PReMA Guideline on Patient and Patient Organization Interactions

Introduction

The Ethos of the Pharmaceutical Research & Manufacturers Association (PReMA) is centered on Trust. 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.

Patients, their families, and caregivers are at the core of the mission of the research-based pharmaceutical industry. It is important for pharmaceutical companies to observe clear ethical boundaries when interacting with patients and caregivers, individually or as part of patient organizations. Interactions between pharmaceutical companies and patients must always respect the physician-patient relationship, and patient support provided by companies can never be an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

This Guideline intends to provide mandatory practices for PReMA members when interacting with patients, caregivers, and patient organizations, as well as patient support programs that may be implemented by members. In case the applicable national laws or regulations established in Thailand are stricter, member companies should adhere to such stricter requirements.

Scope of Guideline

This Guideline is focused on activities with patients and patient organizations outside of the clinical research, market research and development process although the principles can be applied, as appropriate, to research and development interactions. For such interactions, members are encouraged to refer to PReMA Code of Practices in principles to be applied on section 7. Interaction and 8. Gift and other items and other recommendations established by regulatory bodies and other non-governmental initiatives.

This Guideline covers:

- Interactions with Patient Organizations
- Interactions with individual patients, caregivers, and their families
- Members initiated programs intended to provide services related to improving patient or healthcare outcomes
- Interactions carried out by members directly and interactions conducted by agencies, consultants and other third parties acting on behalf of members.

This Guideline shall apply PReMA Code of Practice section 17. Complaint Procedure if there is any complaint submission to PReMA.

Definitions

Patient Organization: a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers. Patient Organizations may be comprised of volunteers and/or professional staff; they may or may not be formally constituted entities. Patient organizations may focus on broad or narrow disease states and may engage in a variety of activities including, but not limited to, disease and treatment education, pre and post-diagnosis support and counseling and advocacy. Patient Organizations may be described as patient organizations, patient advocacy groups, or healthcare consumer organizations depending on the country/region.

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

Patient Advocate: an individual who speaks on behalf of patients; may or may not be affiliated with a Patient Organization.

Patient Organization Representative: an individual authorized to represent the interests and views of a Patient Organization (e.g., a director, officer, spokesperson).

Patient Expert: an individual with personal experience of living with a disease and has other technical expertise (i.e., a patient who develops expertise on the regulatory process through training and experience), who is solely representing him/herself and his/her views/opinions/experiences.

Caregiver/Carer/Supporter/Care Partner: a patient's friends, family, or other supporters who provide care to the patient. May also include individuals who provide services to a patient on a compensated basis, such as a home health aide, companion, or social worker.

Principles of Interaction

Clarity of Purpose[1,2,3]**:** Companies should develop a statement of purpose consistent with applicable laws, regulations, and PReMA Code of Practice to govern interactions with Patients, Caregivers and Patient Organizations, and should adhere to that purpose when considering collaborations and other activities. In all interactions the parties should be clear about the reason for and the planned outcome of the activity, and why the activity will benefit patients. Companies should consider how best to appraise those who provide input about the progress of the project and final outcomes.

Independence[1,2,3]**:** The independence of Patients, Caregivers and Patient Organizations must be respected. No company may require that it be the sole funder of the patient organization or any of its programs. Companies are encouraged to avoid situations where only one company requests to provide all financial support for a Patient Organization. A best practice is for no single company to be a majority funder of a Patient Organization. Patient Organizations are encouraged to seek financial and non-financial support from a wide variety of pharmaceutical company and non-pharmaceutical company sources. This may not be possible in all cases, particularly with rare diseases afflicting small patient populations and with limited treatment options.

Respect[1,2]**:** Respect all people and embrace a culture of diversity and inclusion. Interactions with Patients, Caregivers and Patient Organizations should be based on integrity and mutual respect, with the views and decisions of each having value. Interactions between patients and pharmaceutical companies must not interfere with the physician-patient relationship, must be voluntary, and must be conducted on the basis of full transparency.

Privacy[1]**:** Respect privacy rights and appropriately manage and protect personal information. Patient privacy and the confidentiality of patient medical information are paramount and should adhere to applicable laws and regulations.

Written Agreement[1]**:** When companies or associations provide financial support, significant indirect support and/or significant non-financial support to Patients, Caregivers, and/or Patient Organizations there should be an easy-to-understand written agreement signed by all parties that makes clear the rights and obligations governing the activity.

