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CODE OF PRACTICE
9TH EDITION, 2012

Pharmaceutical Research & Manufacturers Association

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INTRODUCTION

Pharmaceutical Research & Manufacturers Association (PREMA) represents companies who are engaged in the research and development, manufacturing, trading or importing of pharmaceutical products. Membership, as ordinary members, associate members or honorary members, is open to companies who are registered in accordance with the law of the Kingdom of Thailand.

BACKGROUND

The pharmaceutical industry is distinct from other industries in that it is highly regulated, requires expensive up front investment in research, and depends on constant product innovation, excellence in sales and marketing with ethical, appropriate and professional interactions with all stakeholders. This is because healthcare and well-being of patients is the first priority for pharmaceutical companies.

Pharmaceutical companies provide medicines and devices which save many patients from hospitalization, surgery and death. It is important that as a responsible partner in providing healthcare, pharmaceutical companies conduct themselves with integrity and maintain consistently high ethical standards.

All companies should be fully cognisant of the activities that they are supporting and must critically examine these activities to ensure they meet the following criteria:

- Enhance medical knowledge,
- Enhance the quality use of medicines,
- Do not bring discredit to the industry,
- Can successfully withstand public, professional and community scrutiny,
- Conform to professional and community standards.

The revision of this Code of Practice is based on the APEC (Asia Pacific Economic Cooperation) Mexico City Principles for Voluntary Code of Business Ethics in the Biopharmaceutical Sector and the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice 2012.

The voluntary adoption of the PReMA Code of Practice is in accordance with the key objectives of the Association as set out in Section 40 of the PReMA Articles of Association.

An important feature of the PReMA Code of Practice is that ALL members voluntarily accept to observe and adhere to the provisions of the Code as a condition of their membership with the Association.

COMMITMENTS OF PHARMACEUTICAL RESEARCH & MANUFACTURERS ASSOCIATION (PReMA)

Members of PReMA are committed to the improvement of the health of mankind through research and development of new medicines/devices and the production and marketing of pharmaceutical products of reliable quality, in accordance with internationally defined standards of good practice.

As a part of their commitment to healthcare, PReMA members have an obligation and responsibility to provide accurate, balanced and scientifically valid information and education about their products to healthcare providers and users in order to establish a clear understanding of the appropriate use of the medicines/devices.

Promotional activities must be conducted with high ethical standards. All product information should be designed to help healthcare providers improve service to patients. Information must be provided with objectivity, truthfulness and in good taste and must conform to all relevant laws and regulations. Claims for therapeutic indications and conditions of use must be based on valid scientific evidence. Clear statements with respect to side effects, contraindications, and precautions should be included.

High standards of ethical behavior and conduct shall apply equally to promotional activities and all interaction with related stakeholders.

1. Scope and Definitions

Scope

This Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice, of which member companies shall comply.

Definitions

1.1 The term “promotion” refers to activities undertaken, organized or sponsored by a pharmaceutical company with the objective to encourage the prescribing, supply or administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.

“Promotion” includes the activities of sales representatives and all other aspects of sales promotion in whatever form they may occur. Examples of promotion include but are not limited to: product information presented in any form; public relation activities; advertising via electronic media, journal/print and direct mail; participation in exhibitions; use of audio cassettes, films, records, slides, tapes and video recordings; the use of any other data storage and viewing devices reproduced on television; visual display units; the provision of samples.

The term “promotion” does not extend to replies made in response to enquiries from particular doctors or replies in response to a specific communication, including letters published in a medical journal.

1.2 The term “pharmaceutical product” in this concept means any pharmaceutical or biological product intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, which is promoted and advertised to the healthcare profession rather than directly to the lay public.

1.3 The term “healthcare profession”, “healthcare professional”, “practice of medicine”, “doctor” should be interpreted to extend to the dental, pharmacy and other para-healthcare professions as defined in Drugs Act of 1967, 1979 and 1987, and be construed accordingly.

1.4 The term “medical representative” means a company representative whose duties comprise or include calling upon members of the healthcare profession to provide them with information and/or any other purposes about the company’s products/services.

1.5 The term “certified package insert” means comprehensive product information included in each product pack as approved by the Food and Drug Administration (FDA) of the Ministry of Public Health.

