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PURPOSE OF THIS GUIDANCE

This Guidance addresses common questions about the application of the Code to particular scenarios between industry, patients, their carers, their families, and Patient Organisations*. It supports the industry's application of the Code but is not binding.

The Code embraces our industry's evolving needs to better engage with patients or their representatives. As the innovators of our medicines, the Code affirms that our members have a unique responsibility to communicate relevant information to stakeholders who have a role in the research, development, registration, listing, or monitoring of a therapeutic good. Patients, their carers, their families, Patient Organisations and the broader community are some of those stakeholders.

The Guidance highlights several scenarios, and their inherent risks whilst providing some practical considerations that a company may employ to mitigate such risks. These considerations are not compulsory; instead, they are suggestions for a company to consider and employ as they see fit and to support a consistent approach to ethical decision-making across the industry.

WHAT DOES THE MEDICINES AUSTRALIA CODE OF CONDUCT SAY?

As the innovators of our medicines, the Code affirms that our industry has a unique responsibility to communicate relevant information. This responsibility goes beyond informing healthcare professionals (HCPs); it extends to patients, their carers, their families, Patient Organisations, and the broader community.

The Code lays out the parameters for such communication and reflects the positive and beneficial partnerships between pharmaceutical companies and Patient Organisations that can lead to better health outcomes for patients.

The particularly relevant sections include:

- Principle 6: Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.
- Part C – Ethical Interactions with Relevant Stakeholders
 - Section 10: Appropriate Communications with Relevant Stakeholders
 - Section 11: Engagement with Patient Organisations
- Part D - Ethical Interactions with Patients and General Public
 - Section 12: Interactions with the General Public

* Patient Organisations (also commonly referred to as health consumer organisations) are not-for-profit organisations, mainly composed of patients and/or caregivers, that represent the needs and interests of patients, their families and/or caregivers. For simplicity purposes of this Guidance, the reference to POs in this document collectively captures patient organisations and patient representatives interchangeably, however, it is not to be confused with the Code's definition of a Patient Organisation.

PRINCIPLES FOR WORKING TOGETHER WITH PATIENT ORGANISATIONS

The [Working Together Guide](#), developed by Medicines Australia and the Consumers Health Forum, is written for POs and addresses how to build and manage successful and collaborative relationships between industry and POs. It sets out six guiding principles that should underpin all collaborative work in any such relationship:

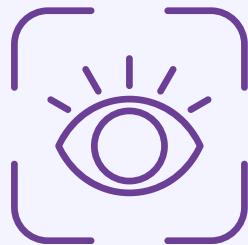
1. Valuing the patient perspective

Gaining patient insights and involving them in all aspects of the medicine lifecycle including access, use, affordability and experience are key to providing better health outcomes.



2. Clarity of purpose

Be clear about the purpose of the collaboration including both benefits and risks.



3. Independence

Each party should maintain its independence.



4. Transparency and accountability

Including the disclosure of relationships is essential for ensuring accountability, building trust and maintaining credibility.



5. Integrity

Both parties must always be open and honest and act with integrity.



6. Confidentiality

Partners in a collaboration must respect the confidentiality and privacy of the relationship in accordance with existing legislation and regulation.



1. PATIENT ORGANISATIONS* ATTENDING COMPANY OR THIRD-PARTY EDUCATIONAL EVENTS

Question: Can pharmaceutical companies invite POs* or patient representatives to attend company or third-party educational events?

Elaboration:

The primary purpose of educational events is the enhancement of medical knowledge and the quality use of medicines. They have traditionally been the domain of pharmaceutical companies, healthcare professionals, and associated researchers, scientists, and academics. POs have expertise in disease states, either through personal experience or formal education and training.

Note that some PO representatives may also be healthcare professionals. As such, interactions with the relevant healthcare professional's code of conduct requirements would be most applicable.

Companies must assess each instance on a case-by-case basis. Many POs are highly skilled in their therapeutic areas, however, in this document we have expanded the PO reference to include patient organisations and patient representatives. As such, we need to consider a wide variation of expertise in this larger group and their educational needs.

The level of responsibility of a company will vary depending on the company's involvement in the event (i.e., company-led meeting or sponsor to a third-party event).