Transparency[1,2,3,4]**:** Support for Patient Organizations and patient-facing initiatives should be meaningfully disclosed in a manner that provides reasonable notice of support and/or collaboration. The impact of the engagement or interaction should be communicated back to those who contributed. Transparent communication can drive further trust and collaboration. Companies and associations should encourage Patient Organizations to be equally transparent and provide meaningful disclosure of funding received from pharmaceutical companies and associations.

Integrity[1,3]**:** Each party should always act, and be understood to have acted, honestly and with integrity always. Companies should assess their relationships with Patients, Caregivers and Patient Organizations to ensure conflicts of interest or perceived conflicts of interest are addressed. Any activity with Patients, Caregivers and Patient Organizations should be conducted in full respect of medical ethical values and should aim to have a positive impact on the overall healthcare system.

[1] IFPMA Note for Guidance on Patient and Patient Organization Interactions
[2] EFPIA Working Together with Patient Groups
[3] ABPI Working with Patients and Patient Organizations
[4] IAPO Healthcare Industry Partners Framework

Interaction

Interactions	DO's	DON'Ts
General	• Non-commercial staff engage with individual patients, caregiver, patient advocate, patient expert, patient organization representative or patient organization representative • Ensure clear communication on purpose of interaction i.e., type of activity (e.g., unrestricted grant, specific meeting or publication etc.), objectives, respective roles of the company and the patient organization, timeframe, amount of funding, etc.	• Request to be the only sole funder of the patient organization or any of its program(s).
Information	• Communicate non-promotional information on human health and diseases which must be clear, legible, accurate, balanced, fair, sufficient and substantiative • Request from individual members of the public for information or advice on personal medical matters, including about the product which has been prescribed, should be redirected to his or her own doctor.	• Communicate the information of prescription drugs directly or indirectly for promotional purposes • Record any specific or sensitive information shared by patients without written consent
Contact channel	• Initiate contact with individual patients and caregivers via any of the following 3 channels: 1. Through legalized patient organizations 2. Under permission of HCPs treating patients or contacting with caregivers or advising medicine to patients 3. Direct contact if patients publicly shared their contact information and publicly established themselves as the advocates and representatives of diseases	
Engaging patients as Consultants/Advisors/ Speakers/Panelists	• Select patients who have the relevant expertise and experience	• Promote drugs to patients • Be an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal

		products. Be an inducement to recommend, purchase, supply, sell products
Supports: Events/Meetings/Travel & Accommodation	• Support the events or meetings to the legalized patient organization • Ensure that the purpose of the events/meetings must be educational/professional/scientific in nature or supporting the mission of patient organization; and should encourage patients to seek further information or explanation from the appropriate healthcare professional, except for fund raising • Ensure appropriateness of venue; Scientific/Educational content; meals or refreshment Display Company Logo, not Product Logo • Provide modest hospitality (any meals or refreshments provided must be modest, not exceed 2,500 Baht (excluding VAT and service charges) per person per meal)	• Support events or meetings directly to an individual patient • Support accompanying persons in addition to the invited attendees except in cases of medical necessity • Display Product Logo • Provide promotional materials
Supports: Patient Support Program (PSP)/ Patient Access Program (PAP)	• Use PSP and PAP as the tool to support patient need or access to drug	• Use PSP or PAP as a tool for drug promotion in disguise • Use materials with promotional content or tone for PSP/PAP
Payment and compensation	• Ensure that the payment amount aligns with fair market value based on PReMA survey • Document the fee and payment condition in writing	• Only have verbal agreement with patients or patient organizations
Support for the establishment of patient organization	• The request must be unsolicited and PReMA members must not initiative or drive the initiation of a new patient organization • PReMA members support the educational sessions for patient organization	• Actively request to support the establishment of patient organization • PReMA members request for promotion of drugs among patient groups in exchange for the support to establish the patient organization

Appendix

Patients and Caregivers as Individuals

Consultants/Advisors:

Additional considerations unique to Patients, Patient Advocates, Patient Organization Representatives, Patient Experts, and Caregivers as consultants/advisors may include:

