PReMA
Pharmaceutical Research & Manufacturers Association

PReMA Code of Practice

13th Edition

2026

Contents

PReMA Code of Practice

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SPIRIT OF PReMA's CODE OF PRACTICE

The Pharmaceutical Research & Manufacturers' Association ("**PReMA**") members 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 and 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 and 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 committing 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, 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

The PReMA Code of Practice Edition 13 replaces the 2019 PReMA Code of Practice Edition 12 and PReMA Code Guideline 2019 (hereinafter shall be referred to as "**PReMA Code**"). Member companies of PReMA must incorporate the PReMA Code into PReMA Members' existing company codes subject to the guidance set out in Articles (IV) and (V) below.

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, Distributor Members or Associate Members, is open 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 PReMA Members' interactions with HCPs and other stakeholders, such as HCOs and Patient Organizations, are appropriate and perceived as such.

IV. It is a requirement of PReMA Members to adopt conditions of PReMA Code as it is in accordance with the key objectives of the PReMA as set out in Section 40 of the PReMA Articles of Association ("**PReMA AoA**") 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 PReMA Members to follow such framework. PReMA acknowledges that many PReMA Members 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 Members and anyone acting on their behalf must comply directly with PReMA Code.

VII. PReMA Members are accountable for addressing and correcting infringements under relevant laws, regulation, and code.

VIII. PReMA is open to receiving 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. In the context of Public Procurement and Supplies Administration Act B.E. 2560 and its subordinates, as amended and the policy recommendation of the National Anti Corruption Commission to the Cabinet in relation to Corruption Prevention on Reimbursement of Civil Servant Medical Benefit Scheme, this implies that no payment is allowed to any government welfare fund if said payment has any linkage or association to government procurement. This provision does not apply to an Ordinary Member acting on behalf of a non-member.

X. The PReMA Code does not restrain or regulate commercial trade terms for the supply of Pharmaceutical Products to customers. The PReMA Code does not cover price lists or other documents describing terms of trade. PReMA encourages competition among companies under Trade Competition Act B.E. 2560 and its subordinates, as amended.

XI. PReMA recognizes the importance of philanthropic activities, and that donations are a matter of the individual member company and its own internal policy. The PReMA Code therefore does not restrict the decision of a company to make a donation. However, there are laws and regulations that govern donations to government agencies, one being that donations cannot be linked to sales.

XII. The PReMA Code and its related documents are available at https://www.prema.or.th/ethics/.

1. SCOPE AND DEFINITIONS

1.1. Scope

The PReMA Code covers interactions with HCPs, HCOs, and Patient Organizations solely for the Promotion of Pharmaceutical Products. Where direct promotion to the public is allowed, this is covered by local laws and regulations. PReMA Members should comply with these local laws, regulations or codes.

The activities conducted by third parties on behalf of PReMA Members are regarded as PReMA Members' own activities.

1.2. Definitions

- **Caregiver:** a Patient's friends, family, or other supporters who provide care to the Patient, which may also include individuals who provide services to a Patient on a compensated basis, such as a home health aide, companion, or social worker.

- **Certified Package Insert:** comprehensive product information included in each product pack as approved by the Thai Food and Drug Administration ("**Thai FDA**") of the Ministry of Public Health.

- **Code Compliance Subcommittee or CCSC:** a subcommittee consists of a representative from PReMA Members with role, responsibility or expertise to oversee compliance activities.

- **Company Representative:** an employee of PReMA Members whose duties comprise or include interacting with or communicating with HCPs to provide them with information or any other purposes relating to the products or services, including, medical representative, marketing personnel, regulatory or medical affairs personnel, management or leadership team involved in such activities.

- **Events:** all types of scientific and/or medical congresses, conferences, symposia, meetings or any type of similar activity (including but not limited to expert meetings, roundtable meetings, training meetings) organized or sponsored by PReMA Members.

- **Healthcare Organization or HCO:** an entity that provides healthcare or conducts healthcare research, which is not an individual Healthcare Professional, but comprised of a group of HCPs. Examples are hospitals, clinics, drugstores, 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.

- **Healthcare Professional or HCP:** 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, dispense, administer, or other influence decisions relating to use, procurement, access, pricing, reimbursement or formulary inclusion of Pharmaceutical Products. This includes without limitation doctors, dentists, nurses, midwives, reproductive healthcare providers, pharmacists, pharmacy assistants, primary care managers and/or officials or representatives of hospitals who are responsible for the hospitals' purchasing decisions, as well as members of formulary committees or payer, pricing and/or reimbursement bodies for Pharmaceutical Products, including those as defined under current Drugs Act B.E. 2510 and its subordinates ("**Drug Act**") and related regulations.

- **Over-the-Counter (OTC) Medicine**: non-dangerous, non-specially controlled medicine and household medicine according to the drug classification of current Drugs Act.

- **Patient:** an individual with personal experience of living with a disease, who is solely representing him/herself and his/her views, opinions, or experiences.

- **Patient Organization:** a not-for-profit institution that primarily represents the interests and needs of Patients, their families or Caregivers.

- **Pharmaceutical Product:** 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 HCPs rather than directly to the lay public. This includes medical equipment that is directly associated with, used in connection with, or necessary for the proper administration or use of such Pharmaceutical Product.

- **PReMA Membership or PReMA Members** include:
  - **Ordinary Members**, which shall be juristic persons (whether incorporated in and under the laws of Thailand or not) whose business objectives involve, whether directly or indirectly, the manufacturing, importation, sale, or marketing of Pharmaceutical Products, medical diagnostics, or medical devices, with a foundation in research and development activities, and support the vision and mission of the PReMA.
  - **Distributor Members**, which shall be juristic persons that do not manufacture Pharmaceutical Products, medical diagnostics, or medical devices but provide distribution services for such products.
  - **Associate Members**, which shall be juristic persons or natural persons of good standing who have association to the pharmaceutical industry but who are not eligible for Ordinary Membership. However, persons associated with 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 member as a natural person.

