



AMMDA

Australian Medical Manufacturers
& Distributors Association INC.

Code of Conduct

Background and Purpose of the Code

The Australian Medical Manufacturers and Distributors Association (The Association) has introduced a Code of Conduct to represent the interests of Australian device manufacturers and distributors. We believe that high quality, cost effective medical technologies and related services can make a significant contribution to the safety and wellbeing of patients and contribute to the ongoing improvement of the Australian health care system.

The Association recognises that compliance with Australian laws; regulations and adherence to ethical standards are an obligation and critical step to achieving the aforementioned goals and act to enhance the reputation of Australian Device Manufacturers and Distributors.

This Code of Business Conduct (hereinafter referred to as the "Code") is intended to provide guidance as to the minimum standards which should apply to its business practices in Australia. It is intended to work within Australian laws, regulations and professional codes of conduct.

General Principles

The Australian Medical Manufacturers and Distributors Association within this Code of Business Practice is required to comply at all times with provisions of relevant legislative requirements, which include, but are not limited to;

- The Therapeutic Goods Act 1989
- The Therapeutic Goods Regulations 1990
- The Therapeutic Goods (Medical Devices) Regulations 2002
- The Therapeutic Goods Advertising Code 2007
- Product Safety and consumer protection laws
- Environmental protection laws and regulations
- Competition policy and trade practices laws and regulations
- Corporation and securities laws and regulations

Specific Policies

Quality and Regulatory Compliance

The Australian Medical Manufacturers and Distributors Association are committed to the manufacture and supply of high quality medical devices and related services in the interest of patient safety and well-being. To this end they comply with Australian legal and regulatory requirements as they relate to the design, manufacture and promotion of medical devices and therapies.

Interactions with Health Care Professionals

Ethical standards and compliance with applicable laws are critical to the medical technology industry's ability to continue its successful collaboration with healthcare professionals. Healthcare professionals are defined as clinical or non-clinical, including but not limited to, physicians, nurses, technicians and research co-ordinators and entities such as hospitals or group purchasing bodies that are directly or indirectly involved in purchasing, leasing, recommending the use of, or prescribing medical devices.

Collaboration may take the form of;

- Developing medical technologies
- Provide training, education, service and support to enable the safe and effective use of various medical technologies; and
- Supporting medical research, education, and enhancement of professional skills.

These activities are necessary to advance medical science and improve patient care and outcomes.

The following guidelines are based on the key principles of

- Separation: Interaction between member companies and Health care professionals must not be misused to influence through undue or improper advantages or purchasing decisions, nor should interaction be contingent upon sales transactions or use or recommendation of products and services.
- Transparency: Interaction must be transparent and comply with Australian federal and state laws.
- Equivalence: Where Health Care Professionals are engaged by member companies to perform a service for or on behalf of that company, the remuneration paid must be commensurate with, and represent fair market value for the services performed by the Healthcare Professional.
- Documentation: For interactions between member companies and a Health Care Professional, for or on behalf of that company, there must be a written agreement setting out the purpose of the interaction, the services to be provided, the method

of reimbursement of expenses as well as the remuneration to be paid by the company.

The Australian Medical Manufacturers and Distributors Association requires that third party intermediaries, both sales intermediaries and other third party agents, including but not limited to consultants, distributors, sales agents, marketing agents, brokers, commission agents and independent sales representatives, who interact with Health Care Professionals in connection with the sale, promotion or any other activity involving member company products, comply with standards equivalent to these guidelines.

Company Sponsored Product Training and Education

Companies have the responsibility of making product education and training available to Health Care Professionals to facilitate the safe and effective use of medical technology. Such education and training programmes should occur at appropriate locations taking into account the convenience of the attendees and the nature of the training:

Programmes and events should be conducted in clinical, laboratory, educational, conference, or other appropriate settings, including member company premises or commercially available meeting facilities, which are conducive to effective transmission of knowledge and any required "hands-on" training. The training staff should have the appropriate expertise to conduct such training.

A company may provide attendees with reasonably priced meals in connection with the programme, and for educational programmes necessitating overnight stays, additional hospitality may be appropriate. Any hospitality should be reasonable in value, subordinate in time and focus to the educational purpose of the training.

Supporting Third Party Educational Conferences

Bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective healthcare. To these ends, member companies may support such events provided the educational conference content promotes scientific knowledge, medical advancement and the delivery of effective healthcare and is consistent with relevant guidelines established by professional societies or organisations for such meetings e.g. Australian Medical Council, Australian Orthopaedic Association.