Risks (real, potential, or perceived):

- Attending an educational event may expose the PO to promotional¹ messaging or material relating to prescription medicines (i.e. the risk which arises is direct-to-consumer advertising).
- Raising unfounded hopes of successful treatment.
- If the PO* misunderstands the information shared at the educational event, there is a risk of misinformation being used by or shared with PO members.

¹ Medicines Australia Code of Conduct defines "Promote" as, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.

Practical considerations that may mitigate these risks:

- **Non-promotional intent:** The event's intent and content must be non-promotional, as defined by the Code. Should there be a promotional component to the event, such as a promotional symposium, ensure attendance or access to this component is limited to a verified HCP audience. This includes limiting visible displays, leave-behinds, and presentations.
- **Non-promotional content:** All provided content must be non-promotional and suitable for the PO and their patient constituents.
- **Adjust:** Companies must be aware of the delegate make-up, and adjust booths, activities or other presentations with this in mind, including making the visible content non-promotional and advising company staff not to provide information on specific products other than to HCPs. Companies may implement a screening process (potentially in collaboration with the event organiser), to be able to identify their audience (e.g. colored-coded name badges, other recognizable tools) and therefore tailor the conversations and material appropriately.
- **Limiting exposure in common areas:** If there are common areas with promotional content and it is not reasonably possible to avoid PO exposure (e.g., lunch for all attendees is provided in an area where there is promotional signage), preventive measures should be implemented such as limiting the time of exposure, visibly identifying the PO (e.g., color-coded name badges), and making clear the content is for HCPs only.
- **Purpose:** The rationale for the PO to attend must be legitimate, primarily educational and aligned to that PO's specific educational needs. Whilst there may be opportunities for the PO to interact with HCPs, these must be secondary to the purpose of the educational activity. Companies must ensure the purpose of inviting an PO to attend is not to gain favour, provide entertainment or solicit product discussions.
- **Balance:** Information must be balanced and complete, avoid raising unfounded hopes of successful treatment, and not stimulate demand for the prescription of a particular product.
- **Appropriateness of content for PO:** Evaluate if the content is being presented at an appropriate level for an PO invitee's expertise and if the invitee has requisite expertise and qualifications within their PO role to benefit from the content.
- **Restricted attendance:** Restrict PO attendance to certain parts of the agenda and brief the PO on reasons why certain sessions are not available for them to attend (e.g. promotional sessions).
- **Consider who interacts with PO:** As the Code requires all interactions with POs be non-promotional and conducted by appropriately qualified and selected company personnel, consider the appropriateness of inherently promotional roles, for example sales, to interact with POs at these meetings. Briefing company personnel who are attending the meeting, on identifying and appropriately interacting with POs is recommended.
- **Consider other methods:** If not appropriate for an PO to attend a medical educational event, consider other methods to support the knowledge-gap through other educational formats.

2. COMMUNICATING WITH PATIENT ORGANISATIONS ABOUT SPECIAL ACCESS PROGRAMS

Question: Can pharmaceutical companies provide information to POs about special access programs?

Elaboration:

Special Access programs (programs) allow access to medicines, including medicines that are pre-registration or in research and development, and thus information on the programs is usually only available to HCPs. Whilst an HCP's role is to be able to access information about these programs to understand the availability of a medicine for consideration in an individual patient's treatment, it may be that the HCPs are not aware of the programs available.

Companies can provide information about programs to POs to ensure that POs have the most current and accurate information to respond to questions asked by patients. Practically, POs learn of the programs and take on a role to share information, and respond to patient questions.

Companies should communicate with the PO about their expectations for any on-sharing of this information. Ideally, the PO should not share the information proactively or broadly with their membership (such as making all details plain on their website) which may risk the perception of promotion. Instead, the expectation for this information-sharing should be to equip the PO to respond to patient questions.

As a point of clarity, Special Access programs differ from clinical trials. Clinical trial information (without reference to product/molecule) can be shared with POs if they are taking place in Australia. POs may share information on clinical trials with patients for the purpose of trial recruitment and awareness (see #5).

Risks (real, potential, or perceived):

- Providing information about medicines to non-HCPs may be or be perceived as promotional, whether it be an unregistered or registered medicine.
- Leveraging a PO as a conduit for otherwise prohibited activity, such as direct-to-consumer promotion of registered and unregistered medicines.