1.6 “patient organization” means typically a not-for-profit institution that primarily represent the interests and needs of patients, their families and/or caregivers

1.7 “medical institution” means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

1.8 Categories of PReMA Membership include:

1.8.1 Ordinary Members, are Juristic persons of good standing who are manufacturers, traders or importers of medicines or other pharmaceutical products and who have applied to become members and have been approved by the Board of Directors of PReMA. Juristic Persons incorporated in and under the laws of other countries which manufacture, trade, or import medicines or other pharmaceutical products in Thailand either directly or through other parties are also entitled to become Ordinary Members of the Association.

1.8.2 Associate Members, are Juristic persons or natural persons of good standing who have association with the pharmaceutical industry but who are not eligible for Ordinary Membership. However, persons associated with a business or who take part in the activities of any company which is eligible for membership as a Juristic person shall not be eligible for a membership as a natural person.

1.8.3 Honorary members are natural persons who have rendered valuable services to the development of healthcare in Thailand the pharmaceutical industry, or the Association, PReMA.

2. PRINCIPLES

2.1 Healthcare and well-being of patients is the first priority for pharmaceutical companies.

2.2 Interaction with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.

2.3 Member companies shall comply with local law and regulations.

2.4 Member companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities. In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional material or events.

2.5 Only products registered in Thailand should be promoted by brand name to ‘healthcare professionals’ as defined in Section 1.2. While promoting products, the information should be accurate, balanced, objective and

scientifically valid and presented in such a way as to conform not only to legal requirements but also to high ethical standards and to be in good taste. Claims should not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity and making off-label product claims.

No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.

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 investigation 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.

2.6 Discounts and rebates associated with the sales of pharmaceutical products (medicines and medical equipment) shall be made by a/c payee cheque, bank transfer to a bank account associated with the respective hospital or on the invoice only

2.7 Information in promotional material should be based on an up-to-date evaluation of evidence that is scientifically valid and approved by the Thai FDA.

2.8 Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primary scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.

2.9 The methods of promotion employed must be appropriate to the learning and professional status of the healthcare profession to whom they are directed.

2.10 All clinical trials and scientific research sponsored or supported by member companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Member companies are committed to the transparency of industry sponsored clinical trials in patients.

2.11 Privacy and personal information of patients must be respected.

2.12 It is the responsibility of all member companies to ensure that all relevant company personnel are adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate, responsible and ethical manner. They must also feed-back to their company, from contacts in the medical and allied professions, information which they receive on the use of products and particularly reports of adverse event.

2.13 All trademarks duly registered in the Kingdom of Thailand must be respected and copyrights observed.

2.14 No member should seek to benefit from the limited protection provided to pharmaceutical patents in the Kingdom of Thailand, at the expense of the discoverer, or his licensee, who remains the rightful owner of such property in the originating country.

2.15 All member companies should establish and maintain appropriate procedures to ensure full compliance with appropriate national and international Codes and to review and monitor all of their promotional activities and materials.

2.16 Donations to institutions must be wholeheartedly for the sole purpose of humanity support and/or non-scientific purpose and with no expectation on business return. While grants to institutions must be for scientific purpose only and with no conflict of interest. Such donation and grant shall not be used for inappropriate causes, for examples, for excursion or non-scientific purposed activities.

2.17 This Code of Practice is to be applied in the spirit as well as in the letter.

3. General Provision Applicable to All Promotional Practices

3.1 Promotional Practices should never be such as to bring discredit upon the pharmaceutical industry. Promotional practices utilized should be able to withstand public scrutiny.

3.2 Information about the product (or sometimes referred to as "product information") furnished to the healthcare profession should be current, accurate, balanced, and should not be misleading either directly, by implication, by omission or addition. Scientific data to support the claims and recommendations for use should be made available, on request, to healthcare providers.

3.3 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.

3.4 Disparaging references to other products or manufacturers should be avoided.

3.5 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. The word “Safe” or “No Side Effect” must not be used in promotion, without qualification (i.e. it should be ‘Safe’ relating to ...+ reference).

3.6 Particular care should be taken that essential information on any pharmaceutical products’ safety, contra-indications, side effects or toxic hazards is properly communicated to the Thai regulatory authorities and to healthcare profession of Thailand.

To comply with the above, in all printed promotional materials (with the exception of reminder (short) advertisements, as mentioned under Section 3.9), the following list of information should be printed:

- the name(s) of the active ingredient(s) using either International Non-proprietary Names (INN) or the approved generic name of the drug;
- the brand name;
- content of active ingredient(s) per dosage form or regimen;
- name of other ingredients known to cause problems;
- approved therapeutic uses;
- dosage form or regimen;
- side-effects and serious adverse drug reactions;
- precautions, contra-indications and warnings;
- serious interactions;
- name and address of manufacturer or distributor;
- reference to scientific literature as appropriate;
- 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.

