SECOND EDITION 2015

DISTRIBUTION AND MARKETING OF DRUGS

A GLOBAL GUIDE FROM PRACTICAL LAW

This second edition of *Distribution and Marketing of Drugs* provides a high level practical overview of a number of key legal issues involved in the distribution and marketing of drugs in 28 jurisdictions around the world. Some of the key issues covered include the pre-conditions for distribution; licensing; wholesale distribution; marketing to consumers; marketing to professionals and engagement with patient organisations.

Written by leading lawyers in their countries, contributors are ideally placed to provide clear, concise and practical commentary on the inner workings of their respective legal systems.

General Editors:
Eric Stupp and Markus Schott, *BÄR & KARRER AG*
Alison Dennis, *FIELDFISHER*

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PREFACE

Eric Stupp, Markus Schott, BÄR & KARRER AG and Alison Dennis, FIELDFISHER

Given the recent developments in the field, two years after the successful launch of the first edition seemed to be a good time to follow up with a second edition of the handbook. We are delighted that so many of the authors of the first edition have been able to work over their contributions within a short timeframe. We are equally happy to have new, distinguished colleagues among the contributors who have agreed to participate in this book's second edition, adding some new jurisdictions such as Australia, Brazil, Canada, Indonesia, Russia, and South Korea. We also thank Emily Kyriacou and her fine editorial team at Thomson Reuters for all their efforts in bringing the project to fruition. Any errors or omissions are, however, ours alone and we welcome comments and ideas for the improvement of future editions from our readers.

Eric Stupp, Markus Schott and Alison Dennis

FOREWORD

Dr Oliver P Kronenberg, Group General Counsel, GALENICA

Demand for effective medicines is rising. As the population ages and increases, new medical needs emerge and the disease burden of the developing world increasingly resembles that of the developed world. The main emerging countries (that is, Brazil, China, India, Indonesia, Mexico, Russia and Turkey) are also becoming increasingly prosperous, with projections suggesting that these countries could account for as much as one-fifth of global pharmaceutical sales by 2020.

At the same time, commercialisation of pharmaceutical products has become more complex as the competitive and regulatory environment has evolved. Today, regulatory regimes not only aim to protect public health and to ensure that there is robust data to support the safety and efficacy of pharmaceutical products, but also to limit expenditure on pharmaceutical products by countries (for example, market access, pricing and reimbursement and distribution channels, among others). One recent development is the implementation of transparency regulations in the US, Europe and some other countries. These regulations require manufacturers of medicines, medical devices and medical supplies to collect and track all financial relationships with healthcare professionals and healthcare organisations, and to report this information to either the local regulators or to publish it on their own website.

This book focuses on the legal environment surrounding the distribution and marketing of medicines. As explained above, the legal framework has been tightened and the standards for compliance have been raised by the regulators. This has led to an increasing need for legal support (whether in-house or external). Jurisdictions differ significantly around the world and, as a consequence, this book has become an important reference guide for the industry.

As in the first edition, the topics addressed in this book cover all relevant aspects of the sale, distribution and marketing of drugs for human use. These range from substantive issues such as the existence of compassionate use programs; admissibility of direct mailing; provision of free samples and discounts and the ability to communicate directly with consumers, to more procedural aspects such as identifying the competent authorities and legal remedies available to parties. As professional and other industry organisations have set up their own codes of conduct in many countries, individual chapters also refer to such codes and describe their implementation.

In conclusion, this book provides everything in-house or external counsel need to understand the distribution and marketing of medicines in the jurisdictions covered. This will assist readers in evaluating legal risks and in providing sound legal and compliance advice to the organisations which they support.

Dr Oliver P Kronenberg, Group General Counsel, Galenica

THAILAND

Alan Adcock, Siraprapha Rungpry and Areeya Pornwiriyangkura, TILLEKE & GIBBINS

DISTRIBUTION

PRE-CONDITIONS FOR DISTRIBUTION

1. WHAT ARE THE LEGAL PRE-CONDITIONS FOR A DRUG TO BE DISTRIBUTED WITHIN THE JURISDICTION?

Authorisation

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

A modern drug is a "drug intended for use in the practice of modern medicine or the cure of an animal disease" (*Section 4 of the Drug Act, as amended*), whereas a traditional drug is "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" (*Section 4 of the Drug Act, as amended*).

The importer or manufacturer must:

- 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.

After the manufacturing licence or import licence is obtained, modern and traditional drugs must be registered with the Thai Food and Drug Administration (FDA) prior to 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 (BE 2510 (AD 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 (BE 2532 (AD 1989)) regarding Bases, Procedures, and Conditions Respecting 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, the drug store requires a licence to sell, yet the hospitals or clinics can sell drugs directly to his or her patients without having applied for a licence to sell.

2. DO ANY TYPES OF NAMED PATIENT AND/OR COMPASSIONATE USE PROGRAMMES OPERATE? IF SO, WHAT ARE THE REQUIREMENTS FOR PRE-LAUNCH ACCESS?

Drugs sold by medical practitioners to their patients do not have to obtain a licence from the regulator (that is, the Thai Food and Drug Administration (FDA)) (*section 13(3), Drug Act BE 2510 (AD 1967)*). However, a doctor must still apply for an import licence. Only the following are allowed to import drug products without applying for an import licence or product licence (*section 13(5), Drug Act*):

- Ministries.
- Sub-ministries (in their official disease prevention and treatment duties).
- 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 the (*section 79(4), Drug Act*):

- Permanent Secretary of the Ministry of Public Health (for example, the chairman).
- 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:

- A manufacturer.
- Importer.
- Ministry.
- Department with duties of prevention and treatment of diseases.
- The Thai Red Cross Society.
- The Government Pharmaceutical Organisation.

