality, Safety and Efficacy, which provides guidelines on analytical and process validation, stability studies, and bioavailability/bioequivalence. It means that in ASEAN, the same requirements exist for all drug products, which facilitates the registration process. However, some local specificities still remain.

What about parallel imports, is there a simplified procedure for these?
Parallel imports are not regulated in Thailand, because the exhaustion of rights principle is recognised by most intellectual property laws in Thailand.

However, parallel imports are not permitted in the pharmaceutical sector, because it is mandatory for a company to preliminarily obtain an import license and product registration locally. Moreover, it is important to note that the FDA will not accept an application for a product that has a trademark that is identical to other products in the Thai market, unless this product has the same manufacturer and the manufacturer has given its authorisation to use and sell such product.

1.5 Is it possible to distribute drugs 'virtually' from your jurisdiction (ie, the physical products never enter the country but are distributed using the authorisation obtained in your country).

It is not legally possible to market pharmaceutical products online, by email, and/or by mail order. If a company has applied for an import license and a drug product license, but does not actually import such product within two consecutive years, the company would have its product license for that product withdrawn, according to section 85 of the Drug Act.

1.6 Is there a legal remedy (appeal) against licensing decisions?

If a license is not being granted or if it is being revoked or withdrawn, the applicant has the right to appeal to the Minister of Public Health within 30 days from the date of the knowledge of the order (section 99 of the Drug Act). The decision of the Minister shall be final. The Minister can either dismiss the appeal or amend the order. There is no other official remedy against licensing decisions. In practice, companies would also contact the relevant officials and the head of each relevant group if a license cannot be obtained.

1.7 What are the costs of obtaining a licence?

The government fees for a drug import license are THB10,000 (around EUR 248) per year. A drug import license can cover different types of drugs, but cannot cover narcotics.

The government fees for the registration of pharmaceutical products are THB2,000 (around EUR 50) per product. There are no renewal fees.

2. DISTRIBUTION TO CONSUMERS

2.1 What are the different categories of drugs for distribution?

Under Thai laws, there are four main drugs categories:

- new drugs;
- new generic drugs;
- generic drugs;
- traditional drugs.

Other drug categories exist, namely biological drugs and narcotic drugs, but those are governed by a different sub-department at the FDA, and have different requirements to comply with. For example, narcotic drugs in categories 1 and 2 have to go through a tender process. There is also an

orphan drugs category with an easier registration process. However, the list of orphan drugs is strictly controlled and limited.

2.2 Who is entitled to distribute prescription drugs to consumers? What authorisation do they require?

The marketing authorisation holder or distributor, who holds the drug import license and product registration licenses which have been approved by the FDA, is responsible for the distribution of drug products to hospitals, clinical institutes, or pharmacies.

The marketing authorisation holder or distributor needs to register its company in order to get the drug import license. In addition, it also needs to register a drug product with the FDA before distributing such drug product to consumers in Thailand.

2.3 Who is entitled to distribute over-the-counter drugs to consumers?

The marketing authorisation holder or distributor, who holds the drug import license and product registration licenses which have been approved by the FDA, is responsible for the distribution of OTCs to hospitals, clinical institutes, or pharmacies.

2.4 Which drugs may be distributed by the attending physician, and under what circumstances?

The attending physician may distribute non-registered drug products and registered drug products to patients for clinical research purposes only.

2.5 Who may prescribe prescription drugs to consumers?

Physicians and dentists may prescribe prescription drugs for human use to consumers.

2.6 Is direct mailing/distance selling of drugs admitted? Under what conditions, by whom, and to whom? Might sales be made beyond the borders of your country?

No. Direct mailing or the distance selling of drugs is not allowed in Thailand, pursuant to the Drug Act.

2.7 Which body (agency) is responsible for supervising distribution activities regarding consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The FDA under the supervision of the Ministry of Public Health is responsible for supervising drug distribution activities to consumers in Thailand. The Drug Act covers substantial aspects of drug regulation. The FDA is also responsible for licensing the sale of drugs. Applications for licenses must be filed in accordance with the rules, measures, and conditions prescribed in Ministerial Regulations. Regarding the legal remedy, the licensee may appeal the decision of the FDA to the Minister of Public Health within 30 days from the receipt of the decision.