Practical considerations that may mitigate these risks:

- **Non-promotional content:** Do not use product branding.
- **Guardrails:** Develop 'guardrails' for information-sharing that reflect the intent to factually inform POs. Such guardrails could be discussed/determined in conjunction with the PO so that both parties understand and agree on how the information will be used and shared. It is recommended this is agreed in writing to ensure it is understood and acknowledged.
- **Refer to treating doctor:** Treatment decisions related to individual patients are for their doctor to decide, in consultation with the patient. It is recommended to include clear statements to this effect in communications with patients or POs.
- **Limit use:** Communicate to POs that the information about the programs is to be used to respond to specific questions from patients and not proactively disseminate broadly to patients. For example, that "information on the company's special access programs will not be broadly advertised to patients, however, can be used in manners A, B and C."
- **Narrow the messaging to program awareness:** Consider limiting the messaging to the existence of a program, without expanding upon how to engage/enroll in or self-evaluate eligibility for the program, and direct patients to speak with their healthcare provider for further discussion.
- **PO personnel:** Assess who within the PO is most appropriate to share this information with. For example, a PO Medical Officer or Executive may be more appropriate than others within the organisation due to their expertise which reduces the risk of misunderstanding the program and limitations on dissemination. Often, POs have HCPs on staff or as consultants; in such cases, it would be more appropriate to provide information about the program given their qualifications as an HCP.
- **Reactive or proactive communication:** Companies are not limited to reactive communication about Special Access programs. In some contexts, proactive communication may be appropriate for on-label use of registered medicines, however, caution should be exercised as proactive unsolicited information attracts the risk of being perceived as promotional. Proactive communications should be cautiously considered to ensure they are non-promotional in messaging, presentation, and context. Information on programs for unregistered medicines or off-label use of medicines should only be shared reactively.

3. ENGAGING PATIENT ORGANISATIONS REGARDING PBAC SUBMISSIONS

Question: How can pharmaceutical companies directly engage POs about submissions going to the Pharmaceutical Benefits Advisory Committee (PBAC)?

Elaboration:

In a submission for the Pharmaceutical Benefits Scheme (PBS) listing, the PBAC welcomes consultation input from patients, carers, members of the public, health professionals and POs, as stated on their website. While some POs are engaged by the PBAC/ Consumer Evidence and Engagement Unit (CEEU) directly within the submission process, others may not be. As such, companies have a role to provide information and communicate publicly and appropriately.

This role might extend beyond communicating the existence of a PBAC consultation. As key stakeholders in the healthcare ecosystem and in the PBAC process, POs are likely to need information about the submission and key information. This information can be provided via the Summary of Information template. Pharmaceutical companies are well positioned to meet these information needs, whether proactive or reactive as long as they are made in a non-promotional manner.

Risks (real, potential, or perceived):

- By making known the product and therapeutic indication(s), the communication could be deemed direct-to-consumer or off-label promotion.
- Providing key information on PBAC submissions, such as patient population, patient eligibility, adverse events, and product details is product-specific information usually reserved for healthcare professionals only, and thus perceived as direct-to-consumer or off-label promotion.
- Lobbying by a PO could appear to be orchestrated by the company rather than driven independently by the PO thereby eroding the submission's credibility and/or independence of the PO.
- Any active encouragement by companies to POs to provide input to the PBAC or TGA that supports their medicine is likely to raise questions over whether the pharma company has promoted their medicine directly to consumers. In addition, communication activities that look-and-feel like a campaign will expose the company to that risk. As will situations where pharma actively mobilizes a group of people to provide input into the filing of a medicine before the PBAC.

