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DISTRIBUTION AND MARKETING OF DRUGS

Distribution and marketing of drugs in Thailand: overview

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DISTRIBUTION

Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation

To distribute modern and traditional drugs into Thailand, a pharmaceutical company or its Thai distributor must apply for an import licence or a manufacturing licence.

Under section 4 of the Thai Drug Act BE 2510 (AD 1967) (Drug Act), a modern drug is defined as a "drug intended for use in the practice of modern medicine or the cure of an animal disease", whereas a traditional drug is defined as "a drug intended for use in the practice of traditional medicine or the cure of an animal disease which appears in a pharmacopoeia of traditional drugs 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 manufacturer must satisfy all of the following conditions to obtain an import or manufacturing licence:

- 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 a resident of Thailand.
- Not have been convicted for an offence against certain laws (for example, 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.
- 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 licence has been suspended or revoked for less than a full year.

A licensee that obtains a manufacturing licence or an import licence will also be considered to be licensee to sell drugs. After a manufacturing licence or import licence is obtained, modern and traditional drugs must be registered with the Thai Food and Drug Administration (FDA) before they can be distributed in Thailand.

Exceptions

There are some rare exceptions under which certain drugs do not need product registration. According to section 79(4) of the Drug Act, 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 BE 2532 (AD 1989) regarding Bases, Procedures, and Conditions in Respect to Importation of Medicines with No Need to Apply for Pharmacopeia Registration, as amended in 2009. Additionally, active pharmaceutical ingredients, semi-finished products, and sample drugs for registration purposes do not require product registration. With regard to the sale of drugs, drug stores require a licence to sell drugs, while hospitals or clinics can sell drugs directly to their patients without having to apply for a licence.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

For drugs sold to their patients, medical practitioners do not require a drug-selling licence from the regulator (that is, the Thai Food and Drug Administration (FDA) (*section 13(3), Drug Act*). For compassionate use programmes, only the following parties are allowed to import drug products without applying for an import licence or drug product licence (*section 13(5), Drug Act*):

- Ministries, public bodies, and departments that have a duty to prevent or treat disease.
- The Thai Red Cross Society.
- The Government Pharmaceutical Organisation.

Medicines can also 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, of (*section 79(4), Drug Act*):

- The Permanent Secretary of the Ministry of Public Health as chairperson.
- The director-generals of the Departments of Medical Services, Communicable Disease Control, Medical Sciences, and Health.
- Not less than five but no 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 (BE 2532) (AD 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 can 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:

- Manufacturers.
- Importers.
- Ministries, public bodies, and departments that have a duty to prevent or treat disease.

- The Thai Red Cross Society.
- The Government Pharmaceutical Organisation.

The importer must also submit the relevant application and supporting documents proving that it falls into the scope of the exception.

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

- Labels of all of the 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.
- Information on manufacturing and quality control of the drug.

Approval, as reported by the Institutional Review Board (IRB) or the Independent Ethics Committee (IEC) in Thailand, is quite burdensome, as it requires compliance with lengthy administrative steps.

To apply for importation of a drug for charitable/donation purposes, the following documents are required:

- Labels of all of the containers.
- Package inserts.
- Certificate of free sale.

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

Structure

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

- Obtain a licence from the Thai Food and Drug Administration (FDA) to manufacture, sell or import drugs in Thailand. An import licence must be renewed every year and is valid from 1 January to 31 December for each year.
- After obtaining the import licence, obtain an authorisation to manufacture or import drug samples.
- Submit a full marketing approval application, including 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 licence also needs to be renewed.

Regulatory authority

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 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.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

Even if a company has already obtained a market authorisation issued in a foreign jurisdiction, it cannot benefit from a simplified or relaxed licensing and registration process. In their application to the Thai Food and Drug Administration (FDA), the applicant will still need 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 will support the registration process and could be used as evidence to support the application for marketing approval.

Additionally, following the Association of Southeast Asian Nations (ASEAN) Harmonisation on Pharmaceutical Product Registration of 1 January 2009, the FDA implemented the ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD) on quality, safety and efficacy, which provides guidelines on analytical and process validation, stability studies, and bioavailability or bioequivalence. It means that in the ASEAN region, the same requirements exist for all drug products, which facilitates the registration process. However, some local specifics still remain.