3.7 When certified package inserts are required by the Thai FDA to be printed and provided in the Thai and English languages, the information imparted in both languages should be the same unless the text is changed by the FDA.

3.8 Any and all information required by the Thai FDA to be printed on the carton or label should be clearly legible.

3.9 In addition to the recommendations in the Code, special rules apply to “reminder advertisements”. A reminder advertisement is an advertisement which presents only the trade name, the INN (International Non-proprietary Name), a reference to the indication or the therapeutic class, the sentence “Further information available on request”, the company logo and local address.

3.10 All members should have an established procedure for reporting ADR’s (Adverse Drug Reactions) and product recall. All medical representatives and other appropriate staff should be made fully aware of the company’s internal policies and procedures.

3.11 All member companies will assume responsibility, under the Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of facts by any representative.

4. Pre-Approval Communications

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.

4.1 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.

4.2 The company shall respond only upon a written request by the medical association and/or healthcare profession to provide scientific information on pre-authorized products and/or indication. 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 stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

4.3 Companies may display posters or distribute any scientific information materials of a non-approved product/indication, but shall strictly subject to conditions as per consultation with the Thai FDA.

5. Printed Promotional Material, including Advertisements

5.1 Printed Promotional Material

5.1.1 Printed promotional material must conform to the legal requirements set out in the Drugs Act of 1967, 1979 and 1987, be approved by the FDA before publication and used during the approved period only.

5.1.2 It shall conform both in text and illustration, to standards of good taste and should recognize the professional standing of the healthcare profession recipients.

5.1.3 It shall not imitate the devices, copy slogans or general layout adopted by any other company, in a way that is likely to mislead or confuse.

5.1.4 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.

5.1.5 The requirements for printed promotional material also apply to advertisements in MIMS and other similar references.

5.2 Promotional materials for use by medical representatives

5.2.1 Materials used by medical representatives such as detailing aids, hand-outs, leaflets, posters and leave-behind pieces, etc. should meet all requirements of Printed Promotional Material specified in Sections 5.1 (5.1.1 to 5.1.5) and must be handed over only to the healthcare professionals.

5.2.2 All promotional aids (giveaways) which serve as brand name reminders shall have contents, value and character as defined under Section 8.2.

6. Electronic Materials, Audiovisuals, including Digital Media

The same requirements shall apply to electronic promotional materials and audio-visual as apply to printed materials, specifically, in the case of pharmaceutical product related websites and other digital media. The expression “audio-visual” includes sound recordings, VCD, DVD-recordings, tape, slide, presentations, video-recordings and sound or television broadcastings, etc.

6.1 the identity of the pharmaceutical company and of the intended audience should be readily apparent;

- 6.2 the content should be appropriate for the intended audience;
- 6.3 the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- 6.4 country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals

7.1 Events and Meetings

7.1.1 Trade Displays

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

7.1.1.1 Trade displays must be directed only to health care professionals.

7.1.1.2 Trade Display must include, in a prominent position, the name of the sponsoring company.

7.1.1.3 Exhibitors must comply with all requirements of the sponsoring organization when setting up and conducting a Trade Display.

7.1.1.4 Product Information for all products being promoted must be available from the Trade Display stand.

7.1.1.5 Product samples may be distributed, but must not be made available for collection from unattended stands, nor be supplied to unauthorized or non-qualified persons.

7.1.1.6 Raffles and/or games of chance are not to be held by members during the Trade Displays.

7.1.1.7 Companies must not offer financial incentives to healthcare professional to visit their display stands. Such incentives would include cash payment, cheque vouchers, and/or donations to charities or societies.

7.1.1.8 Competitions that are held as part of the Trade Displays must fulfill all of the following criteria:

7.1.1.8.1 The competition is based on medical knowledge or the enhancing of medical knowledge.

7.1.1.8.2 The prize should be directly relevant to the practice of medicine or pharmacy.

7.1.1.8.3 In case that individual prizes offered are not relevant to the practice of medicine or pharmacy, they may have a value of not over 500 baht. Where the prize is to be an item of educational material, the value of individual prizes should be no greater than 3,000 baht (per the Regulation of Medical Council).