The importer must also submit the relevant application and supportive 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 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.
- 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 that are required when applying for importation of a drug for donation purposes are as follows:

- 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 wishing 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.
- After obtaining the import licence, obtain an authorisation to manufacture or import drug samples.
- 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 licence does need 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 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.

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. However, the application requires the applicant to inform the Thai Food and Drug Administration (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 Association of Southeast Asian Nations (ASEAN) Harmonisation on Pharmaceutical Product Registration of 1 January 2009, the FDA implemented the ASEAN Common Technical Requirements and Dossier (ACTR or 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, 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 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.

5. IS VIRTUAL DRUG DISTRIBUTION POSSIBLE FROM YOUR JURISDICTION?

It is not legally 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 would have its product licence for that product withdrawn (*section 85, Drug Act BE 2510 (AD 1967)*).

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

The decision of the Minister is 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 licence cannot be obtained.

7. WHAT ARE THE COSTS OF OBTAINING LICENSING?

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

The government fees for the registration of 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 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. There is also an orphan drugs category with an easier registration process. However, the list of orphan drugs is strictly controlled and limited.

9. WHO IS AUTHORISED TO DISTRIBUTE PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS TO CONSUMERS?

Prescription drugs

The marketing authorisation holder or distributor that holds the drug import licence and product registration licences that have been approved by the Thai Food and Drug Administration (FDA) is responsible for the distribution of drug products to hospitals, clinical institutes or pharmacies.

The marketing authorisation holder or distributor must register its company to get the drug import licence. It must also register a drug product with the FDA before distributing the drug product to consumers in Thailand.

Over-the-counter drugs

The marketing authorisation holder or distributor that holds the drug import licence and product registration licences that have been approved by the FDA is responsible for the distribution of over-the-counter (OTC) drugs to hospitals, clinical institutes or pharmacies.

10. WHAT DRUGS CAN AN ATTENDING PHYSICIAN DISTRIBUTE AND UNDER WHAT CIRCUMSTANCES?

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

11. WHO IS AUTHORISED TO PRESCRIBE PRESCRIPTION DRUGS TO CONSUMERS?

Physicians and dentists can 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 is not allowed under the Drug Act BE 2510 (AD 1967).

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 Drug Act BE 2510 (AD 1967) covers substantial aspects of drug regulation. The FDA is also 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.

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 BE 2510 (AD 1967) include a suspension of the import licence and product registration licence, fines and imprisonment.

WHOLESALE DISTRIBUTION

16. WHAT IS THE LEGAL REGIME REGARDING WHOLESALE DISTRIBUTION OF DRUGS?

The marketing authorisation holder or the legal distributor that holds the import licence, the sales licence or the product licence of a drug approved by the Thai Food and Drug Administration (FDA) is 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 in Ministerial Regulations.

Supervision

As with 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 is also involved in the logistics and distribution activities at the 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 BE 2510 (AD 1967), non-compliance by the product licensee is punished by suspension of the import licence and product registration licence, 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. 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 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 can be advertised directly to consumers and the general public, but that advertising is subject to FDA review and approval before dissemination.

Dangerous drugs cannot be advertised directly to consumers and the general public. Most drugs are classified as dangerous drugs under Thai law and the Advertising must be approved by the FDA before dissemination (*section 88 bis, Drug Act*).

Advertisements must not (*section 88, Drug Act*):

- Boast that a medicine can miraculously or absolutely treat, cure or prevent 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.
- 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 Ministry of Public Health (MOPH) under section 77 of the Drug Act.

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

- 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.

Furthermore, advertisements must meet the 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, 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 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 as dangerous drugs. However, most drugs are classified as dangerous drugs under the law. Also, drugs that are classified as dangerous 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).
- Must follow the conditions (if any) set by the FDA (*section 88, Drug Act BE 2510 (AD 1967)*). 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 about 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 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 BE 2510 (AD 1967)*). The Thai Food and Drug Administration (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.

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 focus on this problem.

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 (*Food and Drug Law BE 2510 (AD 1967)*).

Supervision

The FDA randomly visits 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 the advertising or marketing regulations, a notice is sent to the advertiser with a deadline to provide explanations or defend its 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 BE 2510 (AD 1967). If the advertisement led the public into a misunderstanding of 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 response time before the advertiser takes action 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 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 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 approval for marketing 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:
  - does not have;
  - has in a lower quantity than is 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. 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 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 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 the 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.
- 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

Giving discounts and rebates is acceptable 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 BE 2510 (AD 1967) 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 on 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.

- Conduct of an agreed on 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 and not acceptable or appropriate 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, the PReMA Code contains the guideline that symposia or congresses (local and international) that are initiated by the company (locally only), the 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 (*Food and Drug Law BE 2510 (AD 1967)*) (*see Question 25*). The Pharmaceutical Research and Manufacturers Association (PReMA) also takes an important role in supervising marketing activities that violate the Pharmaceutical Research and Manufacturers Association (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 Chief Executive Officer 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 chief executive officer (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 a fine to the company as follows:

- 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 (that covers 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.

REFORM

35. ARE THERE ANY PLANS TO REFORM THE LAW ON THE DISTRIBUTION AND PROMOTION OF DRUGS IN YOUR JURISDICTION?

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 soon. The bills, as drafted, would dramatically change personal data privacy requirements and would require consent from the subject for some types of data collection.

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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