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 licence and product registration locally. Also, the FDA will not accept an application for a product that has a trade mark which 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.

5. Is virtual drug distribution possible from your jurisdiction?

Under Thai law, it is not possible to market pharmaceutical products online, by e-mail or by mail order. If a company has applied for an import licence and a drug product licence, but does not actually import that product within two consecutive years, the company's product licence for that product will be revoked (*section 85, Drug Act*).

6. What is the procedure to appeal (legal remedy) a licensing decision?

If a licence 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 (Minister) within 30 days from the date of the knowledge of the order (*section 99, Drug Act BE 2510 (AD 1967)*).

According to the Drug Act, the decision of the Minister is final. The Minister can either dismiss the appeal or amend the order. However, in practice, companies can also contact relevant officials and the head of each relevant group if a licence cannot be obtained.

Another official remedy against a licensing decision is an action via the Thai Central Administrative Court. Thailand's Act on Establishment of Administrative Court and Administrative Court Procedure, B.E. 2542 (1999) gives the Administrative Court jurisdiction to issue an order in relation to any unlawful act by an

administrative agency or state official, for a number of specific reasons, for example:

- Acting without or beyond the scope of powers and duties (that is, ultra vires).
- Acting in a manner inconsistent with the law (that is, conflict of laws), or the form, process, or procedure which is the material requirement for such act (that is, procedural impropriety).
- Acting in bad faith.
- Acting in a manner that constitutes unfair discrimination.
- Causing unnecessary process or excessive burden to the public.
- Performing an act that amounts to an undue exercise of discretion.

7. What are the costs of obtaining licensing?

The government fees for a modern drug import licence are THB10,000 per year. A drug import licence can cover different types of modern drugs, but cannot cover narcotics or psychotropic substances.

The government fees for the registration of modern pharmaceutical products are THB2,000 per product. There are no renewal fees.

Distribution to consumers

8. What are the different categories of drugs for distribution?

Under the law, there are four main drugs categories:

- New drugs.
- New generic drugs.
- Generic drugs.
- Traditional drugs.

Other drug categories exist, namely biological drugs, orphan drugs, and narcotic drugs, but those are governed by a different sub-department at the Thai Food and Drug Administration (FDA), and have different requirements to comply with. For example, narcotic drugs in categories 1 and 2 have to go through a tender process. For the orphan drugs category, there is an easier registration process. However, the list of orphan drugs is limited and strictly controlled.

9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription drugs

The marketing authorisation holder (that is, the Thai manufacturer or Thai importer) or distributor that holds a Thai Food and Drug Administration (FDA)-approved drug-manufacturing licence, import licence or licence to sell, is authorised to distribute drug products to hospitals, clinical institutes, or pharmacies.

To obtain a drug manufacturing licence, import licence, or licence to sell, the marketing authorisation holder or distributor must be a company registered in Thailand and must register the drug product with the FDA.

Over-the-counter drugs

The marketing authorisation holder (that is, the Thai manufacturer or Thai importer) or distributor that holds an FDA-approved drug manufacturing licence, import licence, or licence to sell, is authorised to distribute over-the-counter (OTC) drugs to hospitals, clinical institutes, pharmacies, and convenience stores.

10. What drugs can an attending physician distribute and under what circumstances?

The attending physician can distribute registered drug products to patients, if the drugs are listed in the hospital formulary. For non-registered drug products, the attending physician in a government hospital can make a request through the compassionate drug use route.

11. Who is authorised to prescribe prescription drugs to consumers?

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

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Direct mailing or the distance selling of drugs are not permitted under the Drug Act.

13. What regulatory authority is responsible for supervising distribution activities?

The Thai Food and Drug Administration (FDA), under the supervision of the Ministry of Public Health, is responsible for supervising drug distribution activities to consumers in Thailand. The FDA is responsible for licensing the sale of drugs. Applications for licences must be filed in accordance with the rules, measures, and conditions prescribed in Ministerial Regulations. The Drug Act covers substantial aspects of drug regulation.