- **Prescription Medicine:** specially controlled medicine, dangerous medicine, narcotic drug and psychotropic drug according to drug classification under the applicable and current Drugs Act and other related laws and regulations, as amended.

- **Promotion:** activities undertaken, organized, sponsored, or supported by a PReMA Member, directly or indirectly, with the objective of encouraging the prescription, recommendation, supply, administration or consumption of its Pharmaceutical Product(s) through all methods of communication, including the internet or digital platforms.

  "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 relations activities, advertising via electronic media, social media, journal, prints, and direct mail, participation in exhibitions, use of audio and visual recordings the use of any other data storage and viewing devices, including those reproduced on television or visual display units.

  "Promotion" does not extend to replies made in response to enquiries from particular HCPs or replies made in response to a specific communication, including letters published in a medical journal.

2. BASIS OF INTERACTIONS

2.1. Basis of Interactions

PReMA Members 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 related to Pharmaceutical Products and their uses, whether promotional in nature or not, which is supported by a PReMA Member should clearly indicate the supported. Promotional content 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 Thailand except it is requested by HCOs or HCPs, as it may be considered advertising by the Thai FDA. This does not restrict access to scientific or medical information. Pre-approval communication must be reviewed by at least the PReMA Members internal medical or regulatory affairs team to manage the communication. During the pre-approval phrase, no person in commercial functions such as marketing and sales should be actively and directly involved in such activity in any case.

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. PReMA Members shall respond only upon an unsolicited written request by the HCOs or HCPs to provide scientific information on pre-authorized products or indications.

3.4. Pre-launch activities for a new product/indication not yet approved in Thailand may be held only among a group of HCPs at "Key Opinion Leader (KOL)" level, not regards as promotional activity but rather as exclusive, pre-approved/off-label scientific communications, as in the advisory board, investigator, or speaker/KOL development meetings. They must be on a strictly limited scale, with no involvement from the sales function. 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.

3.5. Initiating a topic to promote information on a non-approved product/indication at the symposium or speaker program as part of an association’s meeting is not allowed. However, balanced information scientifically relating to the topic, such as updating the treatment of diseases, and so on, that covers all relevant drugs and methods, may be appropriately and professionally presented, without a promotional tone of non approved product/indication. The pre-approval communication does not prevent compassionate use program which must of course comply with all applicable laws, regulations, and codes. Care should be taken to ensure that communications are not advertisement for unlicensed medicine or use.

3.6. PReMA Members may display or distribute any scientific information materials of a non-approved product/indication in a specific Event or activity. Such materials to be distributed during the international congress held in Thailand for such product/indication not yet approved in Thailand should include appropriate disclaimer and require review and approval by the Thai FDA for exclusive use at specific Event, or alignment with the current the Thai FDA regulations/practice.

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 materials.

- Materials with promotional intent must conform with the Thai FDA requirements set out in the current Drugs Act.

- Respecting the requirement that promotion should be consistent with the label and approved uses in Thailand.

- Particular care should be taken that essential information on any Pharmaceutical Products' safety, contraindications, side effects or toxic hazards is properly communicated to the Thai FDA and HCPs.

- When Certified Package Inserts are required by the Thai FDA to be printed and provided in the Thai and English languages, the information in both languages should be consistent, unless otherwise approved by the Thai FDA.

4.2. Accurate and Not Misleading

- Promotional information on all types of material 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 be misled by distortion, plagiarism, exaggeration, undue emphasis, omission or in any other way. 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 Pharmaceutical 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.

- 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.

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.

- PReMA Members 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

5.1. All Printed Promotional Material, including Advertisements

All printed promotional materials, other than those covered in Section 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 company name, and address or its agent responsible for marketing the product
- date of production and/or expiration of the advertisement
- "abbreviated prescribing information" which should include an approved indication for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions, warnings, interactions, side effects and the sentence "Please refer to the full prescribing information".
- reference to scientific literature clearly cited and properly attributed;
- 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
- approved indications with the dosage and method of use which are consistent with the label and approved uses in Thailand.

For reminder advertisements, abbreviated prescribing information referred to Section 5.1 above may be omitted, anyway, as per Thai FDA advertisement approval.

