



Medical Technology  
Association of Australia



*Medical Technology Industry Code of Practice*  
(Administered by the Medical Technology Association of Australia)  
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### 1 PREAMBLE

Medical Technologies occupy a special place in the healthcare system. They often require Companies to provide 'hands-on' education, supervision and technical support to Health Care Professionals. Company representatives are very often present in theatre to train and advise physicians in the proper use of new tools, products and techniques.

The industry's range and scope is vast. Medical Technologies sometimes serve as extensions of a surgeon's hands. Others are inserted into the human body to replace or strengthen a body part. In still other circumstances, they can be non-invasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other treatments, or are paired with other products that deploy devices in the safest and most effective manner. Many require technical support before, during and after deployment.

The development and evolution of innovative Medical Technologies is a collaborative process between Companies and Health Care Professionals. It very often occurs outside the laboratory. Companies' support of *bona fide* research, education and enhancement of professional skills improves patient safety and increases affordable access to the latest Medical Technologies.

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This is an important distinction from pharmaceuticals, which are administered by physicians without the direct supervision of a representative from the company that created them.

This is based on the principle of evidence-based medicine where clinicians, consumers and evidence are used to make decisions.

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All the above speaks to the unique relationship between Companies and Health Care Professionals, one based on trust, integrity and the primacy of patient well-being. This is given expression through the MTI Code of Practice.

## 2 STATEMENT OF PRINCIPLES

2.1 The Australian therapeutic products industry promotes the principle of good health through the proper use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties in:

a. selecting diagnostic and treatment options and products based on the best available evidence, clinical judgement and the consumer's needs;

and

b. using therapeutic products safely and effectively.

2.2 MTAA members are committed to the improvement of patients' lives through the advancement of medical science and, in particular, the contributions that high quality, effective and innovative Medical Technologies make in achieving these goals. This commitment is given expression through the Medical Technology Industry Code of Practice.

## EXPLANATORY NOTES

The Code sets out self-regulatory standards that MTAA members must follow, and all industry participants are urged to observe. The Code is compulsory for members of MTAA but as a voluntary industry code extends to all companies in the medical technology industry.

The Code is part of a wider regulatory framework for ensuring appropriate behaviour by industry. Several industry codes apply to different therapeutic sectors. It is the intention that the MTI Code to apply to the supply of medical technology products. Where there is another therapeutic industry code that is more relevant in the circumstances, then that code will generally be the more appropriate code. It is complemented and supplemented by a range of training and related programs to assist awareness of the ethical responsibilities of industry.

Many companies in the medical technology industry have their own internal guidelines. To the extent that a company's guidelines might require a higher standard of behaviour in a

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particular area also covered by this Code, the company should have regard to its own guidelines.

MTAA assumes responsibility for maintaining and enforcing the agreed standards of behaviour set out in the Code. Additional guidance can be found through the Frequently Asked Questions pages on the MTAA website which can be accessed at [www.mtaa.org.au](http://www.mtaa.org.au).

### **3 BACKGROUND AND PURPOSE OF THE CODE**

- 3.1 The medical technologies sector is a major component of the therapeutics products industry. It includes companies that develop, produce, manufacture, and market medical products, technologies and related services, and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.
- 3.2 The Medical Technology Industry Code was introduced in 2001 to formalise ethical business practices for member companies and promote socially responsible conduct by all companies in this industry sector. It aims to promote high standards of integrity across the medical technology industry so that patients and Healthcare Professionals can have confidence in their dealings with the industry and its products. The Code provides a framework and mechanisms for setting standards of behaviour, educating Companies in the agreed standards, monitoring Industry activities, and providing self-regulation and disciplinary functions.
- 3.3 The Code is regularly reviewed and updated to keep pace with changes in technology, business practice and community expectations.

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### 4 OBJECTIVES AND SCOPE OF THE CODE

- 4.1 The primary objective of the Code is to build and maintain the trust and confidence of, and accountability to, all communities with which Members engage. The effectiveness of these efforts is assessed through the eyes of the relevant community.
- 4.2 The MTI Code of Practice is a self-regulatory code applying to Medical Technology Companies. Companies are obliged, as a condition of membership in MTAA, to accept and observe all provisions of the Code.
- 4.3 A Company that is not a member of MTAA but which is engaged in the Industry is encouraged to accept and observe the Code as an industry self-regulatory code.
- 4.4 The Code is not intended:
- a. to provide, nor shall it be construed as, legal advice; or
  - b. to take precedence over any relevant law or regulation. To the extent that any provision of the Code conflicts with a law or regulation, that law or regulation will take precedence.
- 4.5 A Company should always have regard to its own company code which may provide a higher standard.

