แนวทางปฏิบัติเรื่องเกณฑ์จริยธรรม
พ.ศ. 2559
ของสมาคมผู้วิจัยและผลิตเภสัชภัณฑ์

GUIDELINE FOR
PReMA CODE OF PRACTICE
2016 EDITION

Pharmaceutical Research & Manufacturers Association

(ใช้สำหรับช่องทางสถานพยาบาล)

แนวทางปฏิบัติเรื่องเกณฑ์จริยธรรม พ.ศ. 2559 ของสมาคมผู้วิจัยและผลิตเภสัชภัณฑ์เป็นเอกสารประกอบการปฏิบัติตามเกณฑ์จริยธรรมสำหรับช่องทางสถานพยาบาล ฉบับที่ 10 พ.ศ. 2559 โดยระบุเฉพาะหัวข้อที่มีคำอธิบายเพิ่มเติมเท่านั้น มิได้ครอบคลุมทั้งหมด ดังนั้น ควรใช้เพื่อพิจารณาควบคู่ไปกับเกณฑ์จริยธรรมฯ ซึ่งมีรายละเอียดข้อบังคับทั้งหมด

Guideline for PReMA Code of Practice, 2016 Edition, is provided as implementation guidance for selected provisions and does not cover all Code provisions. Please refer to Code of Practice for Ethical Channel, 10th Edition, 2016 for all provisions.

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GUIDELINE FOR PReMA CODE OF PRACTICE 2016 EDITION

2 PRINCIPLES

(1) Giving discounts and rebates with the sales of pharmaceutical products under Section 2.6 means giving discounts and rebates as a general trade practice without any dishonest intention which is different from employing an inducement or subterfuge to gain a call under Section 14.5 in which the hidden agenda is a dishonest intention.

(2) The PReMA Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products. PReMA encourages competition among companies under Trade Competition law.

(3) The PReMA Code does not cover price lists or other documents describing terms of trade. PReMA encourages competition among companies under Trade Competition law.

(4) Although there may be various types of hospital accounts that are legitimate, a bona fide account is guided by the principles of transparency and good governance. Bona fide accounts are therefore defined as two types.

❒ For the first type, an account would be bona fide if it bears the hospital name, without any additional prefixes or suffixes, and would be registered at a government bank.

❒ For a second type, if the account is substantiated with information on the governance of the account by an official document from a relevant government agency, then such account is bona fide.

The rationale of substantiating welfare funds or related account with government documentation is to ensure that the account is transparent and has good governance. The minimum documentation would therefore include an official government document that has 1) the names of the individuals currently appointed to serve as the management of said account, 2) the name of the account, which must include the hospital name and the type of account, e.g. “welfare fund ... hospital name” 3) a description of the statutory financial reporting requirements for said account, and 4) a signature from a senior official from the relevant Ministry confirming the above information. The hospital should provide a covering letter on its letterhead with the official documentation whenever there is change in the above description.

(5) The PReMA Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products to customers. However, in all dealings with customers, companies should respect the Code’s principle of transparency, international standards of good governance and procurement, local law, and maintain adequate documentation to ensure adherence to the Code’s standards.

(6) PReMA recognizes the importance of philanthropic activities, and that donations are a matter of the individual member company and its 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.

4 PRE-APPROVAL COMMUNICATIONS AND OFF-LABEL USE

(1) Companies shall not promote off-label indications, except it is requested by doctors as the practice may be perceived by the Food & Drug Administration as advertising. This is subject to contents and the presentation method. Such information must pass the consideration of the company's medical department and communicated by medical affairs personnel. In case company does not have medical affairs personnel, the communication should be handled by regulatory affairs personnel or consulted through company's regional/headquarter medical affairs for advice.

(2) 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... etc., that covers all relevant drugs and methods, may be appropriately and professionally presented, without specifically promoting the non-approved product/indication.