- *Is the individual consulting about their lived experience or their expertise? Patients engaged to consult about lived experience may be remunerated at a flat rate whereas it may be acceptable to pay Patient Experts based on their credentials/qualifications and the value provided to the company.*
- *Is the individual involved in any work that may present a conflict of interest, such as serving as a patient representative on a formulary, technical, Health Technology Assessment (HTA), or guideline writing committee? In such cases, companies should assess whether a conflict exists and if conflict mitigation is possible. At a minimum, companies should require in a written agreement that the individual declare their pharmaceutical company consulting/advising work and withdraw from any matters that could be a conflict of interest.*
- *Does the individual require accommodations due to their medical condition? The health and wellbeing of the individual patient should be a primary consideration and companies should take steps to evaluate the appropriateness of all activities and whether additional services or medical attention may be needed, or whether virtual meetings should be utilized.*

Internal or External Speakers/Panelists:

It is permissible for companies and associations to engage patients as speakers/ panelists, to remunerate them in appropriate circumstances, and to cover reasonable travel expenses. Questions to consider:

- *Is remuneration appropriate given the nature of the activity? For example, if a Patient Advocate or Patient Expert will appear on a panel discussion as an independent patient voice should a company or association compensate the individual or should the transfer of value be limited to covering reasonable travel expenses to facilitate participation? In such cases, reimbursement of travel expenses only is a best practice to preserve independence of the patient voice.*
- *Is the engagement appropriate in light of prohibitions on direct-to-consumer promotion in many countries? For example, is the patient engagement activity conducted in a manner that could inappropriately expose patients to product promotional messages?*
- *How should the transfer of value be disclosed to the audience to avoid any misperceptions? For example, the patient speaker could acknowledge a company's facilitation of travel arrangements at the beginning of the talk.*

Travel and Support:

Company and association support of Patients, Patient Advocates, Patient Experts, and Patient Organization Representatives to travel to symposia, congresses and other educational or professional meetings may be appropriate based on the facts and circumstances of the meeting and the information being conveyed, including prohibitions on direct-to-consumer promotion. Companies are encouraged not to directly provide individual patient travel to attend third-party meetings as a delegate; if direct travel and support is provided such should be consistent with standards applicable to HCPs.

A best practice may be to fund a patient or other organization with a grant or contribute to a pooled funding mechanism. In such a circumstance, the Patient Organization and/or third-party conference organizer will be responsible for selecting delegates to receive travel support. Any travel funded by a company, whether directly or indirectly, must be reasonable, appropriate, and not lavish or extravagant. If required by local law or regulation, travel support provided to a patient organization, patients, and caregivers may be subject to disclosure requirements.

Patient Organizations

Interactions with Patient Organizations are governed by PReMA Code of Practice, section 7 which provides the global minimum standard. In the absence of applicable local or regional standards, additional best practices may include:

- *"No company may require that it be the sole funder of the patient organization or any of its programs." It is in the interest of companies and Patient Organizations to have a wide base of support, as that increases the independence and credibility of all parties.*
- *Companies should avoid being the majority annual funder of a Patient Organization, and Patient Organizations should be encouraged to seek financial support from a wide variety of sources. In some circumstances, such as rare diseases afflicting small patient populations and with limited treatment options, it may not be possible for a company to avoid being the majority or sole funder of a Patient Organization. In circumstances where a Patient Organization has sought support from multiple pharmaceutical companies and non-pharmaceutical company sources and only one company agrees to provide support, the company and the Patient Organization are encouraged to adopt in advance, a set of ethical guidelines in writing that will govern their relationship and ensure that the company's funding does not compromise the Patient Organization's independent and unbiased decision-making.*
- *It may be appropriate for companies and Patient Organizations to partner/collaborate on specific projects where a company provides all financial support for the project.*
- *Company support for Patient Organizations should be meaningfully disclosed in a manner that provides reasonably adequate information of company support and/or collaboration at the occasion of the relevant event. Companies and Patient Organizations are encouraged to voluntarily report support on their websites.*
- *Company support for Patient Organization events and meetings should generally be consistent with PReMA Code of Practice section 7. Interaction when assessing the appropriateness of sponsoring Patient Organization meetings and events and consider applying those principles where relevant.*
- *Patient Organizations are encouraged to develop and share internal guidelines and policies on interactions with the pharmaceutical industry, which will reinforce the independent and ethical basis of the mutual relationship.*
- *Interactions between pharmaceutical companies and Patient Organizations should be structured to enable knowledge sharing unless there are legitimate intellectual property, competitive, or regulatory restrictions that may restrict public dissemination of the collaboration.*