- Companies may support such events by the provision of financial, scientific, technical, organisational and/ or logistical assistance as follows;
- Health Care Professional Sponsorship and Educational Grants. In line with Australian laws, regulations and professional codes of conduct, companies may provide financial support to cover the cost of conference attendance by individual Health Care Professionals. Financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs for faculty members.
- Advertisements and Demonstrations through purchase of advertisements, lease of booth space for displays at scientific meetings.
- Conference Support. Companies may provide financial grants directly to the conference organiser to reduce the overall cost of attendance for participants and to cover reasonable honoraria, travel, meals and accommodation expenses of Health Care Professionals who are bona fide conference faculty members.
- Satellite Symposia. Companies may sponsor satellite symposia at third-party conferences and provide presentations on subjects consistent with the overall content of the third-party conference provided that all information presented is fair, balanced and scientifically rigorous. Companies may determine the content of these events and be responsible for faculty selection.
- Scholarships. Companies may provide educational grants to training institutions, health care institutions or professional societies for medical education programmes by providing financial support for fellowships and similar scholarship awards.

Sales and Promotional Meetings

It may be appropriate for companies to meet with Health Care Professionals to discuss product features, conduct contract negotiations, or discuss sales terms. These meetings should as a general rule, occur close to or at the Health Care Professional's place of business. In connection with such meetings, companies may pay for reasonably priced meals for Health Care Professional attendees in an environment that is conducive to the exchange of information. Where plant tours or demonstrations of non-portable equipment are necessary, companies may also pay for reasonable travel and accommodation costs of Health Care Professional attendees.

Arrangements with Consultants

Health Care Professionals may serve as consultants to a company, in the provision of meaningful bona fide services, including research, participation on advisory boards, presentation at that company sponsored training or third-party educational conferences, and product development. It is appropriate to pay Health Care Professionals reasonable compensation for performing these services. The following factors support the existence of a bona fide consulting arrangement:

- Consulting agreements must be entered into only where a legitimate purpose for the services is identified in advance.

- Selection of consultants should be on the basis of their qualifications and expertise to address the identified purpose.
- Consulting arrangements must be described in a written agreement, signed by all parties and must specify the services to be provided.
- Compensation paid to Health Care Professionals engaged as consultants must be fair market value for the services provided and must not be tied in any way to the value of medical devices which the consultant may use for their own practice. All payments made must comply with applicable tax and other legal requirements.
- Companies must comply with Australian laws with regard to the disclosure or approval requirements associated with engaging Health Care Professionals as consultants.

All consultancy arrangements with Health Care Professionals must be documented in writing.

- The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. The meetings should be conducted in clinical, educational, conference or other suitable settings, conducive to the effective exchange of information.
- Hospitality that occurs in conjunction with a consultant meeting should be subordinate in time and focus for the primary purpose of the meeting.
- When a company contracts with a Health Care Professional acting as a consultant for research service, the written agreement should reference a written research proposal or schedule of work as appropriate and all required consents and approvals should be obtained.
- Where a company contracts with a Health Care Professional for the development of intellectual property, there must be a written agreement providing compensation at a fair market value.

Gifts

Companies may provide branded items as gifts to Health Care Professionals, if they are modest in value and in accordance with Australian law, regulations and professional codes of conduct. Gifts must not be given in the form of cash or cash equivalent.

Donations for Charitable and Philanthropic Purposes

Companies may make donations for charitable or other philanthropic purposes. Donations may be made only to registered charitable organisations or other non-profit entities.

All donations to a charitable organisation should be appropriately documented. The company should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.

Educational Grants

A company may provide funds to support genuine independent medical research, advancement of medical science or education, or patient and public education. Support of these programmes and initiatives by that company should not be viewed as a price concession, reward to favoured customers or inducements to recommend, prescribe or purchase company products. Appropriate documentation of all educational grants should be made.

Examples of appropriate educational programmes and related considerations are as follows:

- Scholarships. Professional organisations, hospitals and universities where Health Care Professionals are in training may be eligible to receive grants to support scholarships. Advancement of Healthcare Education. Companies may support Health Care Professional education by donating funds to institutions or organisations for either accredited or non-accredited healthcare education.

- Research. Research grants to support customer-initiated studies may be permitted for programmes involving clinical or non-clinical research in areas of legitimate interest to a company. That company may provide funds for documented expenses, in-kind services, support clearly defined *bona fide* research activities of Health Care Professionals where permitted by Australian laws, regulations and professional codes of conduct. All requests for research grants must be in writing from the requestor stating the nature and objective of the research activity. No support should be provided until a written agreement is signed by both parties and said agreement should provide for adverse event reporting where appropriate.
- Public Education. Companies may make grants for the purpose of supporting education of patients or the public about important healthcare topics.

Advertising and Promotion

This code fully adopts the Therapeutic Goods Advertising Code (TGAC) as it relates to comparative advertising, promotion and direct to consumer, promotion to healthcare practitioners via media and publications as outlined in the TGAC 2007.

Data Privacy

A company should ensure that patient data and other types of confidential or personal data is maintained and used in accordance with Australian privacy laws and regulations.

Compliance and enforcement

The Code will be incorporated into the member companies Quality and Assurance system to the standard of ISO 9001.

Operative Commencement

The operative commencement of this code of practice will be 1st January 2016.