(3) Only upon a written request by the medical association to organize a lecture or to provide a speaker specifically on the topic may the pharmaceutical company be allowed to do so. In this case, registration status of such product/indication must be informed to the speaker and the association. Only generic name may then be used during the lecture.

(4) Pre-launch activity for a new product not yet approved in Thailand may be held only among a group of healthcare professionals at "key opinion leader (KOL)" level, not regarded as a promotional activity, but rather as an exclusive, pre-approved/off-label scientific communications, as in the advisory board meeting, investigator meeting, speaker/KOL development meeting. It has to be emphasized that it must be done at a strictly limited scale.

5 PROMOTIONAL MATERIAL

(1) Full Advertisements are those which include promotional claims for the use of the products. The content of the advertisement must accompany all details as per Section 3.6.

(2) The approved name shown should be the International Non-proprietary Name (INN) when this exists and should not conflict with local regulations or requirements.

(3) The statement that "further information is available upon request" or equivalent meaning should normally appear in the advertisement but the requirement will deem to have been met if a general notice to this effect, referring to all advertisements, is clearly printed on the same page of the publication.

(4) FDA informs that highlight symposium with no trade name and, if the text is of scientifically proven content, it does not need to be submitted to the 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 FDA requires that for the latter case, it must be submitted for FDA consideration as they must look at the intent of the material as well. According to Drug Acts of 1967, 1979 and 1987, the document can be used during the approved period only (see Code Section 5.2).

(5) Documents distributed in international symposium with no trade name cannot be distributed in other non-international symposium because the international symposium is more flexible. 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.

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

(7) Putting the "With the Compliment of...the company name" stickers on items given to doctors is acceptable. However, stickers bearing product name are not allowed.

6 INTERACTIONS WITH HEALTHCARE PROFESSIONALS

6.1 Exhibitions

(1) Any activities of the company 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 good taste. This includes the

appearance and behavior (such as their attire and general demeanor) of all company personnel or third parties acting on their behalf. All personnel manning the booths shall be company authorized personnel.

(2) Regarding Section 6.1.4, Promotional information which appears on exhibition stands or is distributed to participants at

a. International scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

❒ 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 (excluding giveaway) 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 etc.,) 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; and

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

b. In case of a local event held by the company itself :

❒ Theoretically, according to the present Drug Act, promoting 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 healthcare professionals (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 textbook without the permission of the owner can violate copyright law.

(3) 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.

(4) Under Section 6.1.7, activities that involve placing promotional tag lines or disease names on top of a golf hole, giving of prizes such as TVs/VCRs/DVD Players etc. are strictly prohibited.
(5) Product samples shall not be distributed at the exhibition or be placed inside meeting registration packages.

6.2 Sponsorship to Scientific Meeting

6.2.1 Scientific and Educational Objectives

(1) When deciding whether to support an event organized by a third party such as a healthcare organization or medical society, as well as support of a healthcare professional to such events, criteria to be considered are, as follows:-

a. 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.

b. Entertainment, leisure activities, meals

❒ 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.

❒ Meals must not be arranged in tourist or heritage/cultural attractions.

❒ Meals as mentioned on the program must not appear to be excessive (e.g. champagne reception, gala dinner, etc.).

❒ 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 code.

c. Accompanying Persons

❒ They are required to pay the full reasonable costs which are not subsidized or facilitated in any way by the sponsoring company,

❒ Healthcare professionals are expected to participate in the meeting rather than encouraged to join any program with the accompanying persons.

If there is any question (from the above a. to c.) or the meeting deems inappropriate, the companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

(2) The behaviour of company personnel at Educational Meetings must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. 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 doctors at such events.

(3) PReMA members are fully entitled to register and participate in the full program of any symposium / congress / meeting that is organized by a medical society/organization, with sole sponsorship by an individual company, and is open to the public.

However, a company has the full right to invite specific groups to its own standalone symposium/ congress/ meeting. Attendance of other member companies is ethically not appropriate unless prior permission has been obtained.

