What does the Code mean for the Patient Community?



Pharmaceutical engagement with patients should be ethical, transparent, and non-promotional.

Why the Code Matters

The Code sets clear standards for how pharmaceutical companies work with healthcare professionals, the patient community, and other relevant stakeholders.

If you're planning on working with pharmaceutical companies, knowing the Code helps you understand what companies can and can't do. It explains why a company might say no, and when it can say yes - helping to make sure partnerships are ethical, transparent, and productive.

Why is it important?

The Code recognises the important role of patients, carers, patient organisations, and the public. It sets principles to guide ethical engagement between pharmaceutical companies and these groups.

A key distinction is *promotion*:

- a) **Healthcare professionals** companies can promote registered prescription medicines to them.
- b) **Non-healthcare professionals** (including patients and patient organisations) companies cannot promote prescription medicines to them.

Relevant Code sections for the patient community include:

Section 10: Communication with

Stakeholders

Section 11: Engagement with Patient

Organisations

<u>Section 12</u>: Interactions with the Public <u>Section 13</u>: Patient Support Programs

The Code does not decide who can or cannot be promoted to. This is set out by the law:

Who can be promoted to:

Under the *Therapeutic Goods Act 1989*, promotion of prescription medicines is allowed for:

- Healthcare Professionals (including doctors, nurses, pharmacists, and others)
- People and organisations engaged in the purchasing of medicines (such as hospitals, practice managers)
- Some alternative medicine providers (such as chiropractors, naturopaths and practitioners of traditional Chinese medicine)

Who cannot be promoted to:

Direct promotion of prescription medicines is strictly prohibited for:

- X The general public
- Patients
- Patient organisations
- Any other individual or organisation not listed by the Therapeutic Goods Act.

What counts as promotion?

Promotion usually means any statement - spoken, written, or visual - that highlights the positive qualities of a medicine. Context matters - in some cases, even mentioning a specific medicine can be seen as promotion. This is how regulators apply the Therapeutic Goods Act definition of 'promotion', and how it is understood across the industry.

Examples of promotion include:

- Messages about how effective or safe a medicine is.
- Comparisons with other medicines.
- Messages about how easy a medicine might be to use.

If a researcher, scientist, doctor, journalist, or politician shares this kind of message, it may not be promotional. But if a company shares it - and it stands to gain financially from the medicine - it is likely to be considered promotion. This isn't a ban on all information. It just means pharmaceutical companies can't share or announce things in the same way others can, because they benefit financially from the medicine.

Engaging Appropriately with the Patient Community

Companies can work with patient organisations to help improve health outcomes for consumers. The Code sets out how companies may interact with the patient community about their medicines. However, these interactions must follow the law (*Therapeutic Goods Act 1989*) and cannot promote prescription medicines. This means:

- Information and activities must meet genuine needs, and not act as promotion. For example, a genuine need may be factually informing a relevant patient organisation that a medicine is now listed on the *Pharmaceutical Benefits Scheme* (PBS).
- Companies must carefully decide when and how to share information. For example, if a company talks about their medicine without being asked, it's more likely to be seen as promotional than if they are simply answering a question about it.
- Even factual or already-available online content can be seen as promotional if a company uses it to highlight the benefits of a medicine it sells. For example, if a company shares clinical trial results showing how effective their medicine is, this would likely be considered promotional.

When CAN companies engage with the patient community?

In many ways! There isn't a single set of opportunities, but some common examples include:

- Sponsoring educational events (see Fact Sheet 3)
- Grants and donations for initiatives (see Fact Sheet 3)
- Co-creation of patient support materials
- Research initiatives, such as clinical trial development and post-market review
- · Patient advisory boards
- · Quote for a media release
- Comments for Pharmaceutical Benefits Advisory Committee (PBAC) submissions
- · Speaking at company events
- Seeking input on company materials
- Information exchange about *Health Technology Assessment* (HTA) submissions e.g. medicine access.

The pharmaceutical industry values listening to patients at every stage of a medicine's journey. There are many more opportunities beyond this list - it is an evolving journey as the role of patients continues to grow.

For more information and examples of what interactions are and aren't allowed between pharmaceutical companies and the patient community, view **Fact Sheet 5**.

Working together

There is no single "right" way for companies to work with the patient community - they do so in many different ways. What matters is that pharmaceutical companies ensure their interactions with patients and the community are non-promotional. This means companies are likely to:

- **Respond, rather than initiate** an interaction is more likely to be considered promotional if it is unprompted, rather than responding to a specific request.
- **Be cautious with details** companies may direct people to independent sources instead of providing medicine-specific information.
- Have specialised roles staff who engage with patients are separate from sales or marketing teams.
- **Respect independence** companies will ensure they are not over-involved, to avoid any inappropriate influence.
- **Ensure transparency** all financial support and partnerships with patient organisations must be openly documented and reported, as required by the Code.
- Refer to a doctor Company staff cannot give medical advice, diagnose conditions or recommend treatments and will always refer a patient to their doctor. Decisions about individual treatments are made only by the doctor (or other healthcare professional), in consultation with the patient.

Why companies may differ in their approach

The Code sets high standards through clear principles, but it doesn't give step-by-step rules. This means companies make their own decisions within those boundaries. For example, one company might set up a patient advisory board, while another might decide not to.

Other things also shape these choices, like company policies, global rules, budgets, and resources. Just like patient groups, companies differ in size and complexity. Some have staff dedicated to building relationships with patient communities, while others don't have the same capacity.

Even with these differences, the principle stays the same: strong, positive relationships between industry and patient organisations help improve health outcomes for the Australian community.