5.3. Reprints of scientific and medical articles

Where a company finances or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

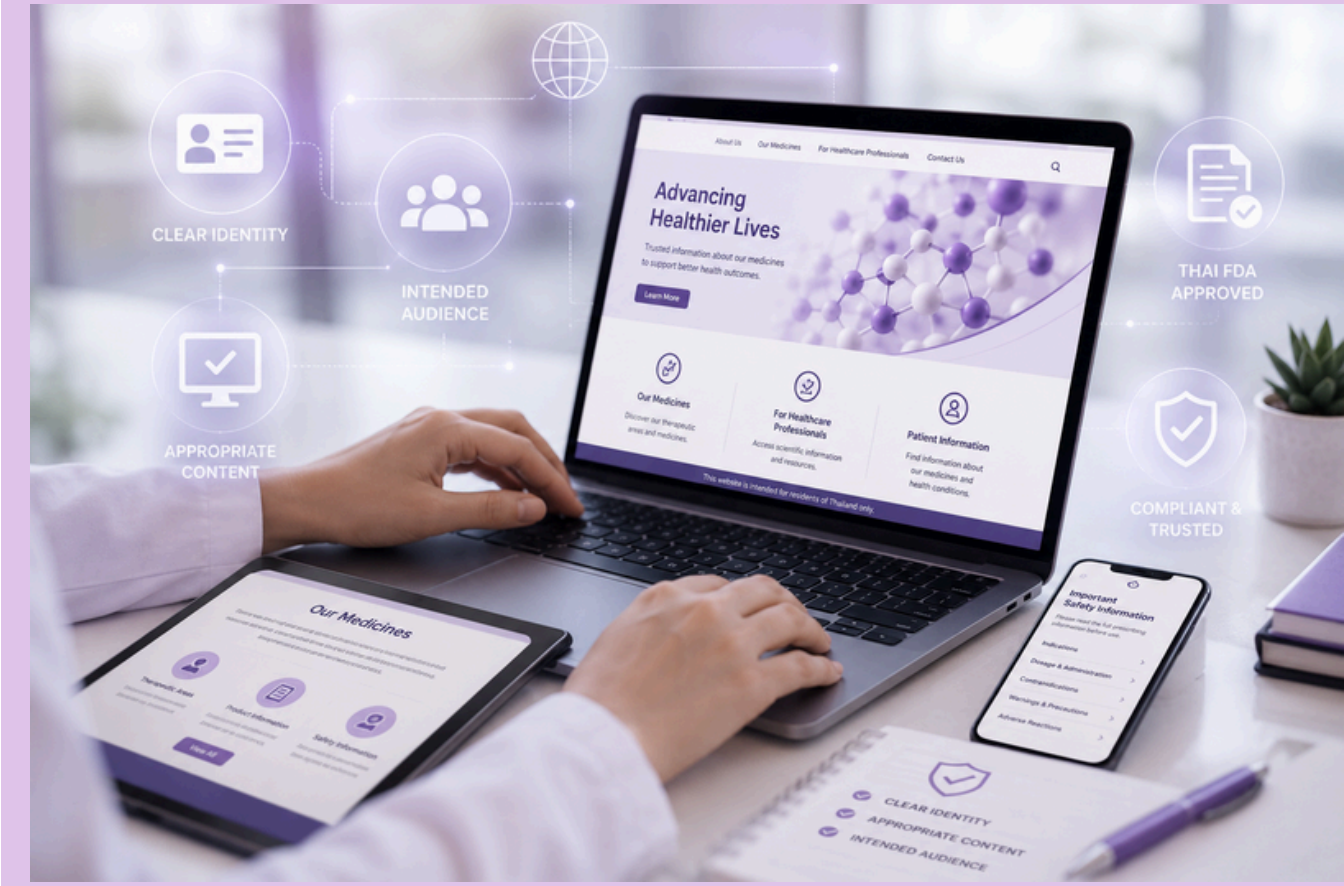
Reprints of scientific and medical articles, when used as standalone documents, are not developed by PReMA Members and as such cannot be considered as promotional materials. If, however, they are proactively presented to a HCP together, with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

5.4. Material for International Symposium

- The Thai FDA informs that highlight symposium with no product branding and, if the text is of scientifically proven content, it does not need to be submitted to the Thai FDA, but it must be used in the international symposium only. However, for printed materials used outside the international symposium, it may be considered as advertisement even though it may contain only generic name. Thus, the Thai FDA requires that for the latter case, it must be submitted for Thai FDA consideration as they must look at the intent of the material as well. According to the current Drug Act, the document can be used during the approved period only.

- Documents distributed in international symposium with no trade name cannot be distributed in other non-international symposium because the international symposium is more flexible. The Thai FDA must consider and approve the use of documents in local symposium on case-by-case basis. However, in case of pre-approved drugs in Thailand, it is not acceptable.

- Proceeding from symposium with no trade name is allowed to be published in medical journal without prior consideration from Thai FDA as long as the content is scientific and contains genuine medical knowledge. However, submission for Thai FDA consideration is recommended because content which includes comparison or displays image, may be interpreted as having hidden intention for commercial benefits.



6. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS

The same requirements including Thai FDA advertisement approval regulation shall apply to electronic promotional materials as well as printed materials.

Specifically, in the case of Pharmaceutical Product related websites:

- The identity of the PReMA Members and of the intended audience should be readily apparent.
- The content should be appropriate for the intended audience.

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.1. Exhibitions

Exhibition is important for the dissemination of knowledge and experience to the HCPs. The primary 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. Any activities of PReMA Members in relation to its exhibition must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and appropriateness. This includes the appearance and behavior (such as their attire and general demeanor) of all PReMA Members personnel or third parties acting on their behalf. All personnel manning the booths shall be PReMA Members' authorized personnel.

7.1.2. Exhibition must be directed only to HCPs.

7.1.3. Exhibition must include, in a prominent position, the name of the sponsoring company.

7.1.4. Exhibitors must comply with all requirements of the sponsored organization when setting up and conducting an exhibition.

7.1.5. Product information for all drugs being promoted must be available at the exhibition booth and/or is distributed to participants at.

a) International event held in Thailand

- The meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place.

- Promotional material for a Pharmaceutical Product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally.

- Promotional material which refers to the prescribing information (indications, warnings and so on) authorized in a country or countries other than that in which the Event takes place, but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

b) Local event held by the PReMA Member:
- Theoretically, according to the present Drug Act, using generic name of new drug that has never been approved in Thailand is considered as promoting the drug itself. Therefore, distributing reprints with generic name may not be accepted, except there has been a written request from HCPs (it is then considered as offering medical information service). Displaying the product at a booth exhibition may not be possibly done, as it is considered as promoting a product that has not been approved yet. Additionally, copying reprints or textbooks without the permission of the owner can violate copyright law.

7.1.6. Regarding reprints of an article showing disadvantages of competitor's product, it may be done if such an article is obtained from publication of medical journal. However, it is not acceptable to do so for the purpose of discrediting the competitors unless it is widely accepted scientific information and must not be for own benefits.

