



# PreMA Code of Practice

2019





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# PReMA Code of Practice

# PReMA Code of Practice

## 12<sup>th</sup> Edition

SPIRIT OF PReMA's CODE OF PRACTICE



The Pharmaceutical Research & Manufacturers' Association (PReMA) member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical companies, represented by PReMA, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare in Thailand.

Trust is the core of PReMA Code of Practice's Spirit - PReMA members shall act with integrity and honesty to improve patient care and to build trust with those we serve and to respect the independence of healthcare providers, patients and other stakeholders.

In order to build Trust, there are four principles that PReMA members shall focus on - Care, Fairness, Respect & Honesty.

Firstly, it is their Care to those who use their products from the conduct of clinical trials and throughout the product life cycle. This is by improving health through innovative products and services, upholding highest ethical, scientific and medical standards and commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

Secondly, PReMA members shall focus on Fairness in trade practices and open competition. This shall be done with integrity, where they shall act responsibly, ethically and professionally. There will be no offer, promise, provide or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage. PReMA members shall also be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.

Thirdly, it is the Respect to all people and embraces a culture of diversity and inclusion, to protect environment and treat animals under our care responsibly. This shall be done through supporting advancement of scientific and medical education for the ultimate benefits of patients and also respect privacy rights and appropriately manage and protect personal information. Last but not least, the fourth factor in building Trust, is Honesty, where our members shall ensure truthful and balanced communication with governmental authorities, healthcare professionals (HCPs), patients and other stakeholders. This shall be done by fostering a culture in our respective organizations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve. Another action is the transparency on advance of science and patient care through sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.

## PREAMBLE

- I. The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that HCPs have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.
- II. PReMA is a non-profit, non-governmental organization, registered under the Ministry of Commerce, Thailand. We represent companies who are engaged in the research and development, manufacturing, trading or importing of pharmaceutical products. Membership, as ordinary members, associate members or honorary members, is opened to companies who are registered in accordance with the law of the Kingdom of Thailand.
- III. The PReMA Code includes standards for the ethical promotion of pharmaceutical products to HCPs and helps ensure that member companies' interactions with HCPs and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.
- IV. It is a requirement of PReMA membership to adopt conditions of PReMA Code of Practice (hereinafter shall be stated as 'PReMA Code') as it is in accordance with the key objectives of the Association as set out in Section 40 of the PReMA Articles of Association and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, PReMA Code.
- V. It is accepted that where there is an established framework of stringent regulatory or legal controls which are effectively as comprehensive in their provisions and application as the PReMA Code, it may be more appropriate for member companies to follow such framework. PReMA acknowledges that many member companies have already established their own codes of conduct, which, together with local laws and regulations, fully embody the principles set forth in the PReMA Code.



- VI. PReMA member companies and anyone acting on their behalf must comply directly with PReMA Code.
- VII. PReMA member companies are accountable for addressing and correcting infringements under relevant codes.
- VIII. PReMA is open to receive complaints from any source on any aspect of the PReMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the PReMA Code, the objective is to correct the matter as rapidly as possible.
- IX. Payment to any government hospital account is not allowed if said payment has any linkage or association with said government hospital's procurement.
- X. Effective 1<sup>st</sup> January 2019, the PReMA Code of Practice Edition 12 replaces the 2018 PReMA Code of Practice Edition 11.1. Member companies of PReMA must incorporate this Code into existing company codes no later than 1<sup>st</sup> January 2019, subject to the guidance set out in Articles (IV) and (V) above.

## 1. SCOPE AND DEFINITIONS

### 1.1 Scope

The PReMA Code covers interactions with HCPs, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations or relevant codes of practice. Member companies should, of course, comply with these local laws, regulations or codes.

### 1.2 Definitions

- In addition to this Code of Practice, there is a 'Guideline for PReMA Code of Practice', of which will elaborate practice in certain areas as reference for members.
- "Promotion" means activities undertaken, organized or sponsored by a pharmaceutical company with the objective to encourage the prescribing, supply or administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.  
"Promotion" includes the activities of company representatives and all other aspects of sales promotion in whatever form they may occur. Examples of promotion include but are not limited to: product information presented in any form; public relation activities; advertising via electronic media, journal/print and direct mail; participation in exhibitions; use of audio cassettes, films, records, slides, tapes and video recordings; the use of any other data storage and viewing devices reproduced on television; visual display units.  
"Promotion" does not extend to replies made in response to enquiries from particular doctors or replies in response to a specific communication, including letters published in a medical journal.
- "Pharmaceutical product" in this concept means any pharmaceutical or biological product intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, which is promoted and advertised to the healthcare professionals rather than directly to the lay public.

This includes medical equipment that is directly associated with the pharmaceutical product.