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For example, the effectiveness of risk management initiatives will be assessed by consumers or consumer health advocacy organisations, health care professionals or their professional colleges, government health agencies, or hospital administrators.

In summary, the Code aims to help Companies:

- adhere to the ethical promotion of therapeutic products;
- provide products that conform to relevant regulatory standards of safety, quality and performance;
- maintain trust and confidence in the industry through transparency and accountability;
- respect ethical requirements and codes of practice which apply to Healthcare Professionals;
- uphold not just the letter but also the spirit of the Code;
- have in place a comprehensive process to monitor behaviour and deal with complaints; and
- remedy behaviour if found to be in breach of the Code.

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### 5 EXPLANATORY NOTES

Explanatory Notes are provided to assist with understanding and implementing the Code at an operational level. They do not form part of the Code itself and are not subject to the enforcement provisions of the Code.

### 6 GLOSSARY

#### 6.1 In the Code:

**Advertising** in relation to a Medical Technology, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the Medical Technology.

**Advertising Code** means the Therapeutic Goods Advertising Code 2007 in Australia as amended or replaced from time to time.

**Association** means MTAA.

**Authorised Representative** means the person nominated by a voting member of MTAA under its constitution to represent and vote on behalf of the voting member.

**Board** means the board of directors of MTAA.

**Brand Name Reminder Advertisement** means an Advertisement for a Medical Technology that:

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Where a word is used with a capital letter at the beginning, it has the meaning given to it in the definitions clause.

The members of MTAA can be found at [www.mtaa.org.au](http://www.mtaa.org.au).

This definition also applies to the terms 'Advertise', 'Advertiser' and 'Advertisement'. For clarity and consistency, the definition aligns with the Therapeutic Goods Advertising Code 2007.

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- a. contains at most a brand name or branding device, and purchasing details or information; and
- b. does not contain a claim or Promotional statement in relation to the Medical Technology.

**Breach** means a breach of any provision of the Code.

**Code** means the Medical Technology Industry Code of Practice as amended from time to time, administered by the MTAA.

**Code Authority (CA)** means the entity established to administer the Code

**Company** means any member of MTAA or any of the following, even if they are not members of MTAA:

- a) Sponsors of any Medical Technology that is the subject of a licence, whereby a condition of the licence is the Sponsor's compliance with the Code;
- b) Any entity within the Industry which agrees to abide by the Code, however that agreement is expressed; and
- c) Any other relevant entity from the Industry who submits to the Complaints process and outcomes in accordance with the provisions of the Code.

**Company Commissioned Article (CCA)** means an article or series of articles which is paid for by a Company and which is represented as the independent opinion of a third party or has the appearance of

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editorial material.

**Company Representative** means any person or entity engaged in representing, acting for or advancing the interests of a Company pursuant to any agreement, arrangement or understanding between that person or entity and the Company, including a contract of employment or other employment arrangement, or any agency or consultancy arrangement.

**Competition** means any promotional activity as a result of which a person may win a prize or receive a reward, and includes a game that involves skill, chance or both.

**Complainant** means a person who lodges a Complaint with MTAA under the Code.

**Complaint** means a complaint lodged with MTAA under the Code.

**Complaints Secretary** means the person from the MTAA secretariat responsible for administration of a Complaint under the Code.

**Conference Organiser** means the organiser of a Third Party Educational Conference.

**Consultant** means a Healthcare Professional who is engaged by a Company under a Consulting Arrangement.

**Consulting Arrangement** means any relationship in which services

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This may include external arrangements which require a person or entity to abide by the Code, such as a condition of participating in a tender.

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are provided to a Company by a Healthcare Professional in exchange for remuneration.

**Consumer** means a person who may undergo a medical procedure or treatment in which a Medical Technology may be used or who may acquire a Medical Technology for use in relation to their own health, but does not include a Healthcare Professional.

**Consumer Representative** is a representative from a Health Consumer Organisation or industry patient support group.

**Educational Material** means any material or literature that provides information about a medical condition or Medical Technology and which does not contain specific Promotional claims.