7.1.7. Raffles or games of chance are not to be held by members during the exhibitions.

7.1.8. Companies must not offer financial incentives to HCPs to visit their exhibition stands. Such incentives would include cash payment, cheques, vouchers, or donations to charities or societies.

7.1.9. 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.

7.1.10. Product samples shall not be distributed at the exhibition or be placed inside meeting registration packages.

7.1.11. During the exhibition, companies shall not serve or make available alcoholic drinks in the display areas.

7.1.12. Any activities during the exhibition shall not disturb (for example 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 Event, including but not limited to symposia, congresses and other promotional, scientific or professional meetings for HCPs organized or sponsored by a company should be to provide scientific exchange, educational information, and/or inform HCPs about products.

Any support to individual HCPs to participate should comply with PReMA Code, law and regulation, including hospital regulation, in Thailand, 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 HCPs 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.

a) When deciding whether to support an Event organized by a third party such as a HCO, as well as support of a HCP to such Events, criteria to be considered are, as follows:

(i) Scientific Program
- The scientific program is available on the event organizer's website well in advance of the meeting.
- The scientific program covers the whole duration of the Event with content generally filling the business hours each day.
- The program content is scientifically grounded and adapted to the targeted audience.

(ii) Entertainment, leisure activities, meals, refreshments at booth
- Any entertainment (such as sightseeing tours or leisure activities) must not be organized in connection with the Event either before, during or after or there is unreasonable or frequent traveling for meals during the Event.
- The company providing sponsorship must ensure that entertainment and hospitality added for their sponsored doctors must be in accordance with the writing and spirit of the PReMA Code.
- Meals must not be arranged in tourist or heritage/cultural attractions.
- Meals as mentioned on the program must not appear to be excessive (for example, champagne reception, gala dinner).
- Refreshments at the booth should be moderate and reasonable. It should not be used as an inducement of promotion or attraction. As a result, labels and packaging for food and drinks must contain only the factual details of the products and/or vendors. Any form of drug brand reminders, disease awareness content or drug advertising on food or drinks are strictly prohibited.

(iii) Accompanying Persons
- HCPs and/or accompanying persons are required to pay the full reasonable costs which are not subsidized or facilitated in any way by the supporting company,
- HCPs are expected to participate in the meeting rather than encouraged to join any program with the accompanying persons.

If there are any questions (from the above (i). to (iii).) or the meeting deems inappropriate, the PReMA Members should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

b) The behaviour of PReMA Members personnel at educational meetings must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and appropriateness. The behaviour of Company Representative must be beyond reproach and must not bring discredit upon the industry. Company Representatives should not act inappropriately in inviting HCPs at such Events.

c) PReMA Members are fully entitled to register and participate in the full program of any symposium, congress, or meeting that is organized by a medical society or medical organization, with PReMA Members being the sole sponsor, and is open to the public.

However, a PReMA Member has the full right to invite specific groups to its own standalone symposium, congress, or meeting. Attendance of other PReMA Members is ethically not appropriate unless prior permission has been obtained.

d) The soft skill training that does not provide scientific or educational content to enhance patient care, for example communication, leadership, negotiation, or emotional intelligence, and other similar competencies, is prohibited.

e) Medical symposia/congresses initiated by PReMA Members must devote a minimum of 75% of the total time to scientific sessions, outside of reasonable travel time. Suggestion for the calculation of 8 working hours per day is as follows: -
   - 2 days 1 night meeting must have 6 hours scientific session. For example, the participants arrive at the meeting venue at noon on the first day and leave the meeting venue at noon on the second day.
   - 3 days 2 nights meeting must have 12 hours scientific sessions. For example, the participants arrive at the meeting venue at noon on the first day and leave the meeting venue at noon on the third day.

f) Hospital, production plant, headquarters or research laboratory visit is not considered scientific meeting and thus it is not acceptable except when the meeting is organized where these places are located.

g) In case of the organization of scientific meeting overseas by the regional office or headquarters with the cooperation of at least 3 countries, it is acceptable for the PReMA Members to invite HCPs to participate in the meeting. However, although there is no set ratio of the participants from Thailand, the number of such visiting participants should not be a majority of the participants.

h) PReMA Members should not organize activities for invited HCPs during the period the luncheon or dinner symposium being held by other companies because theoretically, during HCO's official program, there should be no other activity running in parallel as it is considered inappropriate.

i) It is acceptable to organize medical advisory board or investigator meeting in global or regional level in Thailand for pre-approved drugs in Thailand if it is a medical advisory board meeting or investigator meeting by nature. However, meeting for HCPs in general as product promotional activity is not allowed.

7.2.2. Events Involving Travel

No PReMA Member may organize an Event for HCPs that take place outside the country unless it is appropriate and justified to do so from the logistical or security point of view. PReMA Member may organize an Event for HCPs that take place outside the country if it is justified as regional or international scientific congresses and symposia that derive participants from many countries.

a) Invited HCPs with passive roles must have air travel booked in regular economy class (not premium economy). If an invited HCP wishes to upgrade above economy, they may do so at their own expense, with no subsidy, reimbursement, or facilitation from PReMA Members. For HCPs with active roles (for example, speakers, presenters, moderators), business class air travel may be booked.

b) Group transportation to and from meeting venue for HCPs is allowed. However, the individual transportation arrangement for specific HCPs (i.e. where the individual travels alone and not part of a group) are generally not permitted, except where objectively justified by legitimate logistical necessity and documented in advance. Any such exception must not create the appearance of personal benefit or preferential treatment.

c) Transportation of the invited HCPs where the routes and schedule differs from the airport, meeting venue, hotel or home place, and restaurant must be avoided. The unreasonable distance travelling for meals is not acceptable.

d) It is not appropriate to organize an international trip that allows unreasonable extra days prior or after the formal scientific program except there is another educational meeting/symposium with proven evidence.

e) When inviting HCPs to attend conferences, PReMA Members may arrange suitable and reasonable travel and accommodation for the HCPs to attend such scheduled conference. The HCPs may pay additional expenses, for example airfare, accommodation, and so on, for their extended stays if such stays do not overlap with the conference time.