14. What is the procedure to appeal (legal remedy) a distribution decision?

The licensee can appeal the decision of the Thai Food and Drug Administration (FDA) to the Minister of Public Health within 30 days from the receipt of the decision.

15. What are the legal consequences of non-compliance with consumer distribution laws?

The penalties for non-compliance by the product licensee under the Drug Act include a suspension of their import licence, manufacturing licence, sale licence, and product registration licence, and fines and imprisonment.

Wholesale distribution

16. What is the legal regime regarding wholesale distribution of drugs?

The marketing authorisation holder who has the import licence or manufacturing licence, and the entity that has the wholesale licence, approved by the Thai Food and Drug Administration (FDA),

are responsible for wholesale distribution of drug products to hospitals, clinical institutes or pharmacies.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority

The regulatory authority responsible for supervising wholesale distribution activities is the Thai Food and Drug Administration (FDA). As with other types of distribution, applications for licences must be conducted in accordance with the rules, measures and conditions prescribed by Ministerial Regulations.

Supervision

As for 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. The Import and Export Inspection Division of the FDA is also involved in logistics and distribution activities at the Thai border.

Rights of appeal

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

18. What are the legal consequences of non-compliance with wholesale distribution laws?

Under the Drug Act, licence penalties for non-compliance by the licensee include suspension of import licences, product registration licences, wholesale licences, and fines and imprisonment.

MARKETING

Promotion

19. What is the general legal regime for the marketing of drugs?

Legal regime

Sections 88 to 90 of the Drug Act regulate the advertising of medicinal products and are enforced by the Thai Food and Drug Administration (FDA). The authorities also take the Consumer Protection Act 1979 into consideration when regulating advertising practice. Further, pharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers Association (PReMA) must comply with the PReMA Code of Practice for Ethical Channel 10th Edition 2016 (PReMA Code). Although the PReMA Code is not considered as law, and the FDA does not have the authority to enforce it, a violation of the PReMA Code can be reviewed by the PReMA Committee, which can sanction its members.

Limits to marketing activities

Advertisements for prescription or pharmacy-dispensed medicines can only be targeted to professionals. Drugs in the household remedy category, which is called OTC in other jurisdictions, can be advertised directly to consumers and the general public, but that advertising is subject to FDA review and approval before dissemination.

Under section 88 of the Drug Act, advertisements must not:

- Exaggerate that a medicine can miraculously or absolutely treat, mitigate, 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 either does not have, or has in a lower quantity than 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.
- Show the properties of 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 Ministry of Public Health (MOPH) under section 77 of the Drug Act.

Further, under the FDA Internal Rules (2002), advertisements must not:

- Be contrary to traditions, for example, local beliefs, norms and morals.
- Persuade patients to consume the product more than necessary or create a misunderstanding that the product must 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.
- Encourage acts or activities contrary to law.

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

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

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). The 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, voluntarily 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 Administration (FDA) does not have the authority to enforce it. A violation of the PReMA Code can be reviewed by the PReMA Committee, which has the power to sanction its members.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Legal regime

Only drugs in the household remedy category can be advertised directly to consumers and the general public. This advertising is subject to Thai Food and Drug Administration (FDA) review and approval before dissemination.

Products

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

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

22. What kinds of marketing activities are permitted in relation to consumers and the products which may 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.

For the household remedy category that can 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, television, motion pictures, or through printed matter must:

- Receive prior permission for the text, sound or picture used in the advertisement from the Thai Food and Drug Administration (FDA).
- Follow the conditions (if any) set by the FDA (*section 88, Drug Act*). The law further provides that no sale of drugs can be advertised impolitely or by means of singing and dancing or by showing the distress or suffering of a patient (*section 89, Drug Act*).

Although the Drug Act is silent on the restrictions on patient education, the general public must have access to information on medical conditions and the treatments that may be prescribed by their doctors. The Pharmaceutical Research and Manufacturers Association (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.

The following criteria must also be satisfied:

- The educational material must be current, accurate and balanced.
- The educational material cannot 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.
- The educational material can 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 contain 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 that 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 increasing unfounded hopes on a particular product.

Patient aids that are solely intended to provide information for the patient once a decision to prescribe that product has been made can be product-specific.

