



Guidelines for Interactions with Patients, Caregivers and Patient Organisations

February 2024

INTRODUCTION

A Shift Toward Patient-Centredness

Across the world, the healthcare sector is embracing a move towards a more patient-centred approach to services. This is a paradigm shift that emphasises greater involvement of patients in decision-making processes through engagement with patients, caregivers, and patient organisations (collectively referred to as ‘patient representatives’) and a focus on improving patient outcomes. Singapore is no exception, as patient groups are now playing a greater role than ever before in shaping the development of the healthcare ecosystem.

The move to patient-centricity is equally true of the pharmaceutical industry, which recognises the importance of including the patient voice at every level of disease and healthcare management and is increasingly involving them. The pharmaceutical industry now interacts with patient representatives throughout the entire lifecycle of a medicine from meeting unmet needs, research and development (R&D), participation in clinical trials, Health Technology Assessment (HTA), and real-world evidence, to co-creating disease awareness campaigns with them.

Purpose of this Document

The Singapore Association of Pharmaceutical Industries (SAPI) firmly believes in the value that this engagement can bring for bettering public health outcomes, particularly when done with some key considerations in mind. These guidelines are intended to provide all SAPI members and their employees with a framework for engaging with patient representatives in ways that are transparent, honest and respectful while prioritising trust, patient welfare and positive healthcare outcomes.

The sections below complement the [SAPI Code of Conduct](#)'s Article 11 (Interactions with Patients and Patient Organisations) and detail best practices for SAPI members when interacting with patient representatives outside of the clinical research and development process, which may include entering into collaborations and contract agreements.