2.8 What are the legal consequences in case of non-compliance?

The penalties for non-compliance by the product licensee under the Drug Act include the suspending of the import license and product registration license, fines, and imprisonment.

3. WHOLESALE DISTRIBUTION

3.1 What is the legal regime regarding wholesale of drugs? Under what conditions, by whom, and to whom is wholesale of drugs admitted?

The marketing authorisation holder or the legal distributor who holds the import license, the sales license, and/or the product license of a drug approved by the FDA, is responsible for wholesale distribution of drug products to hospitals, clinical institutes, or pharmacies.

3.2 Which body (agency) is responsible for supervising wholesale distribution activities? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

Like in the regime regarding consumers, responsibility for supervision of wholesale distribution activities falls on the FDA, which is also responsible for licensing the sale of pharmaceutical products. In addition, the Import and Export Inspection Division is also involved in the logistics and distribution activities at the border.

As with other distribution, applications for licenses must be conducted in accordance with the rules, measures, and conditions prescribed in Ministerial Regulations.

Decisions of the FDA may be appealed to the Minister of Public Health within 30 days from the receipt of the decision.

3.3 What are the legal consequences for non-compliance?

Under the Drug Act, non-compliance by the product licensee will be punished by suspension of the import license and product registration license, fines, and imprisonment.

B. MARKETING

4. PROMOTION (MARKETING)

4.1 What is the general legal regime regarding marketing of drugs (overview)? What are the general limits on marketing activities?

Sections 88 to 90 of the Drug Act regulate the promotion of medicinal products, and such law is enforced by the FDA.

The general requirement is that any advertisement must be truthful and must not be exaggerated, and advertisements must be approved by the FDA before dissemination.

Section 88 of the Drug Act provides specific requirements about what advertisements must not do, as follows:

- boast that a medicine can miraculously or absolutely treat, cure, or prevent a disease or illness;
- exaggerate or falsely declare properties of the medicine;

- give the impression that the drug has a substance as its chief or component ingredient that it:
  - does not have; or
  - has in a lower quantity than is believed to be present;
- give the impression that it is an abortifacient or a strong emmenagogue;
- give the impression that it is an aphrodisiac or a birth control drug;
- advertise specially controlled drugs or dangerous drugs;
- contain certification or endorsement of its therapeutic properties by any other person;
- show its therapeutic properties as being capable of curing, mitigating, treating, or preventing diseases (or symptoms of them) as notified by the Minister of Public Health under section 77 of the Drug Act:
- such Ministerial Regulation includes several diseases, which are diabetes, cancer, paralysis, tuberculosis, leprosy and disease, or health conditions regarding brain, heart, lung, liver, spleen, and kidney;
- no sale of drugs shall be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient. (section 89 of the Drug Act.)

Furthermore, according to the FDA Internal Rules 2002, 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.

Advertisements must meet the FDA information requirements (for example, contain the drug name, ingredients, and manufacturing source).

4.2 Besides the legal regime, are there other codes of conduct, e.g. from professional or industry organisations? How are they implemented? What is the relationship between the industry code (if any) and the legal regime?

Pharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers Association (PReMA) must comply with the PReMA Code of Sales and Marketing Practice 8th edition – 2008 (PReMA Code). PReMA Code provides the standards for the industry's practice of promotional activities, including organising conferences for healthcare professionals. 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 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.

5. MARKETING TO CONSUMERS

5.1 What is the legal regime with respect to marketing to consumers (overview)? Which products might/might not be advertised to consumers?

Only drugs in the household remedy category may be advertised directly to consumers and the general public, and that advertising is subject to FDA review and approval before dissemination.

Drugs that may be advertised directly to consumers and the general public must not be classified as dangerous drugs. However, most drugs are classified as dangerous drugs under Thai law. Also, drugs that are classified as dangerous must be dispensed by a pharmacist or doctor.

Drugs which are not classified as dangerous drugs would be traditional drugs or household remedies that are specifically listed by the Ministry of Public Health as drugs that patients may buy without having a pharmacist dispense the drug. Traditional drugs or household remedies may be advertised to the consumers, but the advertisement and marketing activities must receive prior approval from the FDA.