**Entertainment** includes sporting events, musical and other entertainment.

**Faculty Member** means a Healthcare Professional who is a genuine speaker at a Third Party Educational Conference including as a participant in a panel of speakers.

**Health Consumer Organisation** means any organisation that represents the health interests of Consumers.

**Healthcare Professional** includes any individuals or entities involved in the provision of health care services and/or items to patients; which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Medical Technologies in Australia. This definition includes a person under the direction and control of a Healthcare

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Professional.

**Hospitality** means the provision of food and beverages.

**Industry** means that sector of the healthcare and medical industry that is engaged in the manufacture, import, distribution, and the maintenance, servicing or repair, of Medical Technology.

**Industry Complainant** means a Complainant acting in the capacity of participant in the Industry.

**Institution** means an institution, corporation, government body, agency or committee and any other organisation involved in the purchase or other acquisition, supply or distribution, assessment, funding or recommendation of Medical Technologies (other than the Company's contracted distributors), the administration or regulation of Medical Technology or the provision of information and education in relation to Medical Technology.

**Laws and Regulations** means any law or regulation in force in Australia to which any act or omission the subject of the Code applies, including the Therapeutic Goods Act.

**Market Research** means the gathering of data on the scope or dimensions of a market and its components including the needs of customers in that market.

**Medical Device** has the meaning given to it in section 41BD of the Therapeutic Goods Act.

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**Medical Technology** includes medical devices, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.

**Medical Technology Demonstration** means demonstration of the operational use of a product and includes discussions about product features and performance.

**MTAA** means Medical Technology Association of Australia Limited.

**Non-Industry Complainant** means a Complainant that is not an Industry Complainant or a Consumer.

**Practitioner in Training** means a person training to become Healthcare Professional.

**Professional Association** means a clinical or other professional body representing Healthcare Professionals.

**Promotion**, in relation to a Medical Technology, means any activity that, directly or indirectly, promotes or encourages the use, acquisition or other supply of the Medical Technology, by purchase, sale or otherwise, or discourages such use, acquisition or supply of a competing Medical Technology, and includes the publication or dissemination of an Advertisement.

**Register** means the Australian Register of Therapeutic Goods

**Regulator** means a government agency performing a statutory regulatory function.

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**Respondent** means, in relation to a Complaint, the Company whose conduct is the subject of the Complaint.

**Restricted Medical Device** means a Medical Device that is intended to be used or administered by a Healthcare Professional.

**Scheduled Medicine** has the meaning given in the Therapeutic Goods Act.

**Social media** is an umbrella term that incorporates the various online platforms and activities that engage users to participate in, comment on and create digital content on the Internet to allow them to interact, share information and network with others, including peer-to-peer conversations. Examples of social media include Facebook, YouTube, blogs, Twitter, LinkedIn, wikis and similar communication tools.

**Sponsor** in relation to a therapeutic product, means the holder of a product licence in relation to that product.

**TGA** means Therapeutic Goods Administration

**Therapeutic Goods Act** means the *Therapeutic Goods Act (Cth)* 1989 as amended from time to time.

**Third Party Educational Conference** means a conference or meeting [sponsored or conducted by or on behalf of a Professional Association or a Training Organisation with a genuine educational purpose or function that is:

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- a) independent;
- b) of an educational, scientific, or policymaking nature; and
- c) for the genuine purpose of promoting scientific knowledge, medical advancement or the delivery of effective healthcare.

**Trade Display** means a display of a Medical Technology or an Advertisement or Educational Material about a Medical Technology.

**Training and Education** means the provision of Educational Material, product specification material, lectures and training sessions to Healthcare Professionals in relation to Medical Technologies.

**Training Organisation** means a hospital or other institution that provides training to Healthcare Professionals and/or Practitioners in Training.

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### 7 INTERPRETATION

#### 7.1 In the Code:

- a. the singular includes the plural and vice versa, and a gender includes other genders;
- b. another grammatical form of a defined word or expression has a corresponding meaning;
- c. a reference to a clause, paragraph, schedule or annexure is to a clause or paragraph of, or schedule or annexure to, the Code and a reference to the Code includes a reference to any schedule or annexure;
- d. a reference to A\$, \$A, dollar, or \$ is to Australian currency;
- e. the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions; and
- f. headings are for ease of reference only and do not affect interpretation.