Practical considerations that may mitigate these risks:

- **Engage with organisations:** Engage with POs rather than patients directly. Engaging professionally at an organisation-to-organisation level affords a better framework for clear, informative communication which can be more easily documented. In some instances it may be appropriate to engage directly with patients, for example, if there is no central patient organization that represents their specific disease.
- **Non-promotional intent and content:** The intent and content must be non-promotional, as defined by the Code (e.g. no product branding) and related to specific, factual information for the actual submission and the PBAC process, and not enticing, encouraging or promoting a PO to submit comments supporting a particular medicine. Evaluate the intent and content to avoid actual or perception of promotional boost or increasing awareness of the medicine.
- **Factually raise awareness of agenda and process:** Message around the PBAC agenda webpage and link it back to the PBAC webpage. Avoid language that seeks to encourage, entice, or promote stakeholders to submit input. Rather, raise awareness of the opportunity and avoid content that could be considered disease awareness material.
- **Appropriate audience:** Strive to communicate to stakeholders who have explicitly expressed an interest in receiving alerts about listings. Communicating with a broad audience who have not explicitly expressed an interest in this particular therapeutic area, medicine, or PBAC submission raises the risk the communication may be promotional in intent.
- **Appropriate channels:** Tailor messaging channels to reach the appropriate audience and avoid casting an overly broad reach (e.g. employing social media with targeting controls rather than a broad public announcement in a newspaper). Broad communications to the general public are less likely to be appropriate.
- **Product name & therapeutic area.** Product name by itself does not constitute promotion. In the context of sharing the PBAC opportunity for input, the use of product name alongside the therapeutic area may be useful to communicate to audiences although coupling those two areas runs a risk of it being interpreted as promotional. To mitigate this risk, consider using one or the other – a product name or a therapy area.

4. DISEASE AWARENESS WHERE ONLY ONE TREATMENT IS AVAILABLE

Question: When only one pharmaceutical treatment is available in a therapeutic area, what can be communicated to consumers without being perceived as promotional?

Elaboration:

Pharmaceutical companies play a legitimate and ethical role in providing the general public with information about medical conditions and treatments that may be prescribed by their doctors. Disease awareness activities are often designed to raise awareness of diseases to identify conditions to prompt discussion of symptoms with HCPs. They need to be comprehensive, balanced, fair and not unduly emphasise particular treatment options.

However, where a company has the only available treatment, no matter how comprehensive, balanced, and fair the approach may be, there remains a risk that any disease awareness where the company offers the only treatment, will be perceived as promotion direct to consumers. The material runs a heightened risk of potentially drawing attention to one medicinal product - albeit indirectly, regardless of whether it is referred to or not.

Consumer material in these circumstances requires **particular care** to mitigate the risk that it indirectly encourages the use of that product. It is difficult to 'not duly emphasise particular options' when only one option exists, however, drawing attention to any other standard of care to ensure balance, can assist in mitigating that risk. Disease awareness campaigns /material should aim to focus on the disease itself and its symptoms, refer to consultation with a physician, and take caution around details of any treatment options.

Risks (real, potential, or perceived):

- Disguised promotion
- Direct-to-consumer advertising

Practical considerations that may mitigate these risks:

- **Lead with the HCP need-for-knowledge:** Primarily invest in meeting the knowledge needs of healthcare professionals in the first instance. Information directed to patients should complement the knowledge shared with HCPs, rather than patient communication being the primary focus.
- **Engage POs:** If a PO exists for that disease state, they are likely the preferred candidate to deliver disease awareness, which may remove/reduce the need for a pharma-sponsored campaign. Consider prioritising or supporting independent PO activity that meets a similar patient need.
- **Avoid referring to treatment options altogether:** Focus on the disease and its symptoms, refer/encourage consultation with a physician, and avoid mentioning treatment options altogether. Referring to the doctor is the most appropriate step and it is through the doctor that information about treatments will be made if appropriate to the patient's needs. However, if you decide to refer to treatments, general high-level terminology should be used (e.g. avoid using the class of medicine but instead use broad terms such as "treatments are available" or "treatments are available and covered under PBS") while avoiding generating patient-level prescribing or inferring any perceived real benefit.
- **Evaluate the need:** To decide whether or not to include information about a treatment option, evaluate the need. This need should be 100% based on the patient and not a company need. For example, ensure the activity intends to raise awareness to patients who otherwise would not have a reasonable source of information about the disease due to its rarity or lack of medical knowledge in GPs/Specialists, and/or limited information available online.
- **Document & research:** To demonstrate the rationale for the material and the genuine unmet patient needs that it addresses, undertake research and document your ethical decision-making.

The TGA has Guidance on disease awareness activities:

“While a disease education activity may make reference to a range of treatment options, if the information provided is likely to encourage consumers to seek to obtain a particular good, or seek a prescription for a particular medicine, then it will be considered an advertisement.