5.2 What kinds of marketing activities are permitted with regard to consumers and the products which might be advertised to them?

For a non-household remedy drug, marketing activity to consumers is limited to activities that help create disease awareness, patient education, and basic healthcare education.

With respect to the household remedy category which may be advertised directly to consumers and the general public, the law does not limit the types of activity. However, advertisements to sell drugs through radio, TV, motion pictures, or through printed matter: (1) must receive prior permission for the text, sound, or picture used in the advertisement from the FDA, and (2) must follow the conditions (if any) set by the FDA (section 88 bis). The law further provides that no sale of drugs shall be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient (section 89).

Although the Drug Act is silent about the restriction on patient education, the general public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The PReMA Code gives a guideline that patient education material should be distributed for educational purposes and should encourage patients to seek further information or explanation from the appropriate healthcare professional.

In addition, the following criteria must be satisfied:

- The educational material must be current, accurate, and balanced.
- The educational material may not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.
- Educational material may include descriptions of the therapeutic category, medical condition, and a discussion of the relevant clinical parameters in general.
- The educational material must include the advice 'Please consult your

physician' and the contact address and telephone number of the supplier of the material.
- The educational material must include a statement directing the patient to seek further information about the condition or treatment from his or her doctor. Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a product.
- The tone of the message must not be presented in a way which unnecessarily causes alarm or misunderstanding in the community.
- On all occasions, the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes with regard to a particular product.
- Patient aids which are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific.
- The content of such material must be designed to promote patient compliance by providing information which clarifies the method of administration, precautions, and special instructions and similar information. It must not make comparisons or include promotional claims.

A 'hotline' or 'website' or other similar information service may be set up to provide general information useful to the public (eg, deworming, travel, smoking cessation). Such services must be general and may not include any product promotional information or personal medical advice.

Drug companies may set up or participate in programs that support patients already prescribed a prescription only medicine to improve positive health outcomes. To ensure that such activities are not considered as promotional programs, drug companies must ensure that any statements made or material provided to members of the general public are not promotional and cannot be considered as having the intention of promoting a prescription medicine to members of the general public.

5.3 Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers eg, 'buy one get one free'?

Section 90 of the Drug Act provides that no sale of drugs shall be advertised by means of a gift or lottery drawing. The FDA has adopted a broad interpretation of this section, and has determined that the giving of free samples or buy-one-get-one-free offers is equivalent to advertising by giving a gift.

5.4 Are there particular rules/codes of practice on the use of the internet/social media in respect of drugs and their advertising?

There are no particular rules or codes of practice on the use of the internet or social media for drug advertising. Information distributed on the internet which is intended for customers in Thailand must meet the same requirement as other media. According to the FDA, most advertisements (more than 85 per cent) on the internet are being run without permission, and the FDA has made it a priority to focus on this problem.

5.5 Which body (agency) is responsible for supervising marketing activities to consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The responsible agency is the FDA under the Ministry of Public Health, subsection Food and Drug Law. The FDA randomly visits hospitals and drug stores, and monitors advertisements on TV, radio, and the internet. The FDA will also conduct an investigation when it receives complaints from consumers or competitors. When the FDA finds that an advertiser has violated the advertising/marketing regulations, a notice will be sent to the advertiser with a deadline to provide explanations or defend its case. An appeal against the final decision can be filed with the Office of the Secretary General of the FDA.

5.6 What are the legal consequences for non-compliance?

The Secretary-General of the FDA is empowered to issue a written order to cease any advertisement deemed to be contrary to the Drug Act. If the advertisement led the public into a misunderstanding of information, the FDA may order the violator to issue a corrective advertisement.

Any violation of the Drug Act's marketing provisions is subject to a fine of not more than THB100,000 (EUR 2,480). The calculation of the fine depends on the response time before the advertiser takes action after receiving a warning or notice of violation. The number of occurrences of wrongdoing would also be taken into consideration when calculating the fine. For example, five posters and two gimmick gifts which have never been submitted for FDA approval, being used at a single promotional booth, could be considered as seven offenses.