- “Prescription medicine” means ‘specially-controlled medicine’, ‘dangerous medicine’, ‘narcotic drug’ and ‘psychotropic drug’ according to drug classification of current Drug Act.
- “Over-the-counter medicine” means ‘non-dangerous’, non-specially-controlled medicine’ and ‘household medicine’ according to the drug classification of current Drug Act.
- “Healthcare professional” (HCP) means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product and those as defined under current Drugs Act, in context of PReMA code, including government officers who review and approve pharmaceutical products.
- “Healthcare Organization” (HCO) means an entity that provides healthcare, which is not an individual Healthcare Professional, but may be a group of Healthcare Professionals. Examples are hospitals, clinics, medical schools or universities, group practices, laboratories, including medical society who is independent association of medical or scientific professionals organized to promote medical or scientific knowledge and advances.
- “Company representative” means a company employee whose duties comprise or include calling upon members of the healthcare profession to provide them with information or any other purposes about the company’s products/services.
- “Certified package insert” means comprehensive product information included in each product pack as approved by the Food and Drug Administration (FDA) of the Ministry of Public Health.
- “Patient organization” means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families or caregivers.
- “Medical institution” means typically an organization that is comprised of healthcare professionals or that provides healthcare or conducts healthcare research.

- Categories of PReMA Membership include:
  - Ordinary Members, are Juristic persons of good standing who are manufacturers, traders or importers of medicines or other pharmaceutical products and who have applied to become members and have been approved by the Board of Directors of PReMA. Juristic Persons incorporated in and under the laws of other countries which manufacture, trade, or import medicines or other pharmaceutical products in Thailand either directly or through other parties are also entitled to become Ordinary Members of the Association.
  - Associate Members, are Juristic persons or natural persons of good standing who have association with the pharmaceutical industry but who are not eligible for Ordinary Membership. However, persons associated with a business or who take part in the activities of any company which is eligible for membership as a Juristic person shall not be eligible for a membership as a natural person.
  - Honorary members are natural persons who have rendered valuable services to the development of healthcare in Thailand the pharmaceutical industry, or the Association, PReMA.



## 2. BASIS OF INTERACTIONS

### 2.1 Basis of Interactions

Member companies' relationships with HCPs and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about medicines, providing scientific and educational information and supporting medical research and education.

### 2.2 Transparency of Promotion

Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company, should clearly indicate by whom it has been sponsored. Promotion should not be disguised.

### 3. PRE-APPROVAL COMMUNICATIONS AND OFF-LABEL USE

- 3.1 No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given in the country.
- 3.2 This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stakeholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.
- 3.3 The company shall respond only upon an unsolicited request by the medical association or healthcare professionals to provide scientific information on pre-authorized products or indication.
- 3.4 The company should put clear role and responsible of the staff who can involve in the activity under this section which normally are Medical Affairs personnel or Regulatory Affairs personnel. No person in commercial functions such as marketing and sales should be actively and directly involved in such activity in any case.
- 3.5 Scientific information exchange must not in any circumstances be used as a disguised form of promotion and the research per se must not have a direct objective of influencing the opinions of the informant. The research design should be done in such a way that the data is unbiased and non-promotional.
- 3.6 Due to the restriction conditions, the company may display or distribute any scientific information materials of a non-approved product/indication in a specific event or activity without any product branding.

## 4. STANDARDS OF PROMOTIONAL INFORMATION

### 4.1 Consistency of Product Information

- It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material.
- Promotional material must conform to the legal requirements set out in the current Drugs Act.
- Respecting the requirement that promotion should be consistent with the label and approved uses locally. HCPs have full rights to access to similar data to those being communicated in other countries where having similar approved product information.
- Particular care should be taken that essential information on any pharmaceutical products' safety, contra-indications, side effects or toxic hazards is properly communicated to the Thai regulatory authorities and to HCPs of Thailand.
- When certified package inserts are required by the Thai FDA to be printed and provided in the Thai and English languages, the information imparted in both languages should be the same unless the text is changed by the FDA.

### 4.2 Accurate and Not Misleading

- Promotional information on all type of materials should be clear, legible, accurate, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned.
- Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. Any change of clinical significance relating to product safety, should be incorporated into the Product Information, from the date of notification about the change and it should be indicated in all presentations of the product.
- It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Imitating the devices, copy slogans or general layout adopted by any other company, in a way that is likely to mislead or confuse should be avoided. Every effort should be made to avoid ambiguity.

- In quoting from medical literature, or from the communications of clinical investigators, special care should be taken to ensure that the meaning of the original, taken as a whole, is not distorted.
- Disparaging references to other products or manufacturers should be avoided.
- Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as “safe” and “no side effects” should generally be avoided and should always be adequately qualified (i.e. it should be ‘safe’ relating to ...+ reference..)
- Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique (“unique” means being the first, different from all others and the only one of its class in the Thai market), or has some special merit, quality or property unless such a claim can be substantiated.
- Promotional information shall conform both in text and illustration, to standards of good taste and should recognize the professional standing of the healthcare profession recipient.