(4) The soft skill training, such as management skill training, should not be classified as part of the scientific session.

(5) Medical symposia/congresses (local and international), which are initiated by the company (locally only), the regional office or corporate headquarters, must devote a minimum of 75% of the total time to scientific sessions, outside of reasonable travel time. 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 of the first day and leave the meeting venue at noon of 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 of the first day and leave the meeting venue at noon of the third day.

(6) 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.

(7) In case of the organization of scientific meeting overseas by the regional company or headquarters with the cooperation of at least 3 international companies, it is acceptable for the company to invite healthcare professionals to

participate in the meeting. However, although there is no set ratio of the participants, the number of visiting participants should not be a majority of the participants.

(8) Company should not organize activity for sponsored doctors during the period the luncheon or dinner symposium being held by other company because theoretically, during the Association's official program, there should be no other activity running in parallel as it is considered unethical. And, if that own activity is of non-scientific nature, it also breaches Section 6.2.1.

(9) It is acceptable to organize advisory board or investigator meeting in global or regional level in Thailand for pre-approved drugs in Thailand if it is an advisory board meeting or investigator meeting by nature. However, meeting for healthcare professionals in general as product promotional activity is not allowed.

6.2.2 Events Involving Travel

(1) Travel for all sponsorship of attendee should be by Economy class. Where the sponsored healthcare professional would like to upgrade to a class of travel other than Economy, the healthcare professional may do so at their own expense without any subsidy or facilitation from the sponsoring company.

(2) Transportation of HCP sponsorship 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.

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

(4) It is also not appropriate to organize a trip to other countries that are not the country of the meeting venue before, during or after the scientific program or during the transit for the connecting flight.

(5) With the sponsorship of healthcare professionals to attend overseas conference, the healthcare professionals are to attend the scheduled conference. The healthcare professionals may pay additional fee for their travel as long as it does not overlap with the conference time. In addition, the medical professional must change the plane ticket on their own including be responsible for all related expenses.

6.2.3 Appropriate Venue

(1) Image of the selected venue must not be publicly recognized as a place for entertainment activities, including golf, exclusive spa, etc. No island venue is

acceptable, except for places that have already been regarded as international meeting venue e.g. Phuket Island.

The guideline on location & venue selection should follow:

a. Criteria to consider when assessing the appropriateness of the location of an event (non-exhaustive)

❒ The geographical location is in or near a city or town which is a recognized scientific or business center and is easily accessible for the intended audience.

❒ The location should not be primarily known for its touristic or recreational offering.

❒ The location and venue should not be the main attraction of the event or be perceived as such.

❒ The time of the event should not coincide with local or internationally recognized sporting or cultural events taking place in the same location, at the same time and preferably not just before or just after the meeting.

❒ The location is appropriate in respect to the geographical scope of the event.

Note: Capital cities and other large metropolitan cities considered to be commercial hubs are likely to be reasonable and appropriate locations for meetings. The appropriateness of a location may be assessed differently for strictly local events attended by local healthcare professionals as opposed to regional or international events. The program for an event may justify a particular location if there are valid and cogent reasons for that location such as the availability of relevant expertise, for example, research or manufacturing facilities.

b. Criteria to consider when assessing the appropriateness of a venue of an event (non-exhaustive):

❒ The venue is conducive to the scientific and educational purpose of the meeting.

❒ The venue has the necessary business and technical facilities to accommodate the meeting and its participants.

❒ The meeting facilities should only be accessible to intended audience and minimize travel for the majority of audience.

❒ In the case of cities which are both major scientific or business centers and locations highly desirable for tourists, it is important to select venues which are away from the main tourist spots.

❒ The venue must not be renowned for its entertainment, sports, leisure or vacation facilities.

❒ The venue provides safe & secure accommodation when considering the chosen location.