6. MARKETING TO PROFESSIONALS

6.1 What kinds of marketing activities are permitted with regard to professionals?

Advertisements for prescriptions or pharmacy-dispensed medicines may only be targeted to professionals. As a result, marketing activities in the pharmaceutical industry in Thailand are mainly focused on the professional sector. The types of marketing activities to professionals are more open than those to consumers. However, only products that are registered in Thailand may be promoted to healthcare professionals. When promoting products, the information must be accurate, fair, and objective, and it must be presented in such a way as to conform not only to the legal requirements, but also to high ethical standards. The information should also be in good taste. Claims may not be stronger than the scientific evidence warrants, and every effort should be made to avoid ambiguity and making off-label product claims. No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been obtained (PReMA Code).

6.2 Are there particular types of marketing activities which are not permitted with respect to professionals (eg provision of reprints, non-interventional studies, provision of and type of gifts/ educational items)?

Advertisements of marketing activities may not:
exaggerate or falsely declare properties of the medicine;

- give the impression that the drug has a substance as its chief or component ingredient that it:
  - does not have; or
  - has in a lower quantity than is believed to be present;
- be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient.

Furthermore, the PReMA Code provides a broad guideline for promotional activities to ensure the transparency of such promotion. Clinical assessments, post-marketing surveillance and experience programs, and post-authorisation studies must not be disguised as promotion. Such assessments, programs, and studies must be conducted with a primary scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether or not it is promotional in nature, which is sponsored by a company, must clearly indicate by whom it has been sponsored. Product information furnished to healthcare professionals must be current, accurate, balanced, and may not be misleading, either directly or by implication, omission, or addition. Scientific data to support the claims and recommendations for use must be made available, on request, to healthcare providers.

Payment in cash or cash equivalents (such as a gift voucher) must not be offered to healthcare professionals, and gifts for personal benefits of healthcare professionals are prohibited. However, gifts to healthcare professionals 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 are related to the particular customary occasion, shall not exceed THB3,000 (approximately EUR 75) per healthcare professional per occasion (PReMA Code).

6.3 Are there restrictions on how, when, where or how often professionals might be targeted by sales representatives?

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.

6.4 What are the restrictions on meetings with groups of professionals and the provision of hospitality?

There are no explicit restrictions. However, the PReMA Code provides a guideline that the medical representatives should ensure that the frequency, timing and duration of appointments, together with the manner in which they are made, are such as not to cause inconvenience to the doctors, pharmacists, or nurses, especially in the out-patient department.

6.5 What information is legally required to be included in advertising?

For printed promotional materials (with the exception of reminder (short) advertisements), the following information must be included:

name(s) of the active ingredient(s), using either International Non-proprietary Names (INN) or the approved generic name of the drug;

- brand name;
- content of active ingredient(s) per dosage form or regimen;
- name(s) of other ingredients known to cause problems;
- approved therapeutic uses;
- dosage form or regimen;
- side effects and major adverse drug reactions;
- precautions, contraindications, and warnings;
- major interactions;
- name and address of manufacturer or distributor;
- reference to scientific literature, as appropriate; and
- approval number granted by the FDA after approving the contents of the promotional material.

6.6 Are there rules on comparisons with other products that are particularly applicable to drugs?

Comparisons with other products may be done to the extent that such comparison is fair and is not misleading. Any comparison implying a therapeutic advantage which is not in fact justified must be avoided. Furthermore, disparaging references to other products or manufacturers must be avoided (PReMA Code).

6.7 Are discounts permitted? If they are, under what conditions, by whom, and to whom?

Giving discounts and rebates is acceptable in Thailand. Such discounts or rebates associated with the sales of pharmaceutical products shall be made by account payee check, bank transfer to a bank account associated with the respective hospital, or by invoice only (PReMA Code).

6.8 Is it permitted to provide professionals with free samples?

The Drug Act does not address the issue of free samples for professionals. 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:

- familiarisation with presentation and appearance of a product;
- providing to patients for initiation of therapy; or
- conduct of 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 when received.

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

6.9 Is sponsoring of professionals allowed? Under what conditions, by whom, and to whom and for what purpose(s)?

It is acceptable/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.