#### **4.3 Substantiation**

- Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to HCPs.
- Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.



## 5. PRINTED PROMOTIONAL MATERIAL

Where local regulations or codes are in force, which define requirements, those take precedence.

### 5.1 All Printed Promotional Material, including Advertisements

All printed promotional materials, other than those covered in Article 5.2 below, must include:

- The name of the product (normally the brand name);
- The active ingredients, using either International Non-proprietary Names (INN) or approved generic names where they exist;
- The name and address of the pharmaceutical company or its agent responsible for marketing the product;
- Date of production of the advertisement;
- “Abbreviated prescribing information” which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions, warning, interaction, and side-effects;
- Reference to scientific literature as appropriate;
- Advertisement approval number granted by Thai FDA for approved contents of the promotional material, shall be printed on all promotional materials. Such promotional material shall only be used during the validity period of the approval.

### 5.2 Reminder Advertisements

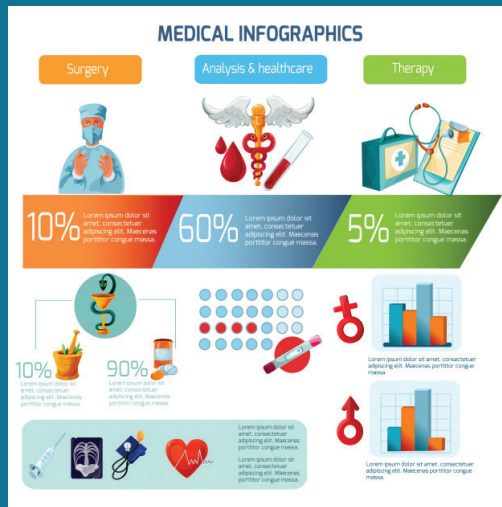
A “reminder” advertisement is defined as a short advertisement containing no more than the name of the product (brand name), the active ingredients (International Non-proprietary Names (INN) or approved generic names) and a simple statement of indications to designate the therapeutic category of the product, the sentence ‘Please refer to the full prescribing information’, the company logo, and advertisement approval number granted by Thai FDA. For “reminder” advertisements, “abbreviated prescribing information” referred to in Article 5.1 above may be omitted, anyway, as per Thai FDA advertisement approval.



## 6. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS

The same requirements shall apply to electronic promotional materials as apply to printed materials including Thai FDA advertisement approval regulation. Specifically, in the case of pharmaceutical product related websites:

- The identity of the pharmaceutical company and of the intended audience should be readily apparent;
- The content should be appropriate for the intended audience;
- Country-specific information should comply with local laws and regulations.



## 7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

### 7.1 Exhibitions

Exhibition is important for the dissemination of knowledge and experience to the healthcare professions. The prime objective in organizing such displays should be the enhancement of medical knowledge. Where hospitality is associated with symposia and congresses, it should always be secondary to the main purpose of the meeting.

- 7.1.1 Exhibition must be directed only to healthcare professionals.
- 7.1.2 Exhibition must include, in a prominent position, the name of the sponsoring company.
- 7.1.3 Exhibitors must comply with all requirements of the sponsoring organization when setting up and conducting an exhibition.
- 7.1.4 Product Information for all products being promoted must be available from the exhibition stand.
- 7.1.5 Raffles or games of chance are not to be held by members during the exhibitions.
- 7.1.6 Companies must not offer financial incentives to healthcare professionals to visit their exhibition stands. Such incentives would include cash payment, cheque, vouchers, or donations to charities or societies.

- 7.1.7 Competitions that are held as part of the exhibitions must be on medical or scientific knowledge or enhancing medical or scientific knowledge. Nevertheless, no prize from competitions can be distributed to HCPs.
- 7.1.8 During the exhibition, companies shall not serve or make available alcoholic drinks in the display areas.
- 7.1.9 Any activities during the exhibition shall not disturb (e.g. in the form of light, noise, or smell) other booths and conference participants.



## **7.2 Events and Meetings**

### **7.2.1 Scientific and Educational Objectives**

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an “Event”) for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information or inform healthcare professionals about products.

Any support to individual healthcare professionals to participate should comply with PReMA Code, law and regulation, including hospital regulation, whichever is stricter, and should not be conditional upon any obligation to promote any medicinal product.

Sponsorship can be made directly to the institution (not individuals) upon the institution’s request to support activities for the 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.

### **7.2.2 Events Involving Travel**

No company may organize an Event for healthcare professionals that take place outside the HCP's country of practice unless it is appropriate and justified to do so from the logistical or security point of view. The company may sponsor an Event for healthcare professionals that take place outside the country if it is justified as Regional or International scientific congresses and symposia that derive participants from many countries.

