


# Factsheet 2: The Pharmaceutical Industry's Code of Conduct: What Companies Can and Can't Do

Working  
Together

## What is the Code?

Medicines Australia's Code of Conduct  sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. It complements the legislation requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act, which also apply to pharmaceutical companies.

## Who does it apply to?

The Code of Conduct is the standard by which the pharmaceutical industries self-regulates its behaviour. It is not voluntary. All Medicines Australia members adhere to the Code as a requirement of their membership. The Therapeutic Goods Administration (TGA) also makes adherence to the Code, in terms of how the company promotes the product, as part of its conditions of registering a prescription product on the Australian Register of Therapeutic Goods (ARTG).

The Code is written specifically for innovative Australian pharmaceutical companies which market prescription medicines. It does not apply to healthcare professionals, or patent organisations, media or the like.

## Why does content and information differ depending on who you are?

Core to Australia's regulations, prescription medicines may not be promoted direct-to-consumers, but they can be promoted to health care professionals, in line with the ethical principles of the Code. The Therapeutic

Goods Act, by setting out the definition of healthcare professional in Section 42AA of the Act, defines the audience who can receive promotional information about prescription products. Companies may not share any promotional information with people who are not captured under that definition, or they risk being non-compliant with the Code and the Therapeutic Goods Act.

**Healthcare professional** means a healthcare professional registered to practice in Australia who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia.

## What are the risks to pharmaceutical companies?

Whilst this may sound clear, the definition and interpretation of 'promotion' is expansive. It is understood to mean all and any 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. Therefore, there are real risks for pharmaceutical companies in their engagements and interactions with patients, patient advocates or representatives, or patient-focused organisations; the risk that they are favourably influencing consumers about their prescription medicine. That risk might be real, potential or perceived.

Should that risk be realised, and a complaint made against the company which results in a decision that the company breached the Code, there are substantial fines and sanctions which can be imposed, and the rational and outcome are made public, negatively affecting their credibility.

## But what does the Code actually say?

As custodians of our medicines, the Code acknowledges that we have a responsibility to appropriately communicate relevant information to those relying on our medicines, including patients, their carers and families, healthcare professionals and the broader community. Section 11 sets out some general parameters for this communication to take place.

### 11. Appropriate Communications with Relevant Stakeholders

Communication with stakeholders who have a role in the research, development, registration, listing or monitoring of a therapeutic good is inherent in the National Medicines Policy and in the concept of the quality use of medicines. Companies are permitted to communicate proactively or reactively with relevant stakeholders, provided that discourse is limited to information that may assist the stakeholder in their role.

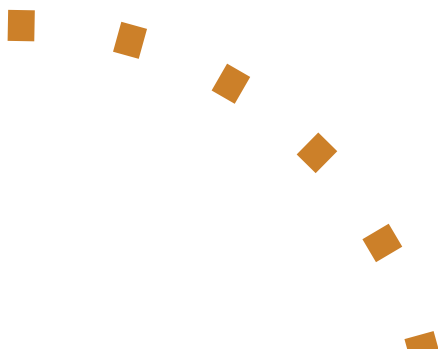
- This communication is to be non-promotional in nature and is not to be made with the intention to inform patient-level prescribing, or any other clinical decision making relevant to individual patients.
- This communication should only be conducted by appropriately qualified and selected company personnel.
- It is appropriate for Companies to solicit information to assist in understanding relevant aspects of the healthcare environment relating their products.

In addition, the Code in Section 12 (“Support for Health Consumer Organisations”) recognises and supports positive and beneficial relationships between industry and health consumer organisations.

### 12. Support for Health Consumer Organisations

- Medicines Australia recognises and supports positive and beneficial relationships between industry and health consumer organisations. Companies may enter into relationships with health consumer organisations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.
- When entering into relationships with health consumer organisations, Companies should refer to Working Together—A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, developed through collaboration between Medicines Australia, the Consumers Health Forum of Australia and other health consumer organisations. The manual is available on the Medicines Australia website [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)
- Companies should consider on a case by case basis whether any offer or proposal to sponsor or fund a health consumer organisation or any of its programs is capable of withstanding professional and public scrutiny.
- The selection criteria for sponsorship to enable patients and representatives from a health consumer organisation to attend third party scientific and medical conferences should be based on their specific interest in a therapeutic area.

Also of relevance is Part A (Overarching Principles) which govern and apply to all activities. Specifically they ensure that companies are committed to transparency in their interactions with health consumer organisations, a cornerstone for building trust and confidence in the industry. This is demonstrated through public reporting of financial or significant in-kind resourcing given to health consumer organisations, published on Medicines Australia’s website. On top of this, all activities undertaken by companies need to be clearly identified to their audience as a company activity by the inclusion of the Company’s name and city/town of the Company’s Australian office.




Further relevant overarching principles include:

- **O/A Principle 3:** Company communications need to be current, accurate, balanced, and scientifically valid.
- **O/A Principle 5:** Consistent with their ethical undertakings, nothing is offered or provided by a company in a manner or with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product.
- **O/A Principle 6:** Companies' interactions with all stakeholders will at all times be professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.

## So, is the Code really a barrier to earlier and more frequent engagement?

Whilst the Code sets out guiding and specific principles, every company is responsible for making its own decisions as to how often and how early to engage patient reps or patient organisations. Each has their own risk appetite, and will have had different past experiences to shape their approach.

Because of this, it is unlikely that industry will ever take a uniform approach to engaging with patient organisations. However over time, a more consistent approach may be possible as companies work through the risks, especially as the Code now affirms explicitly that it supports appropriate communication with relevant stakeholders.

The fact that Medicines Australia members collectively spend more than \$7 million annually on supporting health consumer organisations is a testament to their commitment to enhancing the quality use of medicines and supporting better health outcomes for the Australian community. This support is transparently published on the Medicines Australia website here. 


<https://www.medicinesaustralia.com.au/code/code-education/continuing-education-program-cep/> 

Disease awareness initiatives are recognised as fairly low-risk for pharma, whilst talking about prescription products and using a product name are likely to require a higher degree of scrutiny and care, to ensure there is minimal chance it could be perceived to be a promotional activity, or for a covert promotional purpose.

Companies are usually more comfortable in reactively responding to requests, rather than proactively initiating opportunities, because it offsets risks as mentioned previously.

## Where can I find more about the Code?

**Code Resource Toolkit:**  Medicines Australia has a free online Code Resource Toolkit which includes recorded webinars, templates, ethical decision-making trees and Guidance to suit most situations.

**Continuing Education Program:**  Has a 20-hour online interactive course on the Medicines Australia Code of Conduct – ethical practices within the pharmaceutical industry, including the obligations and practices of companies in their relationship with the health care industry and the public

**Code Information Sessions:**  Free online and open to all, Medicines Australia hosts a series of these throughout each year.

## Find out more

The Working Together Guide is a guide to relationships between health consumer organisations & pharmaceutical companies.

-  Working Together Guide
-  Factsheet #1: Australian and Global Health Context for Collaboration Between Pharmaceutical Industry and Healthcare Consumer Organisations
-  Factsheet #3: Remuneration Framework of Healthcare Consumers
-  Factsheet #4: Principles in Action Across the Different Partnership Stages
-  Factsheet #5: Interacting with Patient Communities: Areas for Pharmaceutical Companies to Consider
-  MA Code of Conduct