❒ The venue must not be lavish even if the cost is low compared to other venues. (e.g. ranking by the local tourism association and/or the average ranking

by travel agencies can help with this assessment).
(2) Movie theatre is logically perceived by general public as an entertainment venue. Thus, it is not an appropriate venue to organise any scientific meetings.
(3) 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.
(4) It is not acceptable to organize a standalone meeting outside Bangkok and surrounding provinces, where majority (more than half) of the attending healthcare professionals are from Bangkok and surrounding provinces[1].

6.2.4 Limits

(1) As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay by themselves. Any hospitality provided by companies either directly or by sponsorship or assistance to the meeting organizers of educational meetings, must be secondary to the educational purpose.
(2) It is clear that attendees are not being encouraged to arrive unnecessarily earlier before the meeting starts or unnecessarily stay longer after the meeting ends. If the official scientific session ends during the time that the attendees can travel back to their residence within the same day, last night accommodation is not allowed. However, on the exceptional basis under specific circumstances, the last night accommodation may be given if warranted by logistical considerations (e.g. flight schedule or late night travelling).
(3) A company may however provide sponsorship for a modest conference dinner at which a medically related keynote address is given. An appropriate level of hospitality would be what is expected in a normal business meeting. For example, buffet meals or set lunches would be appropriate for lunch. Lavish hospitality such as lobster, caviar, and matsusaka beef would not be appropriate.
(4) In case meals are not specified in the agenda of Royal College meeting, meals may be offered to the healthcare professionals the company sponsors the meeting registration at a moderate scale. However, if they are not the company's sponsored healthcare professionals, dinner offer is not acceptable as it is regarded as "stand-alone entertainment" which is prohibited.

6.2.5 Entertainment

(1) When a company organizes a meeting and refreshments are provided, e.g.,

[1] refer to a government defined political definition of the urban region surrounding Bangkok Metropolis, or the built-up area i.e. urban agglomeration of Bangkok, Thailand, which varies in size and shape, and gets filled in as development expands. The political definition is defined as the metropolis and the entire 5 adjacent provinces of Nakhon Pathom, Pathum Thani, Nonthaburi, Samut Prakan and Samut Sakhon.

an evening meal for a meeting stretching over more than one day, it would be permitted to provide some background music during the meal or to have an interlude when some local singers perform. However, it would not be appropriate for a company to fund attendance at a concert as this would be self-standing and not incidental to the refreshments and the PReMA Code also prohibits the purchase of entertainment tickets.

(2) A self-standing sightseeing tour would not be permitted.

(3) The hospitality and entertainment activities, whether organized by the company or through associations or professional organisation, must be simple and modest. The "modest nature" of the entertainment may be interpreted as prohibiting high profile, inappropriate or expensive entertainer - even if their performance is secondary to a necessary meal. So, an appearance by a well-known TV or pop star would not be considered as modest whereas a folk dance display or performance by a local singer would be acceptable as entertainment for a meal interlude.

(4) At the request of a medical institution or hospital for the improvement of healthcare services, it is appropriate for pharmaceutical companies to purchase tickets to a charity concert but the companies cannot give them out to healthcare professionals.

(5) In case of package sponsorship to healthcare organization or medical society, the company need to ensure that the package does not include the elements that are not in line with the PReMA code such as gala dinner, entertainment or extravagant hospitality.

6.2.6 Accompanying Person

(1) Travel costs and expenses for family or traveling companion(s) must not be paid for or subsidized or facilitated by the sponsoring company.

(2) It is not appropriate to include an accompanying person at a meal in connection with the event even though the healthcare professional pays for the meal. This information must be communicated upfront before inviting the healthcare professional to the event.

6.3 Fees for Service

(1) The fair market value of speaker/moderator service for common event shoud be referred to the most recent PReMA survey, of which is conducted once every two years.