Travel for all sponsorship of attendee should be by Economy class. Group transportation to and from meeting venue for healthcare professionals is allowed. However, individual transport should be avoided.

### **7.2.3 Appropriate Venue**

All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using renowned or extravagant venues.

The company must ensure that location selection should be based on participant travel convenience (easy to access), security, cost and capability of withstanding public scrutiny; and that the content of the meeting and event, and not the site selection, attracts the audience. The choice of venues in locations emphasizing leisure, sporting facilities, or primarily known for its touristic offering is prohibited. Please refer to detailed guideline of location and venue under no. 7.2.

### **7.2.4 Limits**

Sponsorship to healthcare professionals shall limit to the payment of legitimate travel, registration fees, meals, and accommodation only during the period and location of the sponsored event. The company shall handle arrangement of meeting registration, accommodation reservation and other logistics on behalf of the sponsored attendees. Reimbursement of expenses against official receipt is possible. No cash advance to healthcare professional is

allowed. No payments are made to compensate healthcare professionals for time spent in attending the Event. Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

Refreshments or meals incidental to the main purpose of the Event can only be provided:

- Exclusively to participants of the Event; and
- If they are moderate and reasonable but must not exceed 2,500 Baht (excluding VAT and service charges) per person per meal for local standard. When the Event taken place outside Thailand, company shall comply with standard defined by host country. If host country does not define maximum value, company should consider reasonable amount according to local standard;
- As a general rule, the hospitality provided must not exceed what participants would normally be prepared to pay for themselves.

#### **7.2.5 Entertainment**

No entertainment or other leisure or social activities can be provided or paid for by the company.

#### **7.2.6 Accompanying Person**

Invitations to attend medical and scientific events and meetings must only be given to healthcare professionals. Companies should neither facilitate nor pay any costs associated with individuals accompanying invited healthcare professionals except in cases of medical necessity.

### **7.3 Fees for Services**

Healthcare professionals must be agreed in advance of the commencement engaged as consultants and advisors for services such as speaking at or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation

involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- 7.3.1 A written contract or agreement of the services which specifies the nature of the services to be provided and the basis for payment of those services.
- 7.3.2 A legitimate need for the services must be clearly identified and documented in advance.
- 7.3.3 The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.
- 7.3.4 The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- 7.3.5 The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, or administer any medicine.
- 7.3.6 The compensation for the services must be reasonable and reflect the fair market value of the services provided. The compensation arrangement may include reimbursement of reasonable expense including travel, meals and accommodation. Please refer to suggestion on fair market value under no. 7.3 in the guideline.

#### **7.4 Support for Continuing Medical Education**

Continuing medical education (CME) helps ensure that HCPs obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate. When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.



## 8. GIFT AND OTHER ITEMS TO HEALTHCARE PROFESSIONALS

Items in this section, where permissible, must never constitute an inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product.

### 8.1 Gifts

- 8.1.1 Gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, wreath, calendar.) of healthcare professionals (either directly or through clinics and institutions) are prohibited. However, corporate image items for public, with no promotional intent and with no linkage to pharmaceutical product symbols, e.g., color, font, artwork of the product, are not prohibited.
- 8.1.2 Providing or offering cash, and cash equivalents or personal services are also prohibited. For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit to the HCP.



## 8.2 Promotional Aids

- 8.2.1 A promotional aid (giveaway or gimmick) is a non-monetary item given for a promotional purpose, which does not include promotional materials as defined in other section.
- 8.2.2 Providing or offering promotional aids to HCPs in relation to the promotion of prescription-only medicines is prohibited. Note pad and pen with company logo or company name is allowed to be distributed at company organized events for the purpose of taking notes during the meeting. However, such logo or name shall not link with product symbols, for examples font, artwork, tagline of the product.
- 8.2.3 Providing or offering promotional aids to HCPs in relation to the promotion of over-the-counter medicines may be possible if they:
- are related to the work of the recipient healthcare professionals and should be of minimal quantity. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets are not acceptable.
  - serve as brand name reminders, of which shall include brand name of the product or logo or company name. They are not to contain any promotional claims including promotional tag lines or statements.
  - have value not exceed 500 Baht and are in line with FDA regulations.

## 8.3 Items of Medical Utility to enhance the Provision of Medical Services and Patient Care

Items of medical utility items (such as an anatomical model for use in an examination room) are offered or provided by member companies if such items are in accordance with local laws and regulations and if they are:

- 8.3.1 Value of such items does not exceed 3,000 Baht.
- 8.3.2 The medical utility does not offset routine business practices.

8.3.3 It is beneficial to enhancing the provision of medical services and patient care.

However, the medical utility should not be offered on more than 2 times per year, even if each individual item is appropriate.

Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient and in accordance with local laws and regulations.