The content of such material must be designed to promote patient compliance by providing information that 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 can be set up to provide general information useful to the public (for example, de-worming, travel, or smoking cessation). Such services must be general and cannot include any product promotional information or personal medical advice.

Drug companies can set up or participate in programmes that support patients already prescribed a prescription-only medicine to improve positive health outcomes. To ensure that such activities are not considered as promotional programmes, 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.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

No sale of drugs can be advertised by a gift or lottery drawing (*section 90, Drug Act*). The Thai Food and Drug Administration (FDA) has adopted a broad interpretation of this section, and has determined that free samples or "buy-one-get-one-free" offers are equivalent to advertising by giving a gift.

In addition, the Ministry of Public Health Circular dated 2 March 2018 expressly prohibits the exchange of benefits relating to the procurement of drugs, and is aimed at preventing corruption in the purchasing of drugs and medical devices under the Civil Servant Medical Benefit Scheme. The Circular is aligned with the Cabinet's resolution on Thailand's National Anti-Corruption Strategy. According to the Circular, no discount or free samples will be provided to the welfare fund of the hospitals. The conceptual idea is that the government's payment will be of the net price.

24. Are there particular rules of practice on the use of the internet/social media regarding 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 that is intended for customers in Thailand must meet the same requirement as other media. According to the Thai Food and Drug Administration (FDA), most advertisements (more than 85%) on the internet are being run without permission, and the FDA has made it a priority to address this issue.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The agency responsible for supervising marketing activities to consumers is the Thai Food and Drug Administration (FDA) under the Ministry of Public Health (*Drug Act*).

Supervision

The FDA conducts random visits to pharmaceutical companies, hospitals, and drug stores and monitors advertisements on TV, radio, and the internet. The FDA also conducts investigations when it receives complaints from consumers or competitors. When the FDA finds that an advertiser has violated advertising or marketing regulations, a notice is sent to the advertiser with a deadline to provide explanations or defend their case.

Rights of appeal

An appeal against the final decision can be filed with the Office of the Secretary General of the FDA.

26. What are the legal consequences of non-compliance with consumer marketing laws?

The Secretary-General of the Thai Food and Drug Administration (FDA) can issue a written order to cease any advertisement deemed to be contrary to the Drug Act. If the advertisement led the public to misunderstand information, the FDA can 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. The calculation of the fine depends on the time that the advertiser takes to act after receiving a warning or notice of violation. The number of occurrences of wrongdoing is also taken into consideration when calculating the fine. For example, five posters and two gimmick gifts that have never been submitted for FDA approval, being used at a single promotional booth, could be considered as seven offences.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

Advertisements for prescriptions or pharmacy-dispensed medicines can only be targeted at 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 can be promoted to healthcare professionals.

When promoting products, the information must be accurate, fair and objective, and presented in such a way as to conform not only to legal requirements but also to high ethical standards. The information should also be in good taste. Claims cannot 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 can be promoted for use until the requisite marketing approval for such use has been obtained (*Pharmaceutical Research and Manufacturers Association (PReMA) Code*).

28. Are there any restrictions on marketing to professionals?

Marketing activities

Advertisements of marketing activities cannot:

- 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 either does not have, or has in a lower quantity than believed to be present.
- Be advertised impolitely, by means of singing and dancing, or by showing the distress or suffering of a patient.

The Pharmaceutical Research and Manufacturers Association (PReMA) Code also provides a broad guideline for promotional activities to ensure the transparency of such promotion. Clinical assessments, post-marketing surveillance and experience programmes, and post-authorisation studies must not be disguised as promotion. Such assessments, programmes and studies must be conducted with a primary scientific or educational purpose. Materials 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 cannot 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 the 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 the gifts, the nature and type of which are related to the particular customary occasion, must not exceed THB3,000 per healthcare professional per occasion (*PReMA Code*).

Frequency

The restriction under the PReMA Code is that medical representatives must not employ any inducement or subterfuge to gain a sale. Neither can any fee be paid for that purpose.

Provision of hospitality

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

29. What information is it legally required to include in advertising to professionals?

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.
- Advertisement approval number granted by the Thai Food and Drug Administration (FDA) after approving the contents of the promotional material.

