TPMA CODE OF SALES AND MARKETING PRACTICES

Thai Pharmaceutical Manufacturers Association (TPMA)

INTRODUCTION

Thai Pharmaceutical Manufacturers Association (TPMA) comprises members engaged in manufacturing, research, development and importing quality medicines/pharmaceutical products from overseas into the Kingdom of Thailand. Categories of TPMA membership are:

1. **Ordinary Members** are juristic persons according to the Thai law, which are engaged in manufacturing medicines/pharmaceutical products in Thailand.

2. **Associate Members** are natural persons who are engaged in or connected with pharmaceutical manufacturing industry in Thailand.

3. **Honorary Members** are experts and eminent persons or persons rendering services to the Association who are invited by the Board of Directors' resolution and accept the invitation to become members.

RATIONALE

In the year B.E. 2512 (1969) while the government was in the process of accelerating the industrial development of the nation, a group of entrepreneurs engaged in the pharmaceutical industry led by Pharmacist Dr. Kasem Pangsiwong and Mr. Pichai Rattakul, in cognizance of the responsibility towards the government, the healthcare professions and the medicinal users in general, had gathered members and established an association called "Thai Pharmaceutical Manufacturers Association (TPMA). The association's objectives are to promote and enhance the up-to standard quality manufacture of pharmaceutical products in Thailand such as to benefit the prevention and treatments of illnesses for humans and animals including raising the standards and promotion of the pharmaceutical manufacture to sufficiently meet the demands of the industry in addition to promoting its members' ethical practices of sales and marketing.

Subsequent to Thailand being a member of the World Health Organization in B.E. 2538 (1995) and the issuance of the World Health Assembly Resolution, WHA 41.17, seconding the ethical practices for pharmaceutical sales and marketing since B.E. 2531 (1988) requesting all nations and sectors to adopt the principles, thenceforward, Thailand endeavors to develop local standard ethics for pharmaceutical sales and marketing practices by putting them in the National Drug Systems Development Strategy, B.E. 2555-2559 (2012-2016) under Strategy 2, sub Strategy 7, stipulating the promotion of ethical practices for prescribers and the termination of non ethical practices for pharmaceutical sales and marketing.

Consequently, the Thai Pharmaceutical Manufacturers Association, in cognizance of the importance of such ethical practices, started to develop ethical principles of sales and marketing practices in dealing with hospitals since B.E. 2556 (2013) and has continually developed them by emphasizing on doing business with integrity and transparency, on enhancing knowledge for healthcare providers to perform their duty professionally. This includes an obligation and responsibility to provide accurate, balanced and correct information and education to healthcare providers with a principal aim to encourage Members of the Association to accept and observe the Code as their ethical practices for sales and marketing and the main criteria for accepting persons/juristic persons as Members of the Association.

1. DEFINITION

Association means Thai Pharmaceutical Manufacturers Association.

Drugs mean drugs under drugs law, narcotic drugs under narcotic drugs law and psychotropic substance under psychotropic substance law.

Drug Promotion means providing information/statements, inducing, persuading, or using any means to get prescriptions, orders or the use of medicines.

Advertisement means any act or methods to have the product information seen or known by the public.

Statements mean descriptions or facts be they in the forms of texts, figures, pictures, films, audio-visual aids, marks/signs or any forms conveying the meaning by themselves or via any methods or media.

Gifts mean articles or giveaways distributed by pharmaceutical companies to the individuals.

Donations mean articles given by pharmaceutical companies to healthcare institutions or organizations.

Drug samples mean samples of products distributed to healthcare professionals to familiarize them with the forms and characteristics of the products or to enhance them with clinical experiences.

Prescriber means personnel of healthcare professions or other public health personnel having the right or duty to prescribe drugs.

Professional means a medical practitioner including a dentist, a pharmacist, a veterinarian, a nurse, a medical laboratory technologist, a physiotherapist, a Thai traditional medical practitioner or the other health professional as stipulated in the royal decree enacted in accordance with the License Act unless otherwise stipulated.

Medical Representative or Medical Sales Staff means an employee representing a pharmaceutical company to call on healthcare professionals to present medical information.

Member Company means a company or an organization engaged in manufacturing, importing or distributing pharmaceutical products which are Members of the Association.

Executive means personnel of a medical institute or organization authorized to select, purchase, procure pharmaceutical products on its behalf.

Authorized person means a person or a group of persons authorized to select, propose, procure or order pharmaceutical products on behalf of a medical institute or organization.

Educational institute means a college, a university or an educational institute in the fields of medical healthcare and public health.

Student means an undergraduate in an educational institute.