#### **8.4 Information or Educational Items that enhance Patient Care**

Informational or educational items (such as medical textbooks, disease booklets) provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies in accordance with local laws and regulations and if they are:

8.4.1 Value of such items does not exceed 3,000 Baht.

8.4.2 The items are primarily for educational purposes.

Informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient and in accordance with local law and regulations.

## 9. SAMPLES

- 9.1 Samples of a product may be supplied to healthcare professionals authorized to prescribe that product or medical institution through their system of sample receiving.
- 9.2 The size and quantity of the samples supplied should be appropriate.
- 9.3 Samples are used to enhance patient care.
- 9.4 Samples should not be given with an intention to induce drug prescription or for personal benefit.
- 9.5 No one may buy, sell and offer to sell or trade any drug samples. The term “drug sample” means a unit of drug, which is not intended to be sold but intended for reasons listed in Sections 9.3.
- 9.6 Product samples must not be either made available for collection from unattended stands, or supplied to unauthorized or non-qualified persons.
- 9.7 Samples should be clearly marked as such, e.g., “Sample Not for Sale”, so that they cannot be resold or otherwise misused.
- 9.8 All samples delivered by sole distributors or company representatives should be securely packed and must be signed by the receiver when received samples.
- 9.9 Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of company representatives.
- 9.10 This section does not mean commercial product that is given to institution for product listing.



## 10. CLINICAL RESEARCH AND TRANSPARENCY

### 10.1 Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009, with minor revision as of October 30, 2017) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010, with minor revisions as of October 30, 2017) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations

(EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

## **10.2 Distinct from Promotion**

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised as promotion.

## **10.3 Post-marketing scientific studies, surveillance and dissemination of information**

10.3.1 Post-marketing clinical trials for approved medicinal drugs are important to ensure their rational use.

10.3.2 Post-marketing scientific studies and surveillance should not be misused as a disguised form of promotion.

10.3.3 Substantiated information on serious hazards associated with medicinal drugs should be reported to the appropriate national health authority and healthcare professional concerned as a priority, and should urgently be disseminated internationally whenever possible.

## 11. MARKET RESEARCH

The sole purpose of market research activities must be to collect data and not as a means to promote company's products to or reward healthcare professionals.

- 11.1 Methods used for market research must never be such as to bring discredit upon, or to reduce confidence in, the pharmaceutical industry. The following provisions apply whether the research is carried out directly by the company concerned or by organization acting on the company's behalf.
- 11.2 Market research must not in any circumstances be used as a disguised form of sales promotion and the research per se must not have a direct objective of influencing the opinions of the informant. The research design should be done in such a way that the data is unbiased and non-promotional.
- 11.3 The identity of an informant must be treated as being confidential, unless he/she has specifically agreed otherwise. Regardless of the existence of this agreement, it follows that the information provided (as distinct from the overall results of the research) must not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion.
- 11.4 Precautions should be taken to ensure that informants do not suffer as the result of embarrassment following an interview, or from any subsequent communication concerning the research project.

## 12. INTERACTIONS WITH PATIENT/PATIENT ORGANIZATIONS

### 12.1 Patient Organization

#### 12.1.1 Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.

#### 12.1.2 Declaration of Involvement

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its major programs.

#### 12.1.3 Written Documentation

Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

#### 12.1.4 Events

Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

## 12.2 Patient Education

It is acknowledged that members of the public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The purpose of such information should be educational and should encourage patients to seek further information or explanation from the appropriate healthcare professional. In addition, the following criteria should be satisfied:

- 12.2.1 The educational material must be current, accurate and balanced.
- 12.2.2 The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.
- 12.2.3 Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.
- 12.2.4 The educational material should include the advice “Please consult your physician” and the contact address and telephone number of the supplier of the material.
- 12.2.5 The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor. Such statements must never be designed or made for purpose of encouraging members of the public to ask their doctor to prescribe a product.
- 12.2.6 The tone of the message must not be presented in a way which unnecessarily causes alarm or misunderstanding in the community.
- 12.2.7 On all occasions the information, whether written or communicated by other means, must be presented in a balanced way to avoid the risk of raising unfounded hopes of a particular product.



### 12.3 Patient Aids

Patient aids which are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific, provided that the items are primarily for educational purposes and do not have independent value. The content of such material must be designed to assist with patient compliance by providing information which clarifies method of administration, precautions, and special instructions and like information. It must not make comparisons or include promotional claims.

Informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

### 12.4 Patient Support Programs

The programs should not have any intention to offset routine business practices and to be beneficial to enhancing the provision of medical service and patient care.

Companies should ensure compliance with the following requirements when they have to involve in any patient support program (PSP):

- Any payment for the work undertaken by a healthcare professional in such programs is commensurate with the work undertaken;
- No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these program;
- The program complies with applicable laws;
- All information provided to patients must comply with Sections 12.2 and 12.3 of this Code;
- The data collected from these programs will not be used for any purpose other than to increase positive health outcomes and never for promotional activities; and
- The duration of these programs is appropriate to the disease state treated by the product involved.