Special care is required for disease education activities where there are limited treatment options, as the information may draw attention to one specific therapeutic good, whether that good is named or not.”

5. SHARING CLINICAL TRIAL INFORMATION WITH PATIENT ORGANISATIONS.

Question: How can we provide POs with information on our clinical trials for the purposes of recruitment?

Elaboration:

There is a need to involve the patient voice earlier in the product life cycle. The role of POs may provide an expert and unified patient voice to contribute and help shape aspects of the healthcare ecosystem, including clinical trial design and protocol. Similarly, POs expect to have access to information about treatment options, both current and upcoming, and ways to access them other than via the PBS, including clinical trials.

It is appropriate to share information about clinical trials with relevant stakeholders such as POs and make this information available to the general public. The Code affirms that pharma companies can play a legitimate and ethical role in providing the general public with information on treatments that may be prescribed by their doctors, and this extends to the availability of clinical trial information.

However, any such information cannot be promotional; it cannot encourage the use of a particular prescription product, it cannot advertise prescription medicines to consumers, and it cannot promote off-label or unapproved prescription medicines; whether unintentionally or indirectly.

Social media can be an effective method of reaching relevant communities in a targeted way, to accelerate awareness of clinical trials for the purpose of trial recruitment.

The intent for understanding a level of information around clinical trials is generally different for POs compared to individual patients, and the rationale of the engagement is key in assessing what level of information is appropriate to communicate.

Risks (real, potential, or perceived):

- Disguised promotion
- Direct-to-consumer advertising
- Off-label promotion
- Raise unfounded hopes of treatment or cure when medicines are in development and trial phases.
- Interference with the doctor-patient relationship because traditionally the clinician shares this information with a patient if that patient is eligible.

Practical considerations that may mitigate these risks::

- **Non-promotional intent:** All information provided must be factual and informative, with no real or perceived promotional intent.
- **Clear intentions:** The intent should be made clear and should determine what content is provided. For example, if the intention is to recruit for clinical trials, provide information that addresses that intent and is shaped according to the needs of the respective audience. It should not raise unfounded hopes of successful treatment and should not be combined with a general awareness activity designed to highlight the company's commitment to the research and development.
- **Publicly available information:** Stick to publicly available clinical trial information.
- **Appropriate company personnel:** Communications should be made by the appropriate company personnel, i.e. not commercial.
- **Appropriate PO personnel:** Engagement must be suitable and appropriate to the level of expertise of the audience. For activities such as input into protocol and design, a PO member with suitable expertise and sound rationale should be selected. It could be a person nominated by a PO rather than employed by a PO.
- **Independent websites:** Such as clinicaltrials.gov and australianclinicaltrials.gov.au should be used rather than company sites to reduce the risk of bias and provide equity of trial information shared.
- **Refer to treating clinician:** To avoid the perception or potential of undermining the doctor-patient relationship, information should be limited to confirmation of any active trials for the specific condition in a given location. It is not appropriate to share details of recruitment criteria or any additional information, and should refer an enquirer to their treating HCP for any additional information and discussion.
- **Limit information:** It is appropriate to share information about a general condition or therapeutic area, but should not identify or link to any products, or molecules. Consider search parameters, layout and format for usability. Appropriate initial search measures could be trial name, phase, location and status. Consider inclusion scope for trials that are no longer active and whether it is appropriate to include these in the results.
- **No trial results:** It is not appropriate for a pharma company to host, supply or direct consumers to other external websites to specifically read the results of clinical trials. However, participants in a trial are essentially part of the research and the team, and in those circumstances it will be reasonable for participants to understand trial results that are relevant to their role in the research.

DEVELOPMENT OF THIS GUIDANCE

This Guidance was developed by the Medicines Australia Code Compliance Network (a collective of members who fulfill the Ethics and Compliance function) and members in patient advocacy roles who work closely with POs.

Advice provided by colleagues in our global pharma community, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and The Association of the British Pharmaceutical Industry (ABPI) have been considered in this Guidance's development. Some of these can also be used as resources:

1. The [IFPMA Note for Guidance on Patient and Patient Organization Interactions](#)
2. The [EFPIA Principles for Working Together with Patients](#)
3. The [ABPI Sourcebook on Working with Patients and Patient Organisations](#)