Medical Institute means a hospital of any level of both the government and the private sectors including a clinic.

Pharmacy Service Store means a shop with a pharmacist to provide pharmacy services as stipulated in the Drugs Act, or which is generally known as a drugstore.

Office means a unit of a medical institute or a government sector under the Ministry of Public Health dealing directly or indirectly with the purchasing of pharmaceutical products.

2. GENERAL PRINCIPLES

2.1 In interacting with prescribers or healthcare professionals, medical representatives or medical sales staff must behave themselves in accordance with the ethical principles for sales and marketing, and in an appropriate and professional manner. Proposing or offering anything with conditions which may cause improper inducement should be avoided.

2.2 Member Companies shall observe the law and the ethical rules and regulations as stipulated by the Association and the government units.

2.3 Member companies shall observe the standard criteria for quality, safety and efficacy as required by the Competent Officials for rules and regulations. In all cases, the local rules and regulations and the industrial principles must be observed. It is the Member Companies' responsibility to examine all the local rules and regulations prior to preparing promotional media or activities.

2.4 Only products registered in Thailand can be promoted to healthcare professionals. The information given when promoting the products must be accurate, balanced, unbiased and scientifically correct. Claims should not be over that guaranteed by scientific evidences and every effort should be made to avoid ambiguity and making off-label product claims.

2.5 Information used in promoting products should be based on the latest assessed evidences in accordance with the scientific criteria and should be approved by the Food and Drug Administration (FDA) prior to promoting.

2.6 Promotion must not be made in disguised manner. Clinical assessments, post-marketing surveillance, experience programs and post-authorization safety study must not be disguised but must be scientifically valid.

2.7 The methods of promotion must be appropriate to the learning and the professional status of the healthcare professionals to whom they are targeted.

2.8 The purposes of conducting or supporting clinical and scientific researches by Member Companies must be to develop the knowledge which benefits patients and enhance the scientific and medical progress. Member Companies are obliged to adhere to transparency when supporting clinical researches for patients.

2.9 Member Companies assume the responsibility to ensure that their medical representatives or medical sales staff are adequately trained and possess sufficient medical and technical knowledge to present the companies' product information in an accurate, responsible and ethical manner. They must also bring to their companies' attention the feedback from professionals responsible for prescribing drugs especially that on adverse drug events, the report of which is required to be submitted to the concerned government units by Member Companies.

2.10 Member Companies are obliged to respect the protection of trademarks duly registered in the Kingdom of Thailand and to observe all the relevant laws.

2.11 Donations to organizational units must be made with genuine good governance and must not be used for inappropriate purposes, e.g. as a means to organize educational tours or entertainment activities or any activities without scientific objectives.

2.12 This Code and practices shall be applied with the intent and in the letter.

3. GENERAL PRINCIPLES FOR SALES AND MARKETING PRACTICES

3.1 Promotion of products must not bring discredit to the Association or the local pharmaceutical industry.

3.2 Information on products or the so called "product information" provided to healthcare professionals should be updated, accurate, complete and should not be misleading either directly or by implication or by omission or addition. Scientific data supporting the claims of drug properties or recommendations for drug use should be available, on request, to healthcare-service providers.

3.3 When making references from the medical literatures or the communications of the clinical investigators, special care must be taken to ensure that the meaning of the entire original must not be distorted.

3.4 Making disparaging references to other products or manufacturers should be avoided.

3.5 The word having a meaning of superlative must not be used in promotion. No claims for a product or an active ingredient being "unique" (referring to it being the first and the only one or different from all other products or the only one of its class in the Thai market) are to be used in promotion neither are the claims for its special property to be used without support of evidences. The word "safe" or "without side effects" must not be used in promotion without qualified references. (i.e. it should be safe relating ….. (citing medical literatures or qualified references.)

3.6 Special care must be taken to ensure that essential information on product safety, its contra-indications, adverse drug reactions, side effects or toxic hazards is properly communicated to the local regulatory authorities and healthcare professionals.

In compliance with the above, all printed promotional materials (except short advertisements being product brand reminders as stated under 3.9) must contain the following information:

- The name(s) of active ingredient(s) known internationally as the International Non-proprietary Names (INN) or the approved generic name(s) of the product(s),
- The brand name(s),
- Content of active ingredients per dosage form or regimen,
- The name(s) of other ingredient(s) known to cause adverse effect(s) to drug users,

- The approved therapeutic uses,
- The dosage form and administration,
- Side effects and serious adverse drug reactions,
- Precautions, contra-indications and warnings,
- Major interactions,
- The name and address of the manufacturer or the distributor,
- References to medical literature(s) as appropriate,
- Approval number, granted by the Thai FDA approving the contents of the promotional materials, must be printed on all promotional materials.