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. PReMA Members must avoid using renowned or extravagant venues.

PReMA Members must ensure that location selection should be based on a legitimate consideration such as accessibility for participants, security, cost and capability of withstanding public scrutiny; the content of the meeting and Event, not the site selection that attracts the audience. Venues in locations emphasizing leisure, sporting facilities, or primarily known for its touristic offering are prohibited.

No island venue is acceptable, except for provinces that have already been regarded as an international meeting venue, that is, Phuket.

Image of the selected venue must not be publicly recognized as a place for entertainment activities, including golf, exclusive spa. The guidelines on location and venue selection should follow:

a) Criteria for assessing the appropriate location and venue selection should follow the following principles:

- **Scientific or Business Focus:** The geographical location and venue should be in or near a city or town recognized as a scientific or business center, conducive to the meeting's scientific and educational purpose, and easily accessible for the intended audience.
- **Business and Technical Facilities:** The venue must provide necessary business and technical facilities to accommodate the meeting and its participants.
- **Audience Accessibility:** Facilities should minimize travel for the majority of the intended audience and meeting areas should be restricted to them.
- **Avoid Touristic or Recreational Focus:** Location and venue should not be primarily known or renowned for touristic, recreational, entertainment, sports, leisure, or vacation attractions, nor should they be perceived as the main attraction of the Event. In cities that are scientific hubs and tourist destinations, select venues away from main tourist areas.
- **Event Timing:** The Event should not coincide with local or internationally recognized sporting or cultural events held in the same location, or immediately before or after the meeting.
- **Geographical Appropriateness:** The location should match the geographical scope of the Event.
- **Venue Standards:** The venue must not be lavish, even if low in relative cost; local tourism rankings or travel agency ratings can assist in this assessment.
- **Safety and Security:** The venue should provide safe and secure accommodation considering the chosen location.

b) Movie theatre is an entertainment venue. Thus, it is not an appropriate venue to organize any scientific meetings.

c) A group presentation organized in a restaurant, or rented room with slide presentation during the meal can be done in a simple and modest manner. Meanwhile, the venue must be appropriate and can provide the facilities suitable for the meeting and does not carry an image of entertainment and leisure.

d) It is not acceptable to organize a standalone meeting outside Bangkok and its vicinity (that is, Nonthaburi, Pathum Thani, Samut Prakarn, Samut Sakorn, and Nakhon Pathom) where majority (more than half) of the attending HCPs are from Bangkok and its vicinity.

7.2.4. Limits

The HCP support shall limit to the payment of legitimate travel, registration fees, meals, and accommodation only during the period and location of the Event. PReMA Members shall handle arrangement of meeting registration, accommodation reservation and other logistics on behalf of the invited HCPs. Reimbursement of expenses against official receipt is possible.

No cash advance to HCPs is allowed. No payments are made to compensate HCPs for time spent in attending the Event. Any support provided to HCPs 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 invite HCPs 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, PReMA Members shall comply with the standard defined by host country. If host country does not define maximum value, PReMA Members should consider reasonable amount according to local standard.
- The meal hospitality provided must not be lavish and exceed what an individual would normally and reasonably pay for themselves.
- Any hospitality provided by PReMA Members must be secondary to the scientific or educational purposes.

7.2.5. Entertainment

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

a) When PReMA Members organize a meeting and refreshments are provided, it is permissible to arrange meal at the venue in which some background music is played in common area for example, hotel lobby music, instrumental music in restaurant, and related form of background music.

b) At the request of HCOs for the improvement of healthcare services, it is appropriate for PReMA Members to purchase tickets to a charity event or activity but the PReMA Members cannot distribute those tickets to HCPs.

c) When supporting the HCOs' Events or activities, PReMA Members also need to ensure that the Event or activity does not include entertainment or extravagant hospitality.

7.2.6. Accompanying Person

Invitations to attend Events, including medical and scientific events and meetings must only be given to the invited HCPs. PReMA Members neither facilitate nor pay any costs associated with individuals accompanying invited HCPs.

It is inappropriate to include an accompanying person at a meal in connection with the Event even though the HCPs pay for the meal. This information must be communicated upfront before inviting the HCPs to the Event.

7.3. Fees for Services

HCPs must agree 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 and payment must be signed off by both parties in advance.

7.3.2. A legitimate need, criteria for selecting consultants and reasonable number of consultants needed for the services must be clearly identified and documented.

7.3.3. The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, or administer any medicine.

7.3.4. The fee for services must be reasonable and reflect the fair market value ("**FMV**") of the services provided. The recommended FMV of speaker or moderator service for common events, including social media activities, can be referred to the most recent PReMA survey, of which is anonymously conducted once every two years.

7.3.5. Reasonable expenses related to the service provided, including travel, meals and accommodation can be reimbursed with original receipts.

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 PReMA Members is appropriate. When PReMA members 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. 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.

8.1.2. Gifts for personal benefit or customary occasion (such as sporting or entertainment tickets, sightseeing travels including sight-seeing travel in conjunction with Events, electronics items, social courtesy gifts, funeral wreath, calendar, and other similar gifts) for HCPs (either directly or through HCOs or third parties) are prohibited. PReMA Members are not allowed to provide funeral wreaths or monetary donation or host the funeral rites for the loss of the HCPs or his/her family members. However, due to culture and individual believer, PReMA does not prohibit PReMA Member's employees to provide funeral wreaths or personal monetary donation or host the funeral rites with personal decision and free from hidden intention.