### 13. PROMOTION TO NON-HEALTHCARE PROFESSIONALS (OR PUBLIC)

Prescription products must not be promoted to the public unless such activities are permitted by law. Any information provided must be accurate, balance, factual and not misleading or raising false hopes related to the product.

Where the companies need to interact with the public, in responding inquiries, create disease awareness, provide educational message, . such activities should adhere to the highest standards of accuracy and support the role of healthcare professionals.

#### 13.1 General Inquiries

Request from individual members of the public for information or advice on the company product, diagnosis of disease, choice of therapy or personal medical matters should be refused and the inquirer must be directed to consult their doctor.

## **13.2 Media Release**

- 13.2.1 A prescription product related media release issued by companies is not allowed by the Thai FDA; however, it is acceptable to respond to media inquiries. The information provided must be current, accurate and balanced. Information about the medicine must not encourage members of the public to ask their medical profession to prescribe a particular pharmaceutical product.
- 13.2.2 Company may supply information about a product to the lay press only where this is in the public interest or where the objective is to communicate scientific or technical achievement. Such information should be presented in a balanced way to avoid the risk of raising unfounded hopes.
- 13.2.3 Product information should be released for lay publication only after the medical profession has been properly notified and following approval from the FDA if this is required by the current Drugs Act.
- 13.2.4 Advertising of self-medication products to the public is excluded from the scope of the Code. However, should medicines regarded as 'pharmaceutical products' in most countries, be designated Non-Dangerous in Thailand, it is suggested that any lay promotional material should comply with the guidelines established for "pharmaceutical products".
- 13.2.5 Intentional dissemination of information or hidden advertisement of dangerous medicines through radio disk jockey or television moderator is forbidden.

## **13.3 General Media Articles (Advertorial Articles)**

General media articles concerning specific prescription products must not be initiated by companies. However, information on medical conditions is allowed.

Companies should not attempt to encourage the publication of general media articles or their content with

the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

**13.4 Telephone Hotline and Website**

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

**13.5 Direct Mailing**

Direct mailing of product promotional materials from company to non- healthcare professionals is prohibited.

**13.6 Discredit to, and Reduction of, Confidence in, the Industry**

Activities with, or materials provided to members of the public must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. Such activities would be seen as a Severe Breach of the Code of Practice.



## 14. COMPANY PROCEDURES AND RESPONSIBILITIES

### 14.1 Procedures

It is the responsibility of all companies to ensure that an internal compliance procedure exists that strives for compliance with all provisions of the Code and the spirits it embodies, including applicable laws, and to review and monitor all of their activities and materials in this regard. This procedure should be documented and provided to relevant employees to further enhance Code of Practice compliance.

### 14.2 Training

Companies should ensure that relevant employees receive regular training appropriate to their role.

### 14.3 Responsibilities for Approving Promotional Communications

A designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.



## 15. COMPANY REPRESENTATIVES

- 15.1 Company representatives must be adequately trained and should possess sufficient medical and technical knowledge to present information on the company's products in an accurate, current and balanced manner and cognizant of all provisions of this Code.
- 15.2 Company representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.
- 15.3 Oral presentations as well as written or printed material must aim at accuracy, fairness, balance and good taste. No promotion should be used for off-label product claims.
- 15.4 Unfair or misleading comparisons, or comparisons implying a therapeutic advantage which is not in fact justified, must be avoided.
- 15.5 Company representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid for that purpose.
- 15.6 Companies must prepare and provide to company

- representatives, detailed briefing material on the technical aspects of any product which is to be promoted.
- 15.7 The practice of gaining or extending an interview on the pretext of carrying out a survey is to be avoided. This does not preclude the use of company representatives to obtain bona fide survey information.
  - 15.8 Company representatives must not use cross-channel sales method by using doctors' name as purchaser in selling products to the drugstores.
  - 15.9 Company representatives should dress professionally in business attire or uniform while performing their duties.
  - 15.10 Company representatives should ensure that the frequency, timing and duration of appointment, together with the manner in which they are made, are such as not to cause inconvenience to the doctors, pharmacists or nurses. In addition, company representatives should meet healthcare professionals in place as specified by the hospitals and, if possible, refrain from meeting healthcare professionals in OPD during their operation hours and while healthcare professionals are meeting with or examining patients.