These recommendations are not intended to restrict PReMA member from providing different rate as long as they are not excessive and they reflect the fair market value of the services provided, taking into consideration such factors as the nature of the service, therapeutic area of expertise, experience level or qualification of the healthcare professional engaged, complexity of the subject member, type of the events and roles, and duration of the event.

7 CUSTOMARY GIFTS, PROMOTIONAL AIDS, MEDICAL UTILITIES

(1) The company may present floral wreaths to show respect and condolences for the loss of the healthcare professionals' immediate family members. The immediate family members are father, mother, spouse, and children of the healthcare professionals only. The company is not allowed to offer monetary donation or sponsoring the funeral rites. However due to culture and individual believer, the company may not prohibit its staff to offer personal monetary donation or sponsoring the funeral rites with personal decision without hidden purpose.

(2) A promotional aid must be in line with FDA regulations. Stationary or medical utilities are acceptable as long as they have received approval from FDA and are less than 500 Baht i.e. thumb drive is not acceptable because FDA sees that it may contain unapproved content.

(3) In regards to the items of medical utility, "Not offsetting routine business practices" means that the nature, number or frequency of 'items of medical utility' should not alter significantly normal practices for obtaining these items. So if a company takes on responsibility for always supplying a medical utility item that hospital normally has budget for, it is inappropriate.

9 CLINICAL RESEARCH AND TRANSPARENCY

9.3 Post-marketing scientific studies, surveillance and dissemination of information

(1) Pharmaceutical companies in Thailand are required by the Thai FDA to conduct Safety Monitoring Programs (SMP) for the first 2 years after launch of any new product to collect safety profile data. This is a regulatory requirement to solicit and detect rare adverse events. After 2 years, SMP is voluntary. SMP is a regulatory activity and not a marketing program.

(2) Post Marketing Surveillance (PMS) and Safety Monitoring Programs (SMP) should not be used as a vehicle to drive prescriptions.

(3) Reference should also be made to the PReMA Code of Medical Research, which states:

❒ Rational of sponsoring/supporting research - We sponsor and support medical research for the purpose of answering scientific questions.

❒ Conduct of Research - We conduct research in full compliance with principles of ICH/GCP and local regulatory requirement.

❒ Payments to Healthcare Providers - There should not be any financial inducement or other incentives to the physician in conducting these studies. Payment made should reflect fair market value for work performed. Payment should not be made for the regulatory requirement of SMP collection.

❒ Communication of Research Results - Whenever applicable, we disclose publicly all medical research results that are significant to patients, healthcare providers or payers in an accurate, objective and balanced manner in order for our customers to make more informed decisions about our products. We comply with the International Committee of Medical Journal Editors' "Uniform Requirements For Manuscripts Submitted to Medical Journals".

(4) Conducting a study by asking patients to buy the products themselves, or exercise their medical reimbursement rights depends on case-by-case basis and is up to the decision of the Ethics Committee.

(5) Patient education brochures can be printed with all generic names only if it contains complete list of generic names (fair, balanced information), not just 1 generic name, or many generic names but with biased information that could lead to one specific product. Otherwise, it may fall into drug advertising. It might be more appropriate or less controversial to use name of the drug class (e.g. proton-pump inhibitor etc.).

10 MARKET RESEARCH

(1) Market Research studies must be clearly disclosed as such when the initial approach is made.

(2) Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.

(3) Questions intended to solicit disparaging references to competing products or companies must be avoided.
(4) Section 10 Market Research, under 10.2 it says market research must not be used as a disguised form of sales promotion. This practice should not be done, and may not be regarded as running a trial. To build a patient registry, the matter should be submitted to the Ethics Committee for consideration.

