

Patient and patient organization interactions

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Introduction

The Ethos of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is centered on *trust* to “act with integrity and honesty to improve patient care and 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. In most countries, direct-to-patient product advertising is not permitted; where it is permitted, it must be conducted in full compliance with country laws, regulations, and/or relevant codes of practice.

This Note for Guidance intends to provide non-binding best practices for IFPMA member companies and associations when interacting with patients, caregivers, and patient organizations, as well as patient support programs that may be implemented by member companies. Therefore, the Note for Guidance is advisory only. To the extent national laws, regulations, or industry codes of practice differ, member companies and associations should adhere to requirements established in their respective countries.

IFPMA recognizes the work underway at the local and regional level, both within IFPMA member associations and various non-governmental organizations. Thus, the objective of this Note for Guidance is to complement existing work, and to provide additional interpretation and guidance on the provisions of Article 11 of the IFPMA Code of Practice (Interactions with Patient Organizations).

Scope of Note for Guidance

The IFPMA Code of Practice covers the promotion of pharmaceutical products and interactions with Healthcare Professionals (HCPs), medical institutions, and patient organizations. The IFPMA Code does not cover promotion of medicines to the public, and such activities are out-of-scope for this Note for Guidance. In countries where advertising to the public is permitted,

that activity is governed by local laws, regulations, and/or relevant codes of practice. This Note for Guidance is focused on activities with patients and patient organizations outside of the clinical research and development process although the principles can be applied, as appropriate, to research and development interactions. For such interactions, companies and associations are also encouraged to refer to relevant guidance and recommendations established by regulatory bodies and other non-governmental initiatives.

This Note for Guidance covers:

- Interactions with patient organizations;
- Interactions with individual patients, caregivers, and their families;
- Company initiated programs intended to provide services related to improving patient or healthcare outcomes, or to ensure or assist with access and/or reimbursement (e.g., patient support programs, patient assistance programs, patient programs);
- Interactions carried out by member companies and associations directly and interactions conducted by agencies, consultants, and other third-parties acting on behalf of member companies and associations.

Definitions

There are company, country, and regional variations in the use of terminologies. These variations have implications in how codes and guidance documents attempt to regulate issues such as remuneration and other transfers of value. For this Note for Guidance, the following defined terms are used:

Patient organization: The IFPMA Code defines patient organizations as “typically 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, advocacy, funding of medical research, and partnering with sponsors in R&D to bring the patient perspective to the development of new medicines. 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. Such persons may be covered by other applicable codes. For example, under Section 1.2 of the IFPMA Code, a HCP "means any member of the medical, dental, pharmacy, or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell, or administer a pharmaceutical product."

Principles of interaction

Clarity of purpose: Companies should develop a statement of purpose consistent with applicable laws, regulations, and industry codes 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 and associations should consider how best to appraise those who provide input about the progress of the project and final outcomes.

Independence: The independence of patients, caregivers, and patient organizations must be respected. Under Article 11 of the IFPMA Code "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 provides 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: 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: 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: When companies or associations provide financial support, significant indirect support and/or significant non-financial support to patients, caregivers, and 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: 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: 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.

Agreements

While the IFPMA Code does not cover interactions with individual patients and caregivers, Section 7.4 (Fees for Services) provides that for HCPs “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 these services.” This written agreement principle should extend to patient interactions that involve financial support, significant indirect support, and/or significant non-financial support.

Patient, caregiver, and patient organization representatives are in many cases not legal experts and the agreements used with professional counter-parties may not be appropriate. Where legal agreements are needed, the document should be written in plain and accessible language. For example, some questions to consider:

- Is there unnecessary use of legal terminology and, where legal terminology is necessary, are such clauses and terms explained in a simple and clear manner?
- Are confidentiality and data privacy provisions tailored to the nature of the engagement? For example, are full confidentiality provisions necessary if there is no intention to share confidential information with a patient or patient organization? Do the

confidentiality provisions provide appropriate protections relating to sharing and use of patient information?

- Are intellectual property terms and conditions appropriate? For example, is it appropriate for a company to assert work for hire ownership over materials developed by a patient during an interaction? Companies should be sensitive not to assert ownership over a patient's life story or journey.
- Is the purpose of the engagement, remuneration terms, and expense reimbursement clearly articulated? Is fair market value reasonably assessed?
- Are consequences for breach of contract reasonable and proportionate based on the nature of the service provided by the patient, caregiver, or patient organization representative?
- Are there contractual mechanisms to appraise those who provide input about the progress of the project and outcomes?

Easy to understand text and accessible language should also be used in agreements that do not include transfers of value, including consents to use a patient's image, video, or life story for publicity purposes.

Patients and caregivers as individuals

Companies and associations should carefully consider how and when to engage with patients and caregivers as individuals, with the appropriate intent and Clarity of Purpose. Companies and associations should ensure activities are carried out for a legitimate purpose.

Companies and associations may interact with individual patients, patient advocates, patient organization representatives, patient experts, and caregivers in several ways.

Consultants/Advisors: Companies and associations may engage individuals to provide consulting and advisory services, including through participation in advisory meetings or in connection with market research. These activities must be appropriate and consistent with the stated Clarity of Purpose for patient engagement. Section 7.4 of the IFPMA Code (Fee for Services) and the IFPMA Note for Guidance on Fees for Services can be used for guidance on how to select and engage individuals for consulting/advisory services including compensation levels and frequency of engagements.

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. While Section 7.3 of the IFPMA Code generally does not allow companies to pay costs associated with individuals accompanying HCPs except in cases of medical necessity, companies may consider covering reasonable expenses for Caregiver/Carer/Supporter/Care partner who may accompany a patient.
- How was the individual identified?

Internal or external speakers/Panelists: In many cases, pharmaceutical companies and associations can play an important role to facilitate the patient perspective by engaging with patients to share their perspectives through speaking at internal company events, at external company events, or at third-party organized events. 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.¹

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, regulation, or industry code of practice, 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 Article 11 of the IFPMA Code, which provides the global minimum standard. In the absence of applicable local or regional standards, additional best practices may include:

- The IFPMA Code states that “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

¹ Companies and associations are encouraged to reference the IFPMA Note for Guidance on Sponsorship of Events and Meetings (January 24, 2020).

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 Section 7.1 of the IFPMA Code regarding venue (7.1.4), limits (7.1.5), and entertainment (7.1.6). Companies should refer to the IFPMA Note for Guidance on Sponsorship of Events and Meetings 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 pharma-covigilance 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.

References and further information

- [IFPMA Code of Practice](#)
- [APEC Mexico City Principles](#); Asia-Pacific Economic Cooperation
- [Working with patients and patient organisations: a sourcebook for industry](#); The Association of the British Pharmaceutical Industry (ABPI)
- [Working Together with Patient Groups \(September 2017\)](#); EFPIA Patient Think Tank
- [Principles for Remunerating Patients, Patient Organisation Representatives & Carers for Work Undertaken with the Pharmaceutical Industry \(June 2019\)](#); EFPIA Patient Think Tank
- [Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies](#); Patient Focused Medicines Development
- [Guidance for patient involvement in industry-led medicines R&D](#); European Patients' Academy on Therapeutic Innovation (EUPATI)