The above-mentioned promotional materials shall be used only during the validity period of the approval.

3.7 In the cases where the Thai FDA requires the certified package inserts to be printed in both Thai and English languages, the texts of both languages must correspond unless there are changes made in the texts by the FDA.

3.8 Any information required by the FDA to be printed on the carton or the label must be clearly legible.

3.9 In addition to the requirements stipulated in this Code, Member Companies are obliged to also observe the special rules requiring the printing of the following information on the brand reminders/advertisements: the trade name, the International Non-proprietary Name (INN), indications for therapeutic uses, the sentence "Further information available on request", the company logo and the local contact address.

3.10 Member Companies should have established procedures for reporting adverse drug reactions and product recall. All medical representatives and relevant staff must be informed of the companies' policies and the stated procedures.

3.11 Should there be violation of any of the practices of the Code, or misconduct or misrepresentation by any staff of the Member Companies, the Members shall be responsible for correcting such breaches of the Code.

4. PROMOTIONAL PRINTED MATERIALS INCLUDING ADVERTISEMENTS

4.1 Journal Advertising

4.1.1 All journal advertising must be in compliance with the Drug Act B.E. 2510 and the latest version and approved by the FDA prior to publication. It shall be used only during the validation period of the approval.

4.1.2 Its illustrations and texts must be in the standards appropriate for and in recognition of the professional standing of the professional recipients.

4.1.3 It must not imitate the design of devices, copy other company's slogan or its layouts in such a way to mislead or confuse the public.

4.1.4 Any change in clinical significance relating to product safety should be incorporated into the product information from the date of notification of such change and it should be indicated on all product presentations.

4.1.5 The requirements for journal advertising also apply to advertising in other journals and publications of similar nature.

4.2 Promotional Materials for use by Medical Representatives or Medical Sales Staff

4.2.1 The materials used by medical representatives or medical sales staff, such as detailing aids, hand-outs, leaflets, posters and leave-behind pieces, must comply with the requirements stated in 5.1-5.4 and they must be distributed to healthcare professionals only.

4.2.2 Promotional materials used as brand name reminders must have the following product information printed on them: the contents, the value and the dosage form according to the requirements in 7.2.

5. AUDIO-VISUAL MATERIAL INCLUDING DIGITAL MEDIA

The requirements for journal advertising also applies to the promotion of products via the electronic and the audio-visual aids, especially via websites and other digital media. The word audio-visual material includes sound recordings, VCD/DVD recordings, tape slide presentations, video recordings and broadcastings via the television and the radio, etc.

5.1 The identity of the pharmaceutical company and the target group should be clearly indicated.
5.2 The contents of the message to be communicated via the media must be appropriate to the target group.
5.3 Presentation of the contents linking to the promotion should be appropriate and directing to the target group, and
5.4 Information specific to a country should be in accordance with the local law and the rules and regulations of that country.

6. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

6.1 Trade Displays and Symposia/Congresses

6.1.1 Trade Displays

Trade displays such as product exhibitions are important for the dissemination of knowledge and experiences to healthcare professionals. The prime objectives of organizing such symposia and congresses should be to enhance the medical knowledge and treatments for healthcare professionals. Hospitality associated with symposia and congresses should be of secondary importance.

6.1.1.1 Trade displays should be directed to target groups only, such as healthcare professionals, medical-related associations or clubs, etc.
6.1.1.2 Names of sponsoring companies must be prominently shown at the trade displays.
6.1.1.3 Exhibitors must comply with all the requirements of the major sponsoring organizers with regards booth set-up and product displays.
6.1.1.4 Information on products being promoted must be available at the exhibition stands.
6.1.1.5 Product samples may be distributed during the trade displays. But, they must not be made available for collection from unattended stands nor can they be distributed to unauthorized or unqualified persons.
6.1.1.6 Members are prohibited from holding raffles or games of chance during the trade displays.

6.1.1.7 Offering of financial incentives by Members to invite healthcare professionals to visit their display stands is prohibited. Such incentives include offering of cash and check payments and/or giving donations to charities and associations.

6.1.1.8 Competitions being held as part of the trade displays must fulfill the following requirements:

6.1.1.8.1 The competition is aimed at medical knowledge or enhancing medical knowledge.

6.1.1.8.2 Prizes to be distributed must relate with the medical or the pharmacy professions.

6.1.1.8.3 In the cases where the prizes are not medical/pharmacy profession related, their value must not exceed Baht 500 per item. Or, if they are educational items, the value must not exceed Baht 3,000 per item.