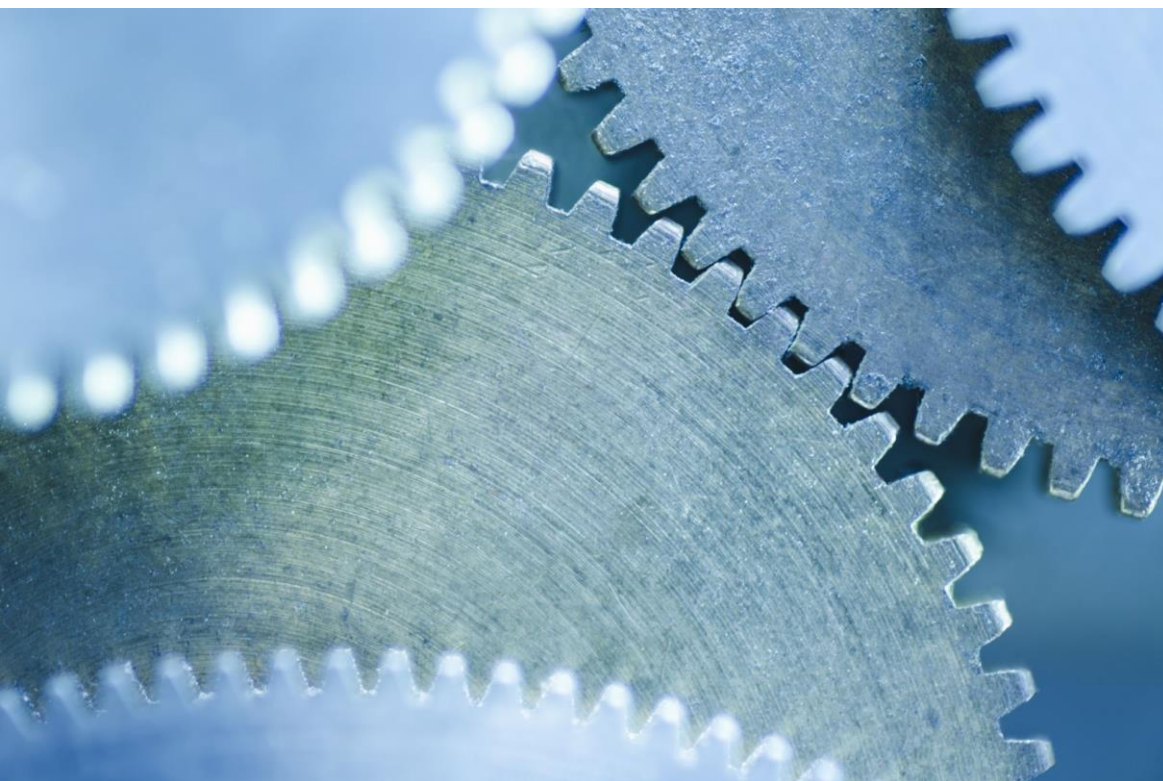
SCOPE

This guide is applicable to 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). It also covers interactions with patient representatives carried out by SAPI members and associations directly and interactions conducted by agencies, consultants and other third parties acting on behalf of SAPI members. In all such situations, SAPI members should prioritize principles of fairness, honesty and diversity, equity and inclusion. While the R&D process is outside the scope of this guide, the principles outlined within can be applied to relevant patient interactions in this context.

Principles of Patient Engagement and Partnership

In general, SAPI members should ensure they operate with the highest level of integrity and ethical standards, with patient welfare as the foremost priority. SAPI members are encouraged to develop their own governance processes for all interactions with patient representatives, regarding how and when to engage these groups. The interactions and governance process must comply with all applicable laws and regulations, as well as SAPI's Code of Conduct.

The following principles should form a foundation for all interactions between SAPI members and patient representatives.



Purpose of Patient Engagement

- SAPI members are encouraged to engage with patient representatives with the primary purpose of empowering and educating to improve healthcare outcomes. First among these considerations is a genuine intent to deliver better patient outcomes and support educational or scientific purposes.
- For all interactions, both parties are required to be clear on the objectives and deliverables of the partnership and collaboration.
- SAPI members should not attempt to use partnership agreements to influence or control individuals' or patient organisations' activities or decision-making processes but should respect their independence.
- SAPI members must not provide any personal, medical, or product advice to patient representatives, and must always refer a patient to the patient's treating physician on all matters related to individual medical care.
- Both parties are to always act with mutual respect, recognising the dignity, privacy, and rights of all the individuals and organisations with whom they interact.

Key Considerations

- Are the purpose and deliverables of the engagement clearly articulated?
- Do the patients involved require special considerations due to their medical conditions? This should be a primary consideration when planning any partnerships or collaborations, as the well-being of the patients involved should always be the priority.

Conflicts of Interest and Transparency

- Conflicts of interest are when decisions are biased in favour of an entity or individual's vested interests, affecting actions, judgment, and/or decision-making.
- SAPI members should establish clear policies and procedures for identifying, managing, and disclosing any potential conflicts of interest that may arise when working with patient organisations, to ensure that their interactions prioritise the best interests of the organisation and the patients it represents.
- SAPI members must avoid offering complimentary gifts to patient representatives. Additionally, they should take necessary steps to prevent conflicts of interest, especially when offering financial support. It is crucial to ensure that any financial assistance provided is independent and free from undue influence.
- SAPI members should respect the independent decision-making of patient organisations and should not request that they be the sole funder of a patient organisation or any of its programmes. In general, SAPI encourages members to avoid any situation where they are the sole funder of a patient organisation, though this may not be possible in all cases, particularly with rare diseases afflicting small patient populations and with limited treatment options.
- To avoid any real or apparent conflict of interest, SAPI members should always be transparent about their relationships with patient organisations and disclose any financial support or other incentives they are providing to all relevant parties.