7.1.1.8.4 Entry into a competition must not be dependent upon prescribing or recommending a product and no such condition shall be made or implied.

7.1.1.9 All promotional materials used at Trade Displays must be consistent with the requirement of section 5.1 and 5.2.

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

7.1.1.11 Any activities during the display shall not disturb (e.g. in the form of light, noise, or smell, etc) other booths and conference participants.

7.1.1.12 Companies may display posters or distribute any promotional materials of a non-approved product/indication, but shall strictly subject to conditions under Section 4.

7.1.2 Symposia and Congresses

Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific or educational objectives should be the principal focus in arranging such meetings and other hospitality shall not be inconsistent with such objectives.

7.1.2.1 Dissemination of scientific/medical knowledge and experience must be the primary focus for symposia, congresses, Continuing Medical Education (CME), or other scientific/medical/healthcare programs related to Company's products or therapeutic focuses.

7.1.2.2 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. Any hospitality/promotional aids (giveaways) provided by Companies either directly or by sponsorship or assistance to the meeting organizers of educational meetings, must be secondary to the educational purpose and not being seen as extravagant by local standards.

7.1.2.3 The company must ensure that location selection should be based on participant travel convenience, security, cost and appearance; and that the content of the meeting, and not the site selection, attracts the audience. The choice of venues in locations emphasizing leisure or sporting facilities is prohibited. Companies shall avoid using extravagant venues.

7.1.2.4 Invitations to attend medical and scientific meetings must only be given to healthcare professionals. Sponsorship shall limit to the payment of travel, meals, accommodation and registration fees. Guests may not be invited nor expenses of persons accompanying the attendee paid for.

No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At events, hospitality of modest nature which is secondary to refreshments and/or meals is allowed.

7.1.2.5 During the medical symposium organized through either domestic or international medical organization, company shall not carry any activities that may disturb or interfere the official sessions certified by the organizer of the meeting.

7.1.2.6 Any support to individual healthcare professionals to participate should not be conditional upon any obligation to promote any medicinal product.

7.1.2.7 Companies should not provide sponsorship for healthcare professionals to attend sporting or other entertainment events, including but not limited to leisure or social activities, as this can be seen as an inducement. Sponsorship can be made directly to the institution (not individuals) upon the institution's request to support activities for the healthcare professionals as long as it can be demonstrated that there is a link to scientific education, patient benefit or charitable contribution that would benefit the improvement of healthcare services.

7.1.2.8 Companies considering providing sponsorship for

healthcare professionals to attend a meeting must critically examine the venue for the meeting to ensure it is an appropriate venue as defined by the Code.

7.1.2.9 It is acceptable/permissible to sponsor healthcare professional to attend an international Congress, and to invite them to a satellite symposium at a Congress they are already attending. It is prohibited and not acceptable or appropriate to run an overseas stand-alone company sponsored meeting for healthcare professionals where all (or nearly all) the attendees and/or the speaker/s are from Thailand.

7.1.2.10 No payments are made to compensate healthcare professionals for time spent in attending the Event.

7.2 Fees for Services

Healthcare professionals may be engaged as consultants and advisors for services such as speaking at and/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:

7.2.1 a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services.

7.2.2 a legitimate need for the services must be clearly identified and documented in advance.

7.2.3 the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.

7.2.4 the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.

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

7.2.6 the compensation for the services must be reasonable and reflect the fair market value of the services provided.

8. Customary Gifts, Promotional Aids, Medical Utilities

8.1 Customary Gifts

8.1.1 Customary gifts are allowed for local occasions on an infrequent basis such as new year, hospital visit, funeral and promotion at organizational level. Gifts for personal benefit of healthcare professionals are prohibited.

8.1.2 Payment in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals.

8.1.3 Gifts to healthcare professionals and institutions for customary and acceptable local occasions shall be allowed on an infrequent basis. The value of such gifts, the nature and types of which are related to the particularly customary occasions, shall not exceed Baht 3000/- per healthcare professional per occasion.

8.2 Promotional Aids

8.2.1 A promotional aid (giveaway) is a non-monetary item given for a promotional purpose. Promotional aids must be related to the work of the recipient healthcare professionals and should be of minimal value and quantity. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets are not acceptable.

8.2.2 All promotional aids which serve as brand name reminders shall include the brand name of the product and/or the logo and/or the company name. They are not to contain any promotional claims including promotional tag lines and/or statements.