Patient Support and Assistance Programs

Patient support and assistance programs ("patient programs") offered by companies are varied depending on the nature of different products, therapies, disease states, local laws, regulations, and codes of practice. Companies should take into consideration the following principles when designing and implementing patient support and assistance programs:

- *Patient programs offered by companies should be designed for the benefit of patients and not HCPs or others.*
- *Company involvement in patient programs should be meaningfully disclosed to patients and HCPs.*
- *Patient programs should not interfere with the HCP-patient relationship or undermine treatment decisions.*
- *Patient confidentiality and privacy should be maintained at all times, and proper privacy practices should be exercised in connection with any potential collection, use or transfer of patient data.*
- *Patient programs should be structured to ensure patient safety is maintained through pharmacovigilance procedures and controls.*
- *Transfers of value to HCPs or others in connection with patient programs should be commensurate with the work performed and payments should never constitute an inducement (or appearance of an inducement) to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.*

- *HCPs should not be compensated for proposing that their patients participate in a patient program. Patient programs should not be used for inappropriate direct or indirect transfers of value to HCPs who prescribe medicines to the patient benefiting from the patient program.*

Agreement

The written agreement must include:

- *Name of the activity*
- *Names of the organizations involved (pharmaceutical companies, patient organizations and any third parties which will be brought in to help)*
- *Type of activity (e.g., unrestricted grant, specific meeting, or publication etc.)*
- *Objectives*
- *Respective roles of the company and the patient organization*
- *Timeframe*
- *Amount of funding*
- *Description of significant indirect/nonfinancial support (e.g., the donation of public relations agency time or free training courses)*
- *Statement that all parties are fully aware that sponsorship must be clearly acknowledged and apparent from the start*
- *Code or codes of practice which will apply*
- *Signatories to the agreement*
- *Date of the agreement*

Events and meetings

The written agreement must include:

- *The venue must be appropriate and conducive to the main purpose of the meeting; lavish, extravagant, or deluxe venues must not be used, companies must not sponsor or organize entertainment (such as sporting or leisure events) and companies should avoid using venues that are renowned for their entertainment facilities.*
- *The meeting must have a clear educational content.*
- *The subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion.*
- *Any hospitality provided must not extend to a spouse or other accompanying person unless that person is a health professional or other relevant decision maker and qualifies as a proper delegate or participant at the meeting in their own right.*
- *Spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting, and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.*

Advisory Boards

Advisory boards are not used to promote a company's medicines and must not be an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. They should only be held to enable companies to answer legitimate business questions to which they do not already know the answer.

If you plan to invite patients or patient organizations to an advisory board, check that the answer to all the following questions is "yes":

If the answer to any of the questions is "no", you should stop and think carefully in case there is a compliance issue.

- *Does the company have a legitimate unanswered business question?*
- *Is an advisory board the most appropriate way of obtaining the information?*
- *Does every participant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?*

- *Is the number of participants limited so as to allow active participation by all?*
- *Does the agenda allow adequate time for discussion? Is a significant majority of the time spent on feedback from the participants?*
- *Has the company wholly and solely determined its need for the advisory board, with no input from expected attendees?*
- *Is the number of delegates/meetings strictly limited to that required to answer the question?*
- *Does the invitation to participate clearly state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken?*
- *Are the participants being paid no more than 'fair market value'?*
- *Are intended presentations to participants relevant to their role in answering the business question?*
- *Is this the only advisory board to address the business question at issue?*
- *Are the participants expected to do any preparatory work?*
- *Are all those involved with the meeting (staff, third parties, participants) clear on the need for and expected output from the meeting?*

Here are some other points to consider:

- *Are the arrangements (e.g., venue, subsistence, travel, contract) appropriate? Academic education as an educator/teacher*
- *How were the participants selected?*
- *Who from, or on behalf of, the company is attending? Do they have a defined role and is the ratio of company employees/others to participants reasonable?*
- *Will there be a conclusions/recommendations report? What use will be made of it?*
- *Have any advisory boards for the same medicine/therapy area already taken place/been planned within e.g., a 12-month period? If so, what is the justification for another one?*
- *What follow-up, if any, is to be undertaken with participants? If so, is this appropriate given the non-promotional nature of advisory boards?*
- *Is this advisory board held in conjunction with any other meeting such as a learned society congress?*