6.1.1.8.4 For entry into a competition, there shall not be a condition of prescribing or recommending a product to be made or implied.

6.1.1.9 All promotional media used during the trade displays must fulfill the requirements as stated in 4.

6.1.1.10 Members should not serve or provide any alcoholic drinks during the trade displays.

6.1.1.11 The activities (whether they are in the form of light, sound or smell, etc.) held during the trade displays must not disturb other exhibitors and/or conference participants.

6.1.2 Scientific Symposia and Congresses

Symposia, congresses and the like are indispensable for the dissemination of scientific knowledge and experiences. Enhancing scientific knowledge for healthcare professions should be their prime objective. Thereby, the scientific focus must not be deviated by the entertainment and the other hospitality programs held during such meetings.

6.1.2.1 Dissemination of scientific knowledge and medical experiences must be the main objective of organizing a symposium, congress, Continuous Medical Education (CME) or a scientific/healthcare program related to the company's product/s or the therapeutic purposes.

6.1.2.2 Entertainment/hospitality/promotional materials provided either directly by the company or by sponsorships or giving assistance to the organizers of medical meetings must be secondary to the educational focus and such must not appear extravagant by local standards.

6.1.2.3 Members must ensure that selection of the meeting venue should be based on the participants' travel convenience and safety, the cost and the appropriateness of the location.

6.1.2.4 Invitations to medical and scientific meetings must be restricted to healthcare professionals only. Sponsorships shall limit to the payments of travel, meals, accommodation expenses and registration fees only. Invitations to guests of healthcare professionals being the attendees, or payments of expenses for persons accompanying the attendees are prohibited.

Arrangement or payment of entertainment/hospitality or recreation/ stand-alone social activities, (which is not part of disseminating scientific information), is strictly prohibited. Decent and non-extravagant entertainment/hospitality programs during the meetings may be arranged. However, such must be secondary to the providing of drinks and/or meals.

6.1.2.5 During the medical symposium organized by either the local or the international organization, the Company must not carry out any activities which may disturb or interfere the official sessions certified by the meeting organizer.

6.1.2.6 Sponsoring individual healthcare professionals to attend a symposium/ congress must not be conditional on an obligation to promote any pharmaceutical products.

6.1.2.7 Members should not sponsor healthcare professionals to participate in any sporting or entertainment/recreation/social activities as such may be regarded as an inducement. Donations or sponsorships should be made directly to the institutions, not to the individuals, upon request by writing from the institutions. The sponsored activities should be specifically for healthcare professions or to improve healthcare services.

6.1.2.8 In considering giving support to healthcare professionals to participate in a symposium organized by those other than the Company, it is essential that the Company carefully examine the meeting venue to ensure that it is an appropriate venue as required by the Code.

6.1.2.9 Payment of cash to healthcare professionals in compensation for the time consumed in attending a symposium/congress is prohibited.

6.1.2.10 Members may display posters or distribute promotional materials of a non-approved product/indication (specifically of a generic name). However, such shall be in accordance with the conditions as stated in 4.

6.2 Honorarium

Healthcare professionals may be invited to be advisors, lecturers and/or chairpersons of joint meetings related to scientific investigations, clinical researches or chairpersons of Advisory Board Meetings or market researches, etc., and thereby are paid an honorarium for such professional services. The payment of honorarium shall be in accordance with the following criteria:

6.2.1 Only healthcare professionals who can provide the services as specified in the requirements and are expert in the field specified shall be selected.

6.2.2 The number of healthcare professionals selected must be reasonable to fulfill the specified services.

6.2.3 Employing healthcare professionals for the mentioned purposes must not be an inducement for them to prescribe, recommend, purchase, procure and/or administer any medicinal products.

6.2.4 The honorarium paid must be reasonable and reflect a standard fair rate being normally paid for such services.

7. OCCASIONAL GIFTS, PROMOTIONAL AIDS AND MEDICAL UTILITIES FOR HEALTHCARE PROFESSIONALS

7.1 Occasional Gifts

7.1.1 Gifts may be given for customary and acceptable local occasions.

7.1.2 Payment of cash/checks or gold or gifts of cash equivalent (e.g. gift checks) to healthcare professionals is prohibited.

7.1.3 Gifts to healthcare professionals and/or medical institutions for customary and acceptable local occasions shall be allowed on an “infrequent” basis. The value of such gifts must not exceed Baht 3,000 per healthcare professional per occasion.