8.2.3 Value of a promotional aid should be less than or equal to 500 Baht and it should be relevant to the practice of the healthcare professionals.

8.3 Items of Medical Utility

Medical utility items might include an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. In accordance with local laws and regulations, items of medical utility may be offered or provided if:

8.3.1 value of such items does not exceed Bht.3,000 (Three thousand baht);

8.3.2 the medical utility does not offset routine business practices

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

However, the medical utility should not be offered on more than an occasional basis, even if each individual item is appropriate.

9. Samples

9.1 Samples of products may only be supplied to the healthcare professionals authorized to prescribe that product, with their consent. The size and quantity of the sample supplied should be appropriate for either of the following:

9.1.1 Familiarization with presentation and appearance of a product, or

9.1.2 Providing to patients for initiation of therapy, or

9.1.3 Conduct of an agreed upon clinical evaluation of the product.

9.1.4 All samples delivered by sole distributors, medical representatives or via mail or courier should be securely packed and must be signed for by the receiver when received.

9.2 No person may sell, or trade, or offer to sell, or trade, any drug samples. For purposes of this paragraph, the term “drug sample” means a unit of a drug, which is not intended to be sold and is intended to for reasons listed in Sections 9.1.1 to 9.1.4, above.

9.3 Product samples must not be made available for collection from unattended stands, nor be supplied to unauthorized or non-qualified persons.

9.4 Samples should be clearly marked as such, e.g., “Sample - Not for Sale”, so that they cannot be resold or otherwise misused.

10 Clinical Research and Transparency

10.1 Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law. Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) and the Joint Position on the Publication of Clinical Trial

Results in the Scientific Literature (2010) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

10.2 Distinct from Promotion

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

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

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

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

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

11 Market Research

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

11.1 Methods used for market research must never be such as to bring discredit upon, or to reduce confidence in, the pharmaceutical industry. The following provisions apply whether the research is carried out directly by the company concerned or by organization acting on the company's behalf.

11.2 Market research must not in any circumstances be used as a disguised form of sales promotion and the research per se must not have a direct objective of influencing the opinions of the informant. The research design should be done in such a way that the data is unbiased and non-promotional.

11.3 The identity of an informant must be treated as being confidential, unless he/she has specifically agreed otherwise. Regardless of the existence of this agreement, it follows that the information provided (as distinct from the overall results of the research) must not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion.

11.4 Precautions should be taken to ensure that informants do not suffer as the result of embarrassment following an interview, or from any subsequent communication concerning the research project.

12 Interactions with Patient/Patient Organizations

12.1 Patient Organization

12.1.1 Scope

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

12.1.2 Declaration of Involvement

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

12.1.3 Written Documentation

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

12.1.4 Events

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

12.2 Patient Education

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

In addition, the following criteria should be satisfied:

12.2.1 The educational material must be current, accurate and balanced.

12.2.2 The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.

12.2.3 Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.

12.2.4 The educational material should include the advice “Please consult your physician” and the contact address and telephone number of the supplier of the material.

12.2.5 The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor. Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a product.

12.2.6 The tone of the message must not be presented in a way which unnecessarily causes alarm or misunderstanding in the community.

12.2.7 On all occasions the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes of a particular product.

12.3 Patient Aids

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

12.4 Patient Support Programs

Companies may arrange or participate in programs that support patients already prescribed a prescription-only medicine to improve positive health outcomes. To ensure that such activities are not considered as promotional programs, companies must ensure that any statements made or material provided to members of the general public are not promotional and cannot be considered as having the intention of promoting a prescription medicine to members of the general public.

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

- Any payment for the work undertaken by a healthcare professional in such programs is commensurate with the work undertaken;
- No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these program;

- The program complies with applicable laws;
- All information provided to patients must comply with Sections 12.2 and 12.3 of this Code;
- The data collected from these programs will not be used for any purpose other than to increase positive health outcomes and never for promotional activities; and
- The duration of these programs is appropriate to the disease state treated by the product involved.

13 Promotion to Non-Healthcare (Medical) Professionals (or General Public)

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

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

13.1 General Inquiries

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

13.2 Media Release

13.2.1 A prescription product related media release issued by companies is not allowed by the Thai FDA; however, it is acceptable to respond to media inquiries. The information provided must be current, accurate and balanced. Information about the medicine must not encourage members of the public to ask their medical profession to prescribe a particular pharmaceutical product.