Key Considerations

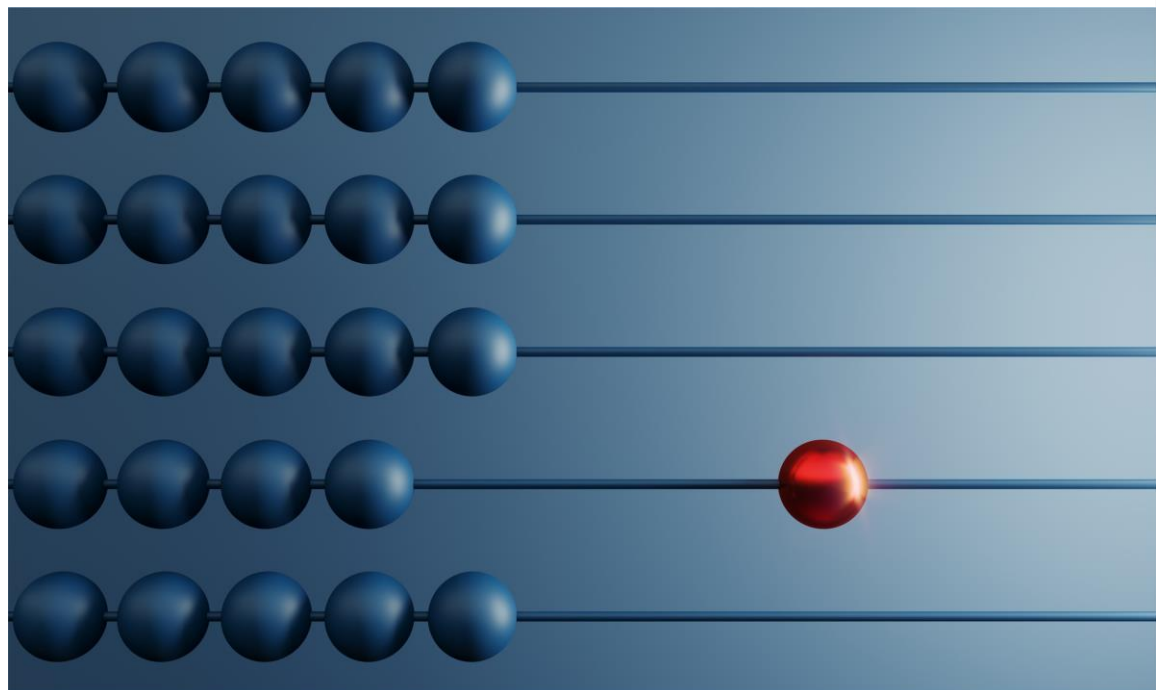
- Is the patient representative involved in work that may present a conflict of interest, such as serving in the Agency for Care Effectiveness (ACE) and being involved in HTA activities, or otherwise working in a formulary, technical, or guideline-writing committee? If so, SAPI members should assess the conflict and determine if conflict mitigation is a suitable option. This could take the form of a written agreement involving an individual's declaration of involvement with a pharmaceutical company in a consulting or advisory capacity.
- Could the provisions being provided to patients and patient groups (including complimentary gifts and accommodation) present a conflict of interest?
- How can the transfer of value between SAPI members and patient representatives be disclosed to audiences to avoid misunderstandings and misperceptions? For example, if a SAPI member funds a patient organisation's research project, this financial contribution should be clearly stated in any public reports, meetings, or communications related to the project.

Compensation

- SAPI members should establish internal guidelines to ensure that remuneration to patients should be fair, reasonable, consistent and reflect the fair market value (FMV) of the services provided. Financial support and other incentives should not be tied to specific products or promotional activities.

Key Considerations

- Have you reviewed the terms of any financial sponsorship or support agreements to confirm that nothing could be misconstrued as linking financial support to specific products or promotional activities?
- Has FMV been assessed and used to inform the remuneration agreement?



Communication Platforms

- SAPI members should choose the most appropriate platforms for communicating with patient representatives.
- For face-to-face meetings, SAPI members are encouraged to engage with patient representatives in a neutral setting that is free from any conflicts of interest.
- In situations where patients have limited mobility or other constraints that prevent physical attendance, virtual meetings may be necessary. In such cases, SAPI members should facilitate online interactions that are accessible, secure, and respectful of the patient representatives' conditions and privacy needs.
- SAPI members must exercise caution in social media interactions which, by their nature, may make it more challenging to provide adequate context.

Key Considerations

- Is the selected platform user-friendly and accessible for patient representatives, taking into account their specific medical conditions?
- Does the selected platform allow for a suitable amount of context for meaningful interactions?

Sharing Patient Stories

- Sharing patient stories requires consideration of content and messaging, particularly on external platforms, which fall under stricter legal standards.
- When SAPI members engage a patient representative to share a personal story at their events, they must be mindful that direct advertisement of prescription-only medicines (POM) is prohibited in Singapore and ensure that the patient representative is not led to make public statements about products that they are not permitted to make, such as off-label messages.
- Patient stories and experiences can be captured via a video recording to be shared both internally and externally, with the prerequisite of patients' written consent and ensuring that no off-label messages are included and that nothing that could be understood as advertising POM is shared publicly.
- Clear communication on how patient representatives' stories or videos will be used should be included in a documented agreement.
- When presenting patient experiences for promotional purposes at internal company meetings, ensure that they pertain specifically to the patient's condition and the treatment's approved uses as defined by its official labelling.

