



09. Transparency: The Need For Strong Ethical Principles



**Medicines
Australia**

Better health
through research
and innovation

The Medicines Australia Code Of Conduct

Medicines Australia represents the research based pharmaceutical industry in Australia. Our members invent, discover, develop, manufacture and supply innovative medicines, vaccines and biotherapeutics that prevent, treat and cure diseases and other conditions. Members undertake this work guided by strong ethical principles and as transparently as possible, to build trust with stakeholders regarding all their activities.

To provide guidance on these activities, Medicines Australia established the Code of Conduct in 1960 and has continued to revise and develop it ever since. The current Code is Edition 18, with Edition 19 under consideration for introduction in 2020. The Code of Conduct can be found on the Medicines Australia website here: <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>

The Medicines Australia Code Of Conduct

Advertising registered prescription medicines to consumers is not permitted under the Therapeutic Goods Act 1989. However, advertising to health professionals is permitted within the scope of the legislation. Unregistered therapeutic goods, not entered on the Australian Register of Therapeutic Goods (ARTG) may not be advertised in Australia to consumers or healthcare professionals.

The Code of Conduct is a self-regulatory scheme that sets the standards for the ethical conduct, marketing and promotion of prescription pharmaceutical products in Australia. It complements the legislative requirements of the Therapeutic Goods Act and the Therapeutic Goods Regulations 1990. It is a TGA imposed condition of registration of therapeutic goods that the promotion of all prescription products (whether by a member company of Medicines Australia or nonmember) complies with the requirements of the Medicines Australia Code of Conduct.¹

The Code of Conduct provisions include standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals. It forms part of a global industry effort to ensure ethical business practices, accountability and transparency of the medicines industry.

The current edition of the Code of Conduct was developed through broad consultation with peak bodies over more than two years and has been authorised by the Australian Competition and Consumer Commission (ACCC). The ACCC has authorised successive Medicines Australia Codes of Conduct since 2003.



Operation Of The Code Of Conduct

Medicines Australia member companies are subject to the Medicines Australia Code of Conduct. Where a breach of the Code of Conduct is suspected, a complaint can be lodged with the Code of Conduct Committee. The Code of Conduct Committee is an independent body chaired by a trade practices lawyer. Companies found to have breached the Code of Conduct can be fined up to \$300,000, depending on the circumstances and nature of the infringement.

Medicines Australia invites scrutiny of these activities. We encourage people to lodge a complaint with the independent Code

of Conduct Committee where they think company behaviour may be inconsistent with the Code.

As the TGA require compliance with the Medicines Australia Code of Conduct as a condition of registration of a prescription medicine, we strongly contend that this compliance should extend to the entirety of the Code. This includes being subject to transparency of conduct, adjudication of complaints and sanctions. Presently, non-members can decline to have complaints heard by the independent Code of Conduct Committee, which creates an uneven playing field.

Under the Code, which sets the standard for ethical business practices, conduct that could inappropriately influence healthcare professionals is prohibited:

- The provision of gifts and inducements, entertainment, and lavish hospitality to healthcare professionals are banned
- Promotional materials that inaccurately represent the data about a prescription product's quality, safety and efficacy are banned
- Activities that encourage patients to seek a prescription for a medicine are banned.

Areas covered by the Code of Conduct include:

- The nature and availability of information of concerning medicines
- Acceptable and unacceptable material – advertisements, brand name reminders, competitions, gifts and offers – used to discuss information concerning medicines
- The standard of conduct required of Member company representatives
- Member company involvement in medical educational symposia, congresses and satellite meetings
- Permissible company sponsorships
- Relationship with the general public
- Relationship with healthcare professionals
- Administration of the Code – complaints process, sanctions and appeals
- Monitoring of company activities
- Compliance Procedures
- Reporting and transparency requirements.

Transparency: Payments To Healthcare Professionals & Health Consumer Organisations.

Medicines Australia is a strong advocate for transparency. This includes transparency of payments and other transfers of value provided by the Australian medicines industry to healthcare professionals and health consumer organisations.

This disclosure should assist the general public to better understand the nature and extent of programs we support in the interest of improving quality use of medicines, advancing patient care and supporting our local communities.

Transparency: Health Care Professionals.

Healthcare professionals help to educate patients about medicines and their safe ongoing use. Exchanging knowledge and skills leads to better treatments and increases a healthcare professional's expertise, which means that patients can be even more confident they are getting the best of care. Payments and transfers of value to healthcare professionals which form part of this exchange must be reported by member companies.

These include:

- Fees paid to healthcare professionals for speaking at an educational meeting or event.
- Sponsorship of a healthcare professional to attend an educational event. Reportable sponsorships are any airfare, accommodation or registration fees for the event.

- Fees paid to healthcare professional consultants, or to their employers on their behalf, for their services. This includes, all consultancy services provided in relation to educational meetings, preparation of promotional materials or product position papers, assistance with training or any other advice to the company. It includes any accommodation and/or airfares associated with providing the consulting service. This does not include payments to consultants in relation to research and development work, including the conduct of clinical trials.
- Fees paid to healthcare professionals as Advisory Board members. This includes all sitting fees, accommodation and airfares associated with the activities of the Advisory Board.

- Fees paid to healthcare professionals for the purpose of market research where the identity of the healthcare professional is known to the company that contracted the market research. must still be disclosed for the individual healthcare professional.
- Member Companies are required to give notice to healthcare professionals when engaging with them that they should reasonably expect that all reportable payments or transfers of value will be disclosed for each healthcare professional, by name.

Where a healthcare professional requests a monetary payment for any of the above to be made to a third party, these payments

The reports of these interactions are currently published on the member companies' web sites and include the following details:

- Date of the event or provision of service
- The healthcare professional's full name
- The type of healthcare professional
- The healthcare professional's practice address
- The type of service (Advisory Board, educational event speaker etc)
- The type of event or activity
- To whom the payment or transfer of value was made
- The amount of the payment or transfer of value

Centralised Reporting System.

To increase the ease of access to these reports, Medicines Australia has developed a Central Reporting System (CRS). The CRS enables the public to access information on payments and transfers of value from all companies to healthcare professionals, from a single location via the internet, and

will be able to search information related to specific healthcare professionals if desired.

The CRS can be accessed here www.DisclosureAustralia.com.au and was launched on 30 August 2019.

Transparency: Health Consumer Organisations.

Health Consumer Organisations (HCOs) are not-for-profit organisations that represent the interests and views of patients and consumers of healthcare. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

Medicines Australia recognises and supports positive and beneficial relationships between industry and HCOs. Companies may enter relationships with HCOs with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Through collaboration between Medicines Australia, the Consumers Health Forum of Australia and other health consumer organisations, a set of guidelines Working Together – A Guide to relationships between Health Consumer Organisations and Pharmaceutical Companies <https://medicinesaustralia.com.au/community/working-together-guide/> has been developed. Companies must consider these principles when forming relationships with HCOs.

Each company must provide to Medicines Australia for publication on its website, a report listing the HCOs to which it provides financial support and/or significant direct/indirect non-financial support. The published report must include:

- the name of the HCO; and
- a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the nature of the support; and
- the monetary value of financial support and of invoiced costs. For significant nonfinancial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the HCO receives.

- 1 Therapeutic Goods Administration 'Advertising prescription medicines to health professionals', <https://www.tga.gov.au/advertising-prescription-medicines-health-professionals>, 2019.



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