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

Comparisons with other products can be done to the extent that the comparison is fair and is not misleading. 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 (*Pharmaceutical Research and Manufacturers Association (PReMA) Code*).

31. What other items, funding or services are permitted to be provided to professionals?

Discounts

It is acceptable to give discounts and rebates in Thailand. Such discounts or rebates associated with the sales of pharmaceutical products can only be made by account payee check, bank transfer to a bank account associated with the respective hospital, or by invoice (*Pharmaceutical Research and Manufacturers Association (PReMA) Code*).

Free samples

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

- Familiarisation with presentation and appearance of a product.
- Provision to patients for initiation of therapy.
- Conduct of an agreed clinical evaluation of the product.

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

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 the reasons stated above. No one can sell or trade, or offer to sell or trade, any drug samples.

Sponsorship of professionals

It is acceptable and 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, unacceptable, and inappropriate to run an overseas stand-alone company-sponsored meeting for healthcare professionals where all or nearly all of the attendees or speakers are from Thailand.

Additionally, under the PReMA Code, symposia or congresses, local and international, which are initiated by a local company, regional office, or corporate headquarters, must devote a minimum of 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 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 is limited to the payment of travel, meals, accommodation, and registration fees. Guests cannot be invited, nor can the expenses of persons accompanying the attendee be paid for.

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

Donations can be made directly to the institution (not individuals) on 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.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority

The agency responsible for supervising marketing activities regarding professionals is the Thai Food and Drug Administration (FDA) under the Ministry of Public Health (*Drug Act*) (*see Question 25*). The Pharmaceutical Research and Manufacturers Association (PReMA) also takes an important role in supervising marketing activities that violate the PReMA Code.

Supervision

PReMA supervises marketing activities that violate the PReMA Code. The Sales and Marketing Ethics Committee (SME) carries 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 performs 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 is administered by the PReMA CEO and the Code of Conduct Committee (CCC).

Rights of appeal

When the allegedly breaching company or complainant disagrees with the decision of the CCC, they can request a second-instance ruling. The re-submission must be made in writing with any new evidence within ten days after receiving the notification from the PReMA's CEO. If new evidence or arguments are put forward, the other party is invited to provide comments within 30 days. The decision of the CCC at this stage is regarded as final.

33. What are the legal consequences in case of non-compliance with professional marketing laws?

The legal consequences of non-compliance with professional marketing laws are the same as for non-compliance for consumer marketing laws (*see Question 26*).

In addition, the Pharmaceutical Research and Manufacturers Association's (PReMA) chief executive officer (CEO), on the decision of the Code of Conduct Committee (CCC), can 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.

- 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 fulfilment.

PReMA can also issue the following fines to the company:

- No more than THB100,000 for a first offence.
- No more than THB500,000 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 might be lodged.

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

Pharmaceutical companies have limited freedom of action when promoting pharmaceutical products. Pharmaceutical companies can join patient support programmes that support patients that have already been prescribed a prescription-only medicine to improve positive health outcomes (*Article 4.11, Pharmaceutical Research and Manufacturers Association (PReMA) Code, covering Promotion to Non-Healthcare (Medical) Professionals (or the general public)*).

However, pharmaceutical companies must 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 programmes 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 programmes.
- The programme 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. This means they must be educational (*see Question 20*).
- The data collected from these programmes is not used for any purpose other than to increase positive health outcomes, and never for promotional activities.
- The duration of these programmes is appropriate to the disease treated by the product involved.

RECENT DEVELOPMENT AND OUTLOOK

35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

While Thailand currently has no comprehensive data protection legislation, a draft "Personal Data Protection Bill" and draft "Data Privacy Bill" have been approved by the Cabinet and will be considered by the National Legislative Assembly. These bills are expected to be passed by the National Legislative Assembly in the near future. The bills, as drafted, would dramatically change personal data privacy requirements and would require consent from the subject for some types of data collection. The Draft Drug Bill is also being scrutinised by all interested parties.

This change could have an impact on the distribution and promotion of drugs, as those two aspects rely heavily on patient and more generally consumer data. After the bills are passed, this may be more difficult to acquire.

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