8.2. Promotional Aids

8.2.1. A promotional aid (giveaway items, gimmick or other items intended for a promotional purpose) is a non-monetary item given for a promotional purpose which does not include printed promotional materials as stipulated in Section 5. Providing or offering them to HCPs in relation to the Promotion of Prescription Medicines is prohibited.

8.2.2. A promotional aid provided to HCO for HCP (indirect) in relation to the promotion of Prescription Medicines is also prohibited. This also means a sponsorship for conference document bag or other items to a medical congress.

8.2.3. Pens and notepads with company logo or company name can be provided to HCPs in the context of company organized Events for the purpose of taking notes during the meeting. They must not bear the name of any medicines but may bear the name of the company providing them. In addition, they must be of minimal value and only the necessary quantity is distributed. Examples of banned promotional aids include sticky notes, mouse pads, and similar items.

8.2.4. 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 HCPs and should be of minimal quantity. The examples of promotional aids to HCPs in relation to the Promotion of Over the-Counter Medicines are pen, pencil, ruler, notepad, sticky note, folder, planner, calendar, document box, and so on. Promotional items intended for the personal benefit of the HCPs, such as music CDs, paintings or food baskets are prohibited.
- 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 values 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 e.g., anatomical model for use in examination rooms may be offered or provided by PReMA Members under the following conditions:

8.3.1. Value of such items does not exceed 3,000 Baht per HCP and distribution is limited to no more than 2 times per year.

8.3.2. Such items must not replace or offset routine business practices. The nature, quantity, or frequency of these items should not significantly alter standard procurement processes. For example, items such as stethoscopes, surgical gloves, blood pressure monitors, and needles are considered routine business expenses and are expected to be supplied by the HCPs or their employing institutions.

8.3.3. The items must contribute meaningfully to the enhancement of medical services and patient care. While the company name may appear on the item, product branding is not permitted—unless the product name is essential for the correct use of the item by the Patient.

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 PReMA Members in accordance with local laws and regulations provided that:

8.4.1. Value of such items does not exceed 3,000 Baht per item per HCP, and distribution is limited to no more than 2 times per year.

8.4.2. The items are primarily for educational purposes. The example of information and education items are memory sticks pre-loaded with educational or informational data may be appropriate if the storage capacity is commensurate with the materials provided, whereas tablet computers may have independent value to a HCP and must not be provided, even if they could also be used to deliver education to Patients.

8.4.3. Subscriptions for medical journals for HCP are prohibited.

8.4.4. 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.

8.5. Information or Educational Items for Patient Use

Minimal, modest and reasonable value of informational and educational items can be provided to HCPs for Patient use (such as patient booklets, disease awareness booklets, and other related items).

8.5.1. Value of such items does not exceed 3,000 Baht per item.

8.5.2. The items 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 Thai FDA regulations.

9. SAMPLES FOR PHYSICIANS

9.1. Free Samples of a Pharmaceutical Product may be supplied to HCPs authorized to prescribe that product or HCO through their system of product sample receiving.

9.2. The size and quantity of the samples supplied should be appropriate. The PReMA Members should establish internal guidelines to manage and control the number of product samples provided to HCPs or HCOs.

9.3. Samples are used to enhance patient care.

9.4. Samples cannot 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 product samples.

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, for example, “Sample – Not for Sale” or similar meanings, so that they cannot be resold or otherwise misused.

9.8. All samples delivered by distributors or Company Representatives should be securely packed and must be signed by the product samples recipients.

9.9. PReMA Members should have adequate systems of control and accountability for samples provided to HCPs including but not limited to how to look after such samples whilst they are in possession of Company Representatives.

9.10. This section does not pertain to commercial products provided to institutions for product listing.

10. CLINICAL RESEARCH AND TRANSPARENCY

10.1. Transparency

PReMA Members 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 HCPs, Patients, and others. Such disclosure, however, must be complied with all related local laws and regulations.

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 purpose of market research must be clearly disclosed when the initial approach is made to collect data and not as a means to promote PReMA Members' Pharmaceutical Products to or reward HCPs.

11.1. Methods used for market research must never be such as to bring discredit upon, or to reduce confidence in, the pharmaceutical industry.

11.2. Market research must not be used as a disguised form of promotion and the research per se must not have an 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.

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.

11.5. Market research payment must be aligned with the fair market value and should not exceed a level commensurate with the work involved.

11.6. Questions intended to solicit disparaging references to competing products or companies must be avoided.

12. INTERACTIONS WITH PATIENT/PATIENT ORGANIZATIONS

PReMA Guideline on Patient and Patient Organization Interactions ("**Guideline**") should be read in conjunction with this section. The Guideline intends to provide mandatory practices for PReMA Members when interacting with Patients, Caregivers, and Patient Organizations, as well as patient support programs.

12.1. Patient Organizations

12.1.1. Scope

The pharmaceutical industry shares many areas of common interest with Patient Organizations. All interactions must adhere to ethical standards, ensuring that the independence of Patient Organizations must be respected.

12.1.2. Declaration of Involvement

When collaborating with Patient Organizations, PReMA Members must ensure that their involvement, as well as the nature of that involvement, is clearly communicated from the outset. No PReMA Members should require exclusivity as the sole funder of the Patient Organization or any of its major programs.

12.1.3. Written Documentation

PReMA Members that provide financial support or in-kind contribution to Patient Organizations must have written documentation clearly outline the nature of support, including the purpose of any activity and its funding.

12.1.4. Events

PReMA Members 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 aligns with the mission of the Patient Organization. When organizing such meetings, PReMA Members must ensure that the venue and location is appropriate and conducive to effective communication and informational sharing. In addition, any meals or refreshments provided by a PReMA Member must be modest and not exceed 2,500 Baht (excluding VAT and service charges) per person per meal for local standard.