This Edition of the Code replaces and supersedes all previous editions of the Code.

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### 8 ADVERTISING AND PROMOTION OF PRODUCTS

#### 8.1 Application

This section of the Code applies to advertisements directed to:

- Healthcare Professionals, and
- those with responsibility for the purchasing of medical devices.

It does not apply to advertisements directed to consumers.

The advertising of therapeutic goods to consumers and Healthcare Professionals is done by a co-regulatory system. All advertisements are subject to relevant laws and regulations including, but not limited to:

- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations
- Competition and Consumer Act 2010

#### 8.2 General

An Advertisement directed to Healthcare Professionals must:

- a. comply with the Code and relevant Laws and Regulations;
- b. not be misleading or deceptive, or likely to mislead or deceive;
- c. reflect a high standard of social responsibility and conform to generally accepted standards of good taste;
- d. be readily recognisable by the target audience as an Advertisement;
- e. not claim that a Medical Technology is unique or has some

Advertisements directed to consumers must follow the Therapeutic Goods Advertising Code.

Advertisements directed to exclusively to Healthcare Professionals must follow the relevant industry code. In the case of medical technology, this is the MTI Code.

Companies have a responsibility to ensure the content and presentation of their advertising and promotional material promotes the proper use of medical technology products through encouraging Healthcare Professionals to select appropriate management options, suitable products for their patients and then to use those products safely and effectively.

While a term such as “unique” may be used to describe some special feature of a device, there is a risk it may be taken as implying general superiority. This is unacceptable unless the claim can be supported.

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special merit, quality or property unless the claim can be substantiated;

- f. not use the term “safe” without appropriate qualification;
- g. not imitate the branding, names, logos, get-up or graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse;
- h. not use, the term “new”, or any other term having the same connotation in an Advertisement to describe a Medical Technology after one year from the date of the product’s launch, unless appropriately qualified;
- i. comply with the advertising laws and regulations for both Medical Devices and Scheduled Medicines where the Medical Technology consists of both a Medical Device and a Scheduled Medicine; and
- j. conform with all requirements of the Code, except to the extent that any such requirement may be in conflict with any provision of the Advertising Code.

### 8.3 Claims and endorsements

a. A Company must:

- (i) be able to substantiate all claims in an Advertisement by reliable technical, scientific or

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The term “new” should not be used for a product that has been available and promoted for more than 12 months in Australia.

Advertisers/sponsors are required to hold appropriate, balanced, comprehensive and credible evidence to substantiate advertised/promotional claims. It is fundamental that any therapeutic

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- other support;
  - (ii) cite the source of the claim where the claim is likely to mislead or deceive if its source is not cited;
  - (iii) if a third party requests substantiation of a claim, provide substantiation to that third party within 10 working days; and
  - (iv) identify any unpublished data as “data on file” when cited in a claim and make the data available on request.
- b. A Company must not use the name or photograph of a Healthcare Professional without their written permission or in any way that is:
- (v) contrary to the codes and ethical requirements of that Healthcare Professional, if so informed by the Healthcare Professional; or
  - (vi) likely to mislead, deceive or confuse.

### 8.4 Comparative Advertising

- a. When comparative claims are made there must be strong evidence to support the claim. Given the potential for competitive disputes arising from comparative claims,

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claim made must be consistent with the intended purpose of the technology and conform to current standards for clinical evidence.

In determining whether sufficient evidence is available to support a claim, companies should have regard to issues such as the study design, the number of patients, the location of the trial or study, its primary purpose and endpoints, the results, its consistency with the current body of evidence and whether or where the study has been published.

Advertising/promotional claims should not rely solely on evidence from sources such as poster presentations or abstracts that do not provide sufficient evidence to assess the veracity of the claim.

Companies should not selectively use evidence to support their claims. Inserting selected abstracts into an advertisement, which do not accurately reflect the results of the study, has the potential to mislead by omission or implication.

In response to a reasonable request, supporting evidence must be made available to Healthcare Professionals, industry members and, where appropriate, consumers within 10 working days. For example, members should be aware that by referencing “data on file” or “in press” material, they commit to honouring the request for supporting data. A statement that the data are “confidential” will not be accepted.

The intent of any comparison should be to provide valuable and accurate information comparing products for the benefit of Healthcare Professionals and their patients. Care should be taken to distinguish between statistical significance and clinical significance. Graphical or

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companies must ensure that claims are current, accurate and balanced and do not mislead by implication or omission.