Key Considerations

- Have you collected written consent to record them from all patient representatives?
- Have you reviewed patient representative statements carefully in consideration of what product messages are allowable, avoiding all off-label messaging?
- Does the selected platform allow for a suitable amount of context for meaningful interactions?

Service Agreements

- SAPI members should base all agreements with patient representatives on a written contract that clearly outlines the purpose of the collaboration and includes services to be provided, the fees, and the obligations or responsibilities of both parties.
- All contracts should be easy to understand and written in plain language.
- Clearly written contracts should be used for all interactions and agreements with patient representatives that include (but are not limited to) service agreements, honoraria, travel expenses, copyright permission to use a patient's images, video or biographical details for publicity purposes, and any other financial or non-financial support.

Key Considerations

- Is the purpose of the engagement, remuneration terms, and expense reimbursement clearly articulated?
- Is there unnecessary or confusing use of legal terminology, and where legal terminology is used with cause, is it done in a manner understandable by patient representatives?
- Are consequences for breach of contract reasonable and proportionate based on the nature of the services provided by the patient representatives?
- Is the engagement appropriate in light of Singapore's prohibition on direct-to-consumer promotion of prescription-only medicines, and restrictions on other categories of medicines?

Medical Terminology

- To ensure clarity and accessibility, SAPI members should consistently convert medical terminology into language easily understood by the public. This is especially crucial when producing materials intended for wider audiences, such as disease awareness advertisements. Medical jargon, which can be confusing or even misleading to non-experts, should be avoided.
- Materials created should undergo an internal review process to ensure that complex medical concepts are communicated in an uncomplicated and straightforward manner. SAPI Members may refer to the Singhealth Patient Advocacy Network's plain English healthcare [glossary](#) as a point of reference for such efforts.
- SAPI members can also consider the co-creation of text with patients and patient organisations to ensure the best possible clarity and accessibility.

Key Considerations

- Where medical terminology is used with cause, is it done in a manner understandable by patient representatives?
- Have cultural norms and values been considered to prevent misinterpretation?
- Has the audience's level of health literacy been assessed to inform the communication approach?
- Is the information presented in the audience's primary language, with necessary translations or interpretations provided?

Privacy and Data Protection

- As a general principle, SAPI members should not collect or have access to the personal, medical data of patients as part of engagements with patient representatives. If personal or medical data are required during the engagement process with patient representatives, SAPI members are encouraged to:
 - Collect the minimum necessary personal or medical data to fulfil a specific, legitimate need. This information should not be used for other purposes without explicit consent. If data collection is necessary for compliance and reconciliation processes, SAPI members are required to de-identify all personal information to maintain confidentiality.
 - Protect the data in accordance with all applicable Singaporean laws and regulations, including the [Personal Data Protection Act \(PDPA\)](#).
 - Once personal or medical data are no longer required, they should be discarded unless they are needed for legal or regulatory obligations.
- It is the responsibility of SAPI members to monitor and document its support of patient representatives in a secure and valid records management system.
- The process and details of data collection, storage and destruction should be communicated to patient representatives in advance.

- For any patient-related events, such as congresses, forums, meetings, or advisory boards, SAPI members must refrain from taking photographs that could identify individuals, whether patients or members of the public, without obtaining their consent. Should an individual decline to give permission, yet photographs are necessary for compliance and reconciliation, all images must be altered to obscure individual identities, either through pixelation or by capturing from non-identifiable angles, such as from behind.

Key Considerations

- Are confidentiality and data privacy provisions tailored well to the nature of the engagement?



REFERENCES

This guide was developed in consideration of patient engagement protocols established by leading biopharmaceutical industry associations in markets around the world, in consultation with patients and their representatives in Singapore. Please find below a list of some of the references consulted in the creation of this guide:

- Medicines Australia: [Working Together Guide \(Published 2015\)](#)
- The Pharmaceutical Research and Manufacturers of America (PhRMA): [PhRMA Principles on Interactions with Patient Organizations \(Published 2014\)](#)
- The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA): [Note for Guidance on Patient and Patient Organization Interactions \(Published 2020\)](#)
- The Association of the British Pharmaceutical Industry (ABPI): [Working with patients and patient organisations - a summary \(Published 2020\)](#)

END