12.2. Patient Education

It is recognized that members of the public should have access to information about medical conditions and the treatments prescribed by their treating physicians. The purpose of such information should be educational and should encourage Patients to seek further guidance from HCP. In addition, the following criteria should be met:

12.2.1. The educational material must be up-to-date, accurate and balanced.

12.2.2. The educational material should not focus on a specific product, unless it is intended to be given to the Patient as patient aids (see Section 12.3).

12.2.3. Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general. Information about disease and all treatment options should be included, and no single treatment option should be promoted. This type of material can be distributed directly to the public as a "community service".

12.2.4. The educational material should include a clear statement advising readers to consult HCPs for further information or medical advice, or other equivalent wording to similar effect, such as "Please consult your physician", and as appropriate and where required by applicable law, should include the contact details (address and telephone number) of the material's supplier.

12.2.5. The educational material must include a statement directing Patients to seek further information about the condition or treatment from their doctors. These statements must not be designed to encourage Patients to request a specific product from their doctor.

12.2.6. The tone of the message must not cause unnecessarily alarm or misunderstanding in the community.

12.2.7. All information, whether written or communicated through other means, must be presented in a balanced manner to avoid raising unfounded hopes about a particular Pharmaceutical Product.

12.2.8. The endorsement of Patient information by a HCO does not preclude a finding of a breach of this section if the other provisions of this section are not fulfilled.

12.2.9. Examples of Patient educational material which may be considered to breach the PReMA Code could include the following:

- Use of brand names
- Material which is not educational or contains medically incorrect educational material; and
- Comparative claims about clinical outcomes of specific products.

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 methods of administration, precautions, and special instructions and like information. It must not make comparisons or include promotional claims.

Examples of patient aids, whether in digital or printed format, include materials such as medication management and safety guidelines; step-by-step visual guides demonstrating the correct use of medical devices (e.g., inhalers, insulin pens, or biologic injectables); and short educational videos explaining medical conditions, treatment processes, potential adverse events, or proper device usage.

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

Patient Support Programs ("**PSPs**") are non-promotional in nature and must not be designed to replace or offset routine business practices. Their primary objective should be to support the enhancement of medical services and patient care.

When initiating a PSP, PReMA Members must ensure the following requirements are met:

- Any remuneration provided to HCPs for their involvement must be proportionate to the work performed and reflect fair market value.
- No incentives—monetary or otherwise—may be offered to Patients or Caregivers to encourage participation in the program.
- The program must comply with all applicable laws and regulations, including those related to data privacy.
- Data collected through PSPs must not be used for promotional purposes.

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

Prescription Medicines or products must not be promoted to the public unless such activities are permitted by the Drug Act and other applicable laws and regulations. Any information provided must be accurate, balanced, factual and not misleading or raise false hopes related to the product.

Where PReMA Members need to interact with the public, in responding inquiries, create disease awareness, provide educational message, such activities should adhere to the highest ethical standards.

13.1. General Inquiries

General inquiries regarding product information, medical diagnoses, treatment options, or personal health matters should be directed to the individual's HCP for appropriate medical advice and guidance.

13.2. Media Release

13.2.1. A Prescription Medicine or product related to media release issued by PReMA Members is prohibited by the Thai FDA; however, responding to media inquiries is permitted. The information provided must be current, accurate and balanced and must not encourage the public to request their HCPs to prescribe a particular Pharmaceutical Product.

13.2.2. PReMA Members may provide information about a product to the lay press only when it serves the public interest or aims to communicate scientific or medical achievement. Such information should be presented in a balanced way to avoid potential 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 if required by the Drugs Act and other applicable laws and regulations, after approval from the Thai FDA.

13.2.4. Advertising of self-medication products to the public is excluded from the scope of the PReMA Code. However, if medicines that are classified as “Pharmaceutical Products” in other countries are designated as Over-the-Counter Medicine in Thailand, it is suggested that any lay promotional material should comply with the guidelines established for “Pharmaceutical Products”.

13.2.5. The intentional dissemination of information or hidden advertisement of Prescription Medicine through radio disk jockey (DJ), television moderator or digital and social media influencer is prohibited.

13.3. General Media Articles (Advertorial Articles)

PReMA Members must not initiate general media articles concerning specific Prescription Medicines or products. However, information related to medical conditions and disease awareness without specific treatment option is allowed.

PReMA Members should not attempt to influence the publication of such articles or their content with the intent to promote their products. They may offer educational materials or review copies to ensure accuracy.

13.4. Telephone Hotline and Website

A telephone hotline or website or similar information service may be set up to provide general information useful to the public (for example, deworming, travel, smoking cessation). These services must remain general and must not include any product Promotion or personal medical advice.

13.5. Direct Mailing and Electronic Mail

Direct mailing or electronic mail of product promotional materials from a company to non-HCPs 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 PReMA Code.

14. COMPANY PROCEDURES AND RESPONSIBILITIES

14.1. Procedures

It is the responsibility of all PReMA Members to ensure that an internal compliance procedure exists that strives for compliance with all provisions of the PReMA 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 PReMA Code adherence.

To comply with this provision, PReMA Members should form a governance panel including qualified representatives from medical, commercial, regulatory, legal, compliance departments, and/or other relevant functions, as applicable, to review all materials and activities before release or execution.

14.2. Training

PReMA Members should ensure that relevant employees receive regular training appropriate to their roles.

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 the PReMA 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. PReMA Members must prepare and provide Company Representatives with 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 survey information in good faith.

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 HCPs. In addition, Company Representatives should meet HCPs in place as specified by the hospitals and, if possible, refrain from meeting HCPs in outpatient department ("**OPD**") during their operation hours and while HCPs are meeting with or examining Patients.

15.11. Seeking comments from the HCPs on side effects of competitor's product is acceptable provided that the conversation is aimed at exchanging scientific information.