## 16. ADMINISTRATION

- 16.1 Complaints regarding breaches of The Code will be administered by the PReMA Chief Executive Officer, the Code of Practice Committee (hereinafter called as “CPC”) and an Appeal Committee. The CPC shall consist of five (5) members - a Chairperson who is an external member, two committee members who are also external members, one representative from PReMA Board of Directors and one Medical Director. PReMA Board of Directors and the Medical Directors of Member Company shall provide a set of three representatives, all of which shall be from a different company, to standby for the CPC. The Appeal Committee shall consist of similar structure like CPC, but there will be change of one or two external members and also change of the two internal members from the ones considering such appealed case.
- 16.2 Code Compliance Subcommittee (hereinafter referred to as ‘the CCSC’) will carry out a review of the provisions of the Code after seeking input from interested parties. Besides regular review of the Code, the CCSC will perform activities to create awareness of the Code. CCSC will set up Code Compliance Advisory Panel (CCAP) to provide consultation and guidance based on the Code to member companies upon request. Guideline recommendation from CCAP shall be binding for all member companies for the particular case being consulted. SOP of CCAP is per details in guideline no. 16.
- 16.3 All valid complaints will be forwarded by the PReMA CEO to the Code of Practice Committee (CPC) and Appeal Committee, if so requested by the alleged company for the latter group.
- 16.4 The role of the CPC will be to meet on a quarterly basis to hear valid complaints and act as judge, jury and cross examiner of the evidence before them and to ultimately decide on any sanction as per section 18.





## 17. COMPLAINTS PROCEDURE

All attempts should be made to settle a dispute through direct communication between the companies involved, at the General Manager (GM) or Chief Executive Officer (CEO) level. The procedures for filing complaints via PReMA are as follows:

### 17.1 Formal Complaints:

- 17.1.1 Complaint Submission - All complaints must be submitted in writing directly to the PReMA CEO. Complaints can be made by either member companies or from non-member sources, e.g. Thai FDA, healthcare professionals or professional organizations, patients or patient groups, .
- 17.1.2 Complaint Validation - Any complaints submitted to PReMA shall be validated by the PReMA CEO to ensure that:
  - it appears to be a genuine matter, submitted in good faith.

- There is sufficient evidence to enable the complaint to be processed.
  - It is not a duplication of a case, which has already been resolved under the Code.
- 17.1.3 The minimum information required is;
- Source of the complaint
    - If the complaint is from a company or organization, it must be printed on the company's or organization's letter head and signed off by the GM or CEO. For complaint from an individual, real name, address and contact telephone number must be provided.
  - Alleged Company
    - For each case in the complaint, the identity of company which is alleged to be in breach of the Code and the name of any product(s) /marketing activities must be specified.
  - Reference material
    - For each case, a specific reference to the source of the advertisement/activity or printed material which is the subject of the complaint as well as any other evidence must be provided.
  - Date
    - The date of the alleged breach of the Code.
  - Summary
    - If possible for each case, a brief description of the complaint with a specific reference to the part of the Code under which the complaint is being made (section & paragraph).
- 17.1.4 Complaint Processing - When the PReMA CEO receives a signed complaint validated in accordance with section 17.1.2, and it appears that the alleged company may have contravened the Code, the case will be accepted for adjudication. The PReMA CEO may request for

additional information or evidence from the complainant or the alleged company. The case with all evidence will then be forwarded to the CPC. The names of the complainant company, healthcare professionals and any third parties involved will remain confidential throughout the process.

- 17.1.5 Complaint Adjudication - The CPC shall review the case. If there is a need for additional information or evidence, a request will be made to the complainant and alleged company via the PReMA CEO. The CPC will then adjudicate whether a breach of the Code has occurred based on the compiled evidence.
- 17.1.6 Complaint Disposal - The decision of the CPC will be reported directly to the PReMA CEO, who will inform both the alleged company and the complainant of the decision. Sanction against the company found in contravention of the Code will be applied by the PReMA CEO, subject to Section 18 of the Code.
- 17.1.7 Complaint Resubmission - Where the alleged company or complainant disagrees with the decision of the CPC they may submit the case for reconsideration by the Appeal Committee. The Appeal must be made in writing with new evidence within 30 days after receiving the notification from the PReMA CEO. If new evidence are put forward by the complainant, the alleged company shall be invited to provide comments within 90 days. The decision of the Appeal Committee at this stage will be regarded as final and executory. The company who requests for the appeal process shall be responsible for the administration costs involved in setting up the meeting(s).

17.1.8 The PReMA CEO shall report all valid complaints received, the CPC adjudications and the actions taken to the members. The name of the complainants will remain confidential but the names of the breaching companies will be disclosed.

## **17.2 Anonymous Complaints**

17.2.1 Complaint Submission - Anonymous complaints can be submitted either in writing or via telephone call to the PReMA CEO. Complainant, either from companies or non-members (as described under 17.1.1), who may request for being anonymous informant.

17.2.2 Complaint Validation - Any anonymous complaints submitted to PReMA shall be validated by the PReMA CEO to ensure that:

- It appears to understand that there being ground for the complaint and the submission was in good faith.