11 INTERACTIONS WITH PATIENT/PATIENT ORGANIZATIONS

11.2 Patient Education

(1) Patient information should include information about disease and all treatment options. No single treatment options should be promoted. This type of material can be distributed directly to the general public as a "community service".
(2) The endorsement of patient information by a professional society does not preclude a finding of a breach of this section if the other provisions of this section are not fulfilled.
(3) Examples of patient educational material which may be considered to breach the Code could include the following:

- ❒ Use of brand names
- ❒ Material which is not educational or contains medically incorrect educational material; and
- ❒ Inclusion of response rates for a specific product of comparative claims

12 PROMOTION TO NON-HEALTHCARE (MEDICAL) PROFESSIONALS (OR GENERAL PUBLIC)

12.1 General Inquiries

(1) Where a specific request is made by a patient or a member of a patient's family about a product which has been prescribed, the company may clarify matters using a Consumer Medicine Information leaflet or a patient aid as described in Section 12.3, but should otherwise recommend inquirers to consult their doctor.

12.2 Media Release

(1) Companies must ensure that their response to any medical inquiry and communication to lay press should not be promotional.
(2) Conduct by agencies engaged by companies in relation to media release and product launches will always be treated as conduct by the company.
(3) This section does not restrict companies from responding to key international developments such as landmark clinical trials but any response must be

current, accurate and balanced and must not be promotional. The intent of this communication must be educational. Companies are also encouraged to seek the advice from FDA prior to arranging press or media statements.

13 COMPANY PROCEDURES AND RESPONSIBILITIES

(1) In order to comply with this provision, companies should consider the creation of a Compliance Panel led by a senior management whose purpose is to review promotional material and planned activities for compliance with the Code. This panel should consist of relevant individuals from departments such as medical, marketing and sales to ensure that all aspect of promotional material and activities comply with the Code. These individuals should possess suitable qualifications and experience to undertake such tasks.

The panel should review promotional material or activities from conception to release in final form or being undertaken.

14 MEDICAL REPRESENTATIVES

(1) Seeking comments of the doctors on side effect of competitorís product is acceptable provided that the conversation is aimed at exchanging scientific information.

(2) Medical representatives should not provide personal services to healthcare professionals, e.g., catering meals, driving, etc.

15 ADMINISTRATION

(1) Code Compliance Subcommittee (CCSC) shall have role to provide consultation as may requested by member companies on a case to case basis through a structure of the Code Compliance Advisory Panel (CCAP) as per below direction:

a. CCAP consists of:
   i. 5 representatives from CCSC
   ii. 1 representative from SASC
   iii. 2 representatives from PReMA administration
   iv. 1 representative from PReMA Board of Directors

b. Meeting quorum: at least two-thirds of CCAP members must present at the meeting

c. Term of representatives from CCSC: 1 year. At least 2 of CCSC members in CCAP of the previous year shall continue their term in the following year.

d. Decision: Decision of CCAP must be consensus from their meeting. Decision of CCAP will be binding as practice of members on particular consultation case.

e. Should CCAP cannot reach for consensus, the consultation case will be forwarded further for PReMA Board of Directors' consideration in the next Board meeting.

f. Duration of operation: CCAP shall call meeting within 10 working days after receiving the consultation. Decision from CCAP or Board of Directors (in case CCAP does not have consensus) shall be communicated to members in general within 2 working days after the meeting. PReMA as secretary of Code of Practice Committee (CPC) shall report such consultation resolution to CPC as basis, should there be complaints in relation to such issue afterwards.

g. Appeal: CCAP will accept appeal only when there is new evidence.

16 COMPLAINT PROCEDURE

(1) "Reference material" can be a person if that person is willing to disclose his/her identity and is ready to undergo an investigation by PReMA CEO.

(2) Code of Practice Committee (CPC) shall not adjudicate any complaints that took place more than one year after the event and the person who breached the code were founded and any complaints that took place more than two years after either the event OR the person who breached the code was founded.

17 SANCTIONS

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

สมาคมผู้วิจัยและผลิตเภสัชภัณฑ์ (PReMA)

"นวัตกรรมยา เพื่อสุขภาพที่ดีกว่า"

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