15.12. Company Representatives shall not provide personal services to HCPs, for example, catering meals, driving, and other similar provisions of services for personal benefits.

15.13. Company Representatives shall not provide or offer excessive, frequent, regular, routine, unreasonable business meals to HCPs that can be interpreted as an inducement or improper influence to prescribe, recommend, purchase, supply, or administer any medicine.

16. ADMINISTRATION

16.1. The Code of Practice Committee ("CPC")

Complaints regarding breaches of the PReMA Code will be administered by the PReMA Chief Executive Officer ("**PReMA CEO**"), CPC and an Appeal Committee. The CPC shall consist of 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 medical director shall provide a set of 3 representatives, all of which shall be from a different company.

The role of the CPC will be to convene as promptly as practicable to review complaints; act as judge, jury and cross examiner of the evidence before them; and to ultimately decide on any sanction as stipulated in Section 18.

The "**Appeal Committee**" shall consist of similar structure like CPC, but there will be change of 1 or 2 external members and also change of the 2 internal members from the ones considering such appeal case.

16.2. Code Compliance Advisory Panel ("CCAP"): CCAP provides consultation, interpretation and guidance based on the PReMA Code to PReMA Members upon request.

- **CCAP structure:** 5 representatives from CCSC, and 1 representative from PReMA Administration.
- **Meeting Quorum:** At least two-thirds of CCAP members must be present for a meeting to proceed.
- **Term of Representatives:** Representatives from CCSC serve a 1-year term, with at least 2 members from the previous year continuing in the following year.
- **Decision-Making:** CCAP decisions shall be made by consensus and are binding on member companies for the particular consultation case. If consensus cannot be reached, the case will be escalated to the PReMA Board of Directors at the next board meeting.
- **Operation Timeline:** CCAP shall convene within 10 working days upon receiving a consultation request. Decisions from CCAP — or from the Board of Directors if consensus is not reached — shall be communicated to members within 2 working days after the meeting.

17. COMPLAINTS PROCEDURE

Each complaint should be resolved within 3 months from the first CPC review session. If more time is needed, PReMA CEO must notify the PReMA Board of Directors specifying the extension period and the reasons for it.

All valid complaints must be reported to PReMA. The complaint filing procedures 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 PReMA Members or from non member sources, for example Thai FDA, HCPs or HCOs, 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 and 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 PReMA Code.

17.1.3. The required minimum information

a) Source of the complaint:
If the complaint is from a PReMA Member or organization, it must be printed on the company's or organization's letter head and signed off by the general manager ("**GM**") or chief executive officer ("**CEO**"). For complaint from an individual, real name, address and contact telephone number must be provided.

b) Alleged Company
For each case in the complaint, the identity of company which is alleged to be in breach of the PReMA Code and the name of any product(s) or activities must be specified.

c) Evidence
For each case, a specific reference to the source of the activity or material which is the subject of the complaint as well as any other evidence must be provided.

d) Date
The date of the alleged breach of the PReMA Code.

e) Summary
If possible for each case, a brief description of the complaint with a specific reference to the part of the PReMA Code under which the complaint is being made (section and 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 PReMA Member may have contravened the PReMA Code, the case will be accepted for adjudication. The PReMA CEO may request for additional information or evidence from the complainant or the alleged PReMA Member. The case with all evidence will then be forwarded to the CPC. The names of the complainant company, HCPs 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 PReMA Member via the PReMA CEO. The CPC will then adjudicate whether a breach of the PReMA 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 PReMA Member and the complainant of the decision. Sanction against the company found in contravention of the PReMA Code will be issued and applied by the PReMA CEO, subject to Section 18 of the PReMA Code.

17.1.7. Complaint Resubmission - Where the alleged PReMA Member 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 is put forward by the complainant, the alleged PReMA Member 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 alleged PReMA Member 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 and the breaching companies shall be kept confidential.

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 PReMA Members or non-members (as described under Section 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.

The minimum information required is:

a) Source of the complaint: As described under Section 17.2.1, the source of complaint would be kept anonymous. Therefore, if available, it will be kept confidential.

b) Alleged Company: For each case in the complaint, the identity of company which is alleged to be in breach of the PReMA Code and the name of any product(s) or activities must be specified.

c) Evidence: For each case, a specific reference to the source of the activity or material which is the subject of the complaint as well as any other evidence may or may not be provided.

d) Time: If possible, there should be time period of the alleged breach of the PReMA Code.

e) Summary: If possible for each case, a brief description of the complaint with a specific reference to the part of the PReMA Code under which the complaint is being made (applicable section and paragraph).

17.2.4. Complaint Processing: When the PReMA CEO receives anonymous complaint, the case will be checked with the alleged PReMA Members. Alleged PReMA Members 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 is 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 decides to bring the case for adjudication by the CPC, the decision must be conveyed to the alleged PReMA Members, 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 HCPs 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 Section 17.1.

18. SANCTIONS

Upon the decision of the CPC, the PReMA CEO, shall apply one or more of the following sanctions to the company found in breach of the PReMA 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 PReMA Member.

18.3. Suspend the offending PReMA Member's membership for not more than 3 years.

18.4. Debar the offending PReMA Member from membership of PReMA, under Section 12.7 (2) of the PReMA AoA.

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 offending PReMA Member, subject to the approval of the CPC prior to release. It is the offending PReMA Member'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 offending PReMA Member 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 PReMA Code.

18.8. PReMA will maintain a record of each resolution to serve as reference for any future complaints or related proceedings.

18.9. Any penalties collected by PReMA will all be used for the Associations Corporate Social Responsibility ("**CSR**") activities. Full disclosure of the exact use of these funds and CSR projects supported, will be reported in the PReMA's annual report. Such funds can in no way be used as a financial income source for PReMA.