17.2.3 The minimum information required is;

- Source of the complaint
  - As described under 17.2.1, the source of complaint would be kept anonymous. Therefore, if available, it will be kept confidential.
- Alleged Company
  - For each case in the complaint, the identity of company which is alleged to be in breach of the Code and the name of any product(s) /marketing activities must be specified.
- Reference material
  - For each case, a specific reference to the source of the advertisement/activity or printed material which is the subject of the complaint as well as any other evidence may or may not be provided.

- Time
  - If possible, there should be time period of the alleged breach of the Code.
- Summary
  - If possible for each case, a brief description of the complaint with a specific reference to the part of the Code under which the complaint is being made (section & paragraph).

17.2.4 Complaint Processing - When the PReMA CEO receives anonymous complaint, the case will be checked with the alleged company. Alleged company will be requested to investigate whether such allegation has ground and keep PReMA informed of any action taken to refrain from such action in the future, if the allegation found valid.

However, it is under PReMA CEO's judgment whether the case should be handled as a kind of warning or submitted to the CPC for adjudication process based on the seriousness of the case. If PReMA CEO so decides to bring the case for adjudication by the CPC, the decision must be conveyed to the alleged company, who should be allowed to provide their defending position and any supporting evidence prior to CPC's consideration. The case with all evidence will then be forwarded to the CPC. The names of the complainant (if any), any healthcare professionals and third party involved will remain confidential throughout the process.

17.2.5 Complaint Adjudication - If anonymous case be brought to adjudication process, it will be treated similar to formal complaint under sections 17.1.

## 18. SANCTIONS

The PReMA CEO, upon the decision of the CPC, shall apply one or more of the following sanctions to the company found in breach of the Code:

- 18.1 Refer the complaint to the International Federation of Pharmaceutical Manufacturers' Association (IFPMA).
- 18.2 Refer the complaint and the CPC's finding to the head office and regional office of the offending company.
- 18.3 Suspend the offending company's membership for not more than 3 years.
- 18.4 Debar the offending company from membership of the Association, under Section 12.7 (2) of the PReMA Articles of Association.
- 18.5 A written undertaking that the practice complained of, will be discontinued on or before a date to be determined by the CPC.
- 18.6 Retraction statements, including corrective letters and advertising, to be issued by the Subject Company, subject to the approval of the CPC prior to release. It is the company's responsibility to ensure that the requirements of the CPC are met and to immediately inform and provide evidence to PReMA of their fulfillment.
- 18.7 The issuing of a fine by PReMA to the Subject Company as per follows:
  - 18.7.1 A fine not exceeding the value of 100,000 Baht, for a first offence.
  - 18.7.2 A fine not exceeding the value of 500,000 Baht for a second offence, within a 12 month period.
  - 18.7.3 The fine to be paid within 30 days of being advised, subject to any appeal that may be lodged under Section 17.1.1 of the Code





**สมาคมผู้วิจัยและผลิตเภสัชภัณฑ์ (PReMA)**  
**“นวัตกรรมยา เพื่อสุขภาพที่ดีกว่า”**



แบบฟอร์มการขอเผยแพร่ข้อมูลผ่านเว็บไซต์ของหน่วยงานในราชการบริหารส่วนกลาง  
สำนักงานปลัดกระทรวงสาธารณสุข  
ตามประกาศสำนักงานปลัดกระทรวงสาธารณสุข  
เรื่อง แนวทางการเผยแพร่ข้อมูลต่อสาธารณะผ่านเว็บไซต์ของหน่วยงาน พ.ศ. ๒๕๖๑  
สำหรับหน่วยงานในราชการบริหารส่วนกลางสำนักงานปลัดกระทรวงสาธารณสุข

แบบฟอร์มการขอเผยแพร่ข้อมูลผ่านเว็บไซต์ของหน่วยงานในสังกัดสำนักงานปลัดกระทรวงสาธารณสุข

ชื่อหน่วยงาน : ศูนย์ปฏิบัติการต่อต้านการทุจริต กระทรวงสาธารณสุข

วัน/เดือน/ปี : ๒๙ มิถุนายน ๒๕๖๔

หัวข้อ: PReMA Code of Practice 2019

รายละเอียดข้อมูล (โดยสรุปหรือเอกสารแนบ)

PReMA Code of Practice 2019

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สุชาภา วรินทร์เวช

(นางสาวสุชาภา วรินทร์เวช)

ตำแหน่ง นักวิเคราะห์นโยบายและแผนชำนาญการพิเศษ

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**ผู้อนุมัติรับรอง**

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**ผู้รับผิดชอบการนำข้อมูลขึ้นเผยแพร่**

พศวีร์ วัชรบุตร

(นายพศวีร์ วัชรบุตร)

นักทรัพยากรบุคคลปฏิบัติการ

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