13.2.2 Company may supply information about a product to the lay press only where this is in the public interest or where the objective is to communicate scientific or technical achievement. Such information should be presented in a balanced way to avoid the risk of raising unfounded hopes.

13.2.3 Product information should be released for lay publication only after the medical profession has been properly notified and following approval from the FDA if this is required by the Drugs Act (1967, 1979, and 1987).

13.2.4 Advertising of self-medication products to the general public is excluded from the scope of the Code. However, should medicines regarded as “pharmaceutical products” in most countries, be designated Non-Dangerous in Thailand, it is suggested that any lay promotional material should comply with the guidelines established for “pharmaceutical products”.

13.2.5 Intentional dissemination of information or hidden advertisement of dangerous medicines through radio disk jockey or television moderator is forbidden.

13.3 General Media Articles (Advertorial Articles)

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

Companies should not attempt to encourage the publication of general media articles or their content with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

13.4 Telephone Hotline and Website

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

13.5 Direct Mailing

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

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

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

14 Company Procedures and Responsibilities

14.1 Procedures

It is the responsibility of all companies to ensure that an internal compliance procedure exists that strives for compliance with all provisions of the

Code and the spirits it embodies. This procedure should be documented and provided to relevant employees to further enhance Code of Practice compliance.

14.2 Training

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

14.3 Responsibilities for Approving Promotional Communications

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

15 Medical Representatives

15.1 Medical 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 cognisant of all provisions of this Code.

15.2 Medical 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 by medical representatives.

15.5 Medical representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid for that purpose.

15.6 Medical representatives must take adequate precautions to ensure that medical products in their possession are secure and stored in accordance with the recommended Storage Conditions.

15.7 Companies must prepare and provide to medical representatives, detailed briefing material on the technical aspects of any product which is to be promoted.

15.8 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 medical representatives to obtain bona fide survey information.

15.9 Medical representatives must not use cross-channel sales method by using doctors' name as purchaser in selling products to the drugstores.

15.10 Medical representatives should dress professionally in business attire or uniform while performing their duties.

15.11 Medical representatives should ensure that the frequency, timing and duration of appointment, together with the manner in which they are made, are such as not to cause inconvenience to the doctors, pharmacists or nurses especially in OPD.

16 ADMINISTRATION

16.1 Complaints regarding breaches of The Code will be administered by the PReMA Chief Executive Officer, the Code of Practice Committee (hereinafter called as "CPC") and an Appeal Committee. The CPC shall consist of five (5) members - a Chairperson, two external members, one representative from PReMA Board of Directors and one Medical Director. PReMA Board of Directors and the Medical Directors of Member Company shall provide a set of three representatives, all of which shall be from a different company, to standby for the CPC. The Appeal Committee shall consist of similar structure like CPC, but there will be change of one or two external members and also change of the two internal members from the ones considering such appealed case.

16.2 Code Compliance Subcommittee (hereinafter referred to as "the CCSC") will carry out a review of the provisions of the Code after seeking input from interested parties. Besides regular review of the Code, the CCSC will perform activities to create awareness of the Code.

16.3 All valid complaints will be forwarded by the PReMA CEO to the Code of Practice Committee (CPC) and Appeal Committee, if so requested by the company for the latter group.

16.4 The role of the CPC will be to meet on a quarterly basis to hear valid complaints and act as judge, jury and cross examiner of the evidence before them and to ultimately decide on any sanction as per section 18.

17 COMPLAINTS PROCEDURE

All attempts should be made to settle a dispute through direct communication between the companies involved, at the General Manager (GM) or Chief

Executive Officer (CEO) level. The procedures for filing complaints via PReMA are as follows:

17.1 Formal Complaints:

17.1.1 Complaint Submission - All complaints must be submitted in writing directly to the PReMA CEO. Complaints can be made by either member companies or from non-member sources, e.g. Thai FDA, healthcare professionals or professional organizations, patients or patient groups.

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

17.1.2.1 It appears to be a genuine matter, submitted in good faith.

17.1.2.2 There is sufficient evidence to enable the complaint to be processed.

17.1.2.3 It is not a duplication of a case, which has already been resolved under the Code.

17.1.2.4 The minimum information required is;

Source of the complaint

➤ If the complaint is from a company or organization, it must be printed on the company's or organization's letter head and signed off by the GM or CEO. For complaint from an individual, real name, address and contact telephone number must be provided.