7.2 Promotional Aids

7.2.1 Promotional aids or giveaway articles are not monetary items. They serve to promote the products and must be relevant to the practice of the recipients who are healthcare professionals. Thereby, the value and the amount distributed should be low.

7.2.2 Promotional aids serving as brand name reminders shall include the trade name of the product and/or the logo and/or the company name only. They must not contain any promotional claims or slogans being identities of any particular products or any promotional statements.

7.2.3 A Promotional-aids item should have a value of not exceeding Baht 500 per piece and should be relevant to the practice of the healthcare professionals.

7.3 Medical Utility Items

Medical utility items include human anatomies used in medical treatment rooms or medical textbooks as both relate to the treatments and the benefits of patients. According to the Code and the local rules and regulations, the Company may offer or give medical utility items if

7.3.1 their value does not exceed Baht 3,000 (Baht Three Thousand) per item,

7.3.2 they are not to substitute the professionals' routine duty but to enhance healthcare services or treatments for patients.

Although medical utility items are appropriate for professionals' practices, they should not be offered/given by the Company frequently.

8. PRODUCT SAMPLES

8.1 Product samples may be distributed to professionals having the authority to prescribe particular products and with their consent only. The size and the quantity to be distributed should depend on either of the following purposes:

8.1.1 for familiarization with the product presentation and the appearance, or

8.1.2 for providing initiation of therapy for patients, or

8.1.3 for conducting a clinical evaluation of a particular product.

8.1.4 Product samples are to be delivered by sole distributors, medical representatives or via mail or courier or other appropriate means and should be securely packed. (This is for the sake of quality administration and the safety of the product.)

8.2 No persons are allowed to sell or trade or offer to sell or trade any drug samples. The term "drug sample" in this paragraph means a unit of a drug or a drug/s in any one pack size, which is not meant for sale or trading but for the purposes as mentioned in 8.1 above.

8.3 Product samples must not be made available for collection from unattended stands at the trade displays and must not be distributed to unauthorized persons or unqualified persons.

8.4 The words "Sample – not for sale" should be clearly marked on all product samples to prevent them from being resold or misused.

9. THE COMPLIANCE PROCEDURE AND THE RESPONSIBILITY OF THE COMPANY

9.1 Members are obliged to establish a compliance procedure within their organization to ensure their employees' full compliance of the Code. Such procedure may be prepared in the form of a document distributed to their staff for information and compliance.

9.2 Members should ensure that all their relevant medical representatives or medical sales staff are consistently trained on their appropriate role in the sales and marketing practices.

10. MEDICAL REPRESENTATIVES OR MEDICAL SALES STAFF

10.1 Members assume the duty to give adequate training and sufficient medical and technical knowledge for their medical representatives/medical sales staff to present current information on the company's products in an accurate and appropriate manner and in cognizance of all the provisions of the Code as follows:

10.2 Medical representatives/medical sales staff must always adhere to professional ethics when carrying out their duty.

10.3 Oral and written presentations or those via printed materials must be accurate, fair, complete and trustworthy. Promotion of off-label product claims is prohibited except those indicated in the leaflets.

10.4 Medical representatives/medical sales staff must avoid making unfair or misleading comparison or making comparison implying a therapeutic advantage which, in fact, is not true.

10.5 Using any inducement or subterfuge to gain calls for offering sales of products to healthcare professionals by medical representatives/ medical sales staff is prohibited. Nor should any payment in return for such a purpose be allowed.

10.6 Care must be taken by medical representatives/medical sales staff to ensure that the pharmaceutical products in their possession are secure, in good condition and kept in accordance with the storage recommendations.

10.7 Companies must prepare and make available to their medical representatives/medical sales staff the detailed briefing materials regarding the technical aspects of the product/s to be promoted.

10.8 Medical representatives/medical sales staff must refrain from using a trick to extend the time for product presentation to healthcare professionals on the pretext of carrying out a survey. This, however, does not prevent them from obtaining survey information with genuine intent.

10.9 Medical representatives/medical sales staff are prohibited from using cross channel sales method by using doctors' name as purchasers, thereby selling the products to drugstores, medical representatives or medical sales persons.

10.10 Medical representatives/medical sales staff should dress tidily and professionally in business attires or the company uniforms while on duty.

10.11 Care must be taken by medical representatives/medical sales staff to ensure that the duration, frequency and timing of making calls on healthcare professionals and their manner when interacting with them must not cause inconvenience/trouble to the doctors, pharmacists or nurses, especially staff in the OPD.

11. DATE OF ENFORCEMENT OF THE CODE

The Code is valid for enforcement from the 1st of August, B.E. 2558 (2015) onwards.