It is prohibited and not acceptable or appropriate to run an overseas standalone company-sponsored meeting for healthcare professionals where all (or nearly all) of the attendees and/or speaker(s) are from Thailand.

Furthermore, the PReMA Code contains the guideline that symposia/congresses (local and international), which are initiated by the company (locally only), the regional office, or corporate headquarters, must devote a minimum of 75 per cent of the total time to scientific sessions, outside of reasonable travel time. Any hospitality/entertainment/gimmick provided by drug companies, either directly or by sponsorship or assistance to the meeting organisers of educational meetings, must be secondary to the educational purpose and not capable of being seen as extravagant by local standards.

Invitations to attend medical and scientific meetings must only be given to healthcare professionals. Sponsorship shall be limited to the payment of travel, meals, accommodation, and registration fees. Guests may not be invited, nor expenses of persons accompanying the attendee be paid for.

Companies should not provide direct sponsorship for healthcare professionals to attend sporting or other entertainment events, as this can be seen as inducement.

Donations may be made directly to the institution (not individuals) upon the institution's request to support activities for healthcare professionals, as long as it can be demonstrated that there is a link to scientific education, patient benefit, or charitable contribution that would benefit the improvement of healthcare services.

6.10 Are other indirect incentives allowed? Under what conditions, by whom, and to whom?

Indirect incentives are not allowed.

6.11 Which body (agency) is responsible for supervising marketing activities regarding professionals? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

For enforcement under the Drug Act, please see question 5.5.

Furthermore, PReMA takes an important role in supervising marketing activities which violate the PReMA Code. The Sales & Marketing Ethics Committee (SME) will carry out a review of the provisions of the PReMA Code after seeking input from interested parties at least every three years. Besides regular review of the PReMA Code, the SME will perform activities to create awareness of the PReMA Code.

If a complaint regarding a breach of the PReMA Code is filed by one of the members, 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 with any new evidence within 10 days after receiving the notification from the PReMA CEO. If new evidence or arguments are put forward, the other party shall be invited to provide comments within 30 days. The decision of the CCC at this stage will be regarded as final.

6.12 What are the legal consequences for non-compliance?

For enforcement under the Drug Act, please see question 5.6.

The PReMA CEO, upon the decision of the CCC, shall order one or more of the following sanctions against a company found in breach of the PReMA Code:

- refer the complaint to the International Federation of Pharmaceutical Manufacturers' Association (IFPMA);
- refer the complaint and the CCC's findings to the head office and regional office of the offending company;
- suspend the offending company's membership in PReMA for not more than three years;
- debar the offending company from membership in PReMA;
- require a written undertaking that the practice complained about will be discontinued on or before a date to be determined by the CCC; or
- require 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 fulfillment.

PReMA may also issue a fine to the company as follows:

Not exceeding THB100,000 (EUR 2,480) for a first offense; or

- Not exceeding THB500,000 (EUR 12,395) for a second offense 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.

7. ENGAGEMENT WITH PATIENT ORGANISATIONS

7.1 What kinds of activities are permitted with respect to engagement with patient organisations?

Pharmaceutical companies have limited freedom of action when promoting pharmaceutical products. Article 4.11 of the PReMA Code (which covers Promotion to Non-Healthcare (Medical) Professionals (or the general public)) covers the possibility for pharmaceutical companies to join patient support programs which support patients who have already been prescribed a prescription only medicine to improve positive health outcomes.

However, pharmaceutical companies have to ensure that their statements are not considered promotional and do not have the objective to promote a prescription drug. More specifically, they have to comply with the following requirements:

- any payment for the work undertaken by a healthcare professional in

such programs is commensurate with the work undertaken;
- no incentives, other than material incentives that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs;
- the program complies with Thailand's privacy legislation;
- all information provided to patients must comply with sections 4.11.4 (Patient Education) and 4.11.5 (Patient Aid) of the PReMA Code, ie, be educational (see question 5.1);
- the data collected from these programs will not be used for any purpose other than to increase positive health outcomes, and never for promotional activities; and
- the duration of these programs is appropriate to the disease treated by the product involved.

7.2 What are the restrictions imposed on relationships with patient organisations?

See question 7.1.