Alleged Company

➤ For each case in the complaint, the identity of company which is alleged to be in breach of the Code and the name of any product(s) /marketing activities must be specified.

Reference material

➤ For each case, a specific reference to the source of the advertisement/activity or printed material which is the subject of the complaint as well as any other evidence must be provided.

Date

➤ The date of the alleged breach of the Code.

Summary

➤ If possible for each case, a brief description of the complaint with a specific reference to the part of the Code under which the complaint is being made (section & paragraph).

17.1.3 Complaint Processing - When the PReMA CEO receives a signed complaint validated in accordance with section 17.1.2, and it appears that the alleged company may have contravened the Code, the case will be accepted for adjudication. The PReMA CEO may request for additional information or evidence from the complainant or the alleged company. The case with all evidence will then be forwarded to the CPC. The names of the complainant company, healthcare professionals and any third parties involved will remain confidential throughout the process.

17.1.4 Complaint Adjudication - The CPC shall review the case. If there is a need for additional information or evidence, a request will be made to the complainant and alleged company via the PReMA CEO. The CPC will then adjudicate whether a breach of the Code has occurred based on the compiled evidence.

17.1.5 Complaint Disposal - The decision of the CPC will be reported directly to the PReMA CEO, who will inform both the alleged company and the complainant of the decision. Sanction against the company found in contravention of the Code will be applied by the PReMA CEO, subject to Section 18 of the Code.

17.1.6 Complaint Resubmission - Where the alleged company or complainant disagrees with the decision of the CPC they may submit the case for reconsideration by the Appeal Committee. The Appeal must be made in writing with new evidence within 30 days after receiving the notification from the PReMA CEO. If new evidence are put forward by the complainant, the alleged company shall be invited to provide comments within 90 days. The decision of the Appeal Committee at this stage will be regarded as final and executory. The company who requests for the appeal process shall be responsible for the administration costs involved in setting up the meeting(s).

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

17.2 Anonymous Complaints

17.2.1 Complaint Submission - Anonymous complaints can be submitted either in writing or via telephone call to the PReMA CEO. Complainant,

either from companies or non-members (as described under 17.1.1), who may request for being anonymous informant.

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

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

17.2.2.2 The minimum information required is;

Source of the complaint

⇒ As described under 17.2.1, the source of complaint would be kept anonymous. Therefore, if available, it will be kept confidential.

Alleged Company

⇒ For each case in the complaint, the identity of company which is alleged to be in breach of the Code and the name of any product(s) /marketing activities must be specified.

Reference material

⇒ For each case, a specific reference to the source of the advertisement/activity or printed material which is the subject of the complaint as well as any other evidence may or may not be provided.

Time

⇒ If possible, there should be time period of the alleged breach of the Code.

Summary

⇒ If possible for each case, a brief description of the complaint with a specific reference to the part of the Code under which the complaint is being made (section & paragraph).

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

However, it is under PReMA CEO's judgment whether the case should be handled as a kind of warning or submitted to the CPC for adjudication process based on the seriousness of the case. If PReMA CEO so decides to bring the case for adjudication by the CPC, the decision must be conveyed to the alleged company, who should be allowed to provide their

defending position and any supporting evidence prior to CPC's consideration. The case with all evidence will then be forwarded to the CPC. The names of the complainant (if any), any healthcare professionals and third party involved will remain confidential throughout the process.

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

18. SANCTIONS

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

a. Refer the complaint to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

b. Refer the complaint and the CPC's finding to the head office and regional office of the offending company.

c. Suspend the offending company's membership for not more than 3 years.

d. Debar the offending company from membership of the Association, under Section 12.7 (2) of the PReMA Articles of Association.

e. A written undertaking that the practice complained of, will be discontinued on or before a date to be determined by the CPC.

f. Retraction statements, including corrective letters and advertising, to be issued by the Subject Company, subject to the approval of the CPC prior to release. It is the company's responsibility to ensure that the requirements of the CPC are met and to immediately inform and provide evidence to PReMA of their fulfillment.

g. The issuing of a fine by PReMA to the Subject Company as per follows:

(1) A fine not exceeding the value of 100,000 Baht, for a first offence.

(2) A fine not exceeding the value of 500,000 Baht for a second offence, within a 12 month period.

(3) The fine to be paid within 30 days of being advised, subject to any appeal that may be lodged under Section 17.1.6 of the Code.

19. OPERATIVE DATE

The Ninth Edition of the Code of Practice shall take effect on the 1st of October 2012.



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