- b. An Advertisement must not denigrate a competitor's Medical Technology.
- c. A Company may report (in an Advertisement) on the outcomes of comparative testing of Medical Technologies, provided
  - (i) the Medical Technologies have been subjected to the same and appropriate testing;
  - (ii) the outcomes are reported in a fair and balanced manner; and
  - (iii) each outcome is referenced and consistent with the body of evidence.
- d. If the comparative data that supports a claim referred to in clause 8.4c arises from separate studies, then a qualifying statement must be included to the effect that substantiating data arise from separate studies.
- e. A Company must not make a claim in an Advertisement that describes or shows a competitor's product as broken, defaced, inoperative or ineffective.
- f. An Advertisement must not contain, whether expressly or by

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visual comparisons should be accurate and appropriate.

For example: product 1 was tested in study A, product 2 was tested in study B and the results are compared (rather than the products being directly compared in the same study).

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implication, exaggerated or unqualified superlative claims.

### 8.5 Specific Information Required

- a. Except for devices which are exempt from entry in the Register, an Advertisement to a Healthcare Professional must contain the following mandatory information:
  - (i) the brand name of the Medical Technology (where appropriate);
  - (ii) the name and contact details of the Sponsor;
  - (iii) claims consistent with the intended purpose of the Medical Technology; and
  - (iv) any other information required by law or as a condition of grant of a licence.
- b. If a third party requests information on the intended purpose of a Medical Technology advertised in accordance with 8.5a, the Company must provide the information within 10 working days.
- c. Despite the terms of this clause, Brand Name Reminder Advertisements do not need to contain any mandatory statements unless otherwise required by law.

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Cl. 8.5 applies to advertisements for products that are on the ARTG.

The Therapeutic Goods Act (s 41MM) makes it an offence for any person to claim (by any means, including an advertisement) that a device can be supplied, if that device is not included in the ARTG or is not exempt. There are a number of 'exceptions' for exempt devices, to which this offence does not apply, that allow companies to communicate with Healthcare Professionals about unregistered products in limited circumstances. These include:

- Custom-made medical devices (Item 1.5 of Schedule 4 of the MD Regulations 2002);
- Devices supplied under the Special Access Scheme for Category A patients in life-threatening cases (Regulation 7.2 of the MD Regulations 2002);
- Samples of medical devices that are imported into Australia, exported from Australia, or manufactured or supplied in Australia for examination, demonstration or display, with notice included to the effect that the device is not available for general supply unless it is included in the Register (Item 1.3(c) of Schedule 4 of the MD Regulations 2002).

Cl. 8.5 does not apply to products that are exempt from being on the ARTG.

For purposes of 8.5b, 'third party' means a person/entity other than the company giving the information and the HCP receiving it. Any third party (for example, another company or hospital ethics committee) can ask for information on the intended purpose.

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### 8.6 Company Commissioned Articles

- a. A Company Commissioned Article (CCA) must be clearly identified as such.
- b. The Sponsor must be clearly identified at either the top or the bottom of the article.
- c. Where a CCA is used solely for the purpose of supporting a claim, including a comparative claim, the claim must be cited.

### 8.7 Social media in Promotions to Healthcare Professionals

- a) All companies should have policies and procedures describing the roles and responsibilities of Company Representatives when interacting with HCPs via social media.
- b) All use of social media by Companies in the Promotion of products to Healthcare Professionals must comply with the requirements of this Code relating to Advertisements.

MTAA members should inform themselves about the social media policies of other health care industry stakeholders. For example, the Australian Health Practitioner Regulation Agency has a social media policy for its members. MTAA members should have regard to this policy when dealing with AHPRA members via social media.

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### 9 INTERACTIONS WITH HEALTHCARE PROFESSIONALS

#### 9.1 General interactions

- a. In all dealings with Healthcare Professionals, a Company must undertake ethical business practices and socially responsible Industry conduct; and
- b. must not use any inappropriate inducement or offer any personal benefit or advantage in order to Promote or encourage the use of its products.

#### 9.2 Company-sponsored Training and Education and Medical Technology Demonstrations:

- a. must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of knowledge and is not selected because of its entertainment, leisure or recreational facilities. The choice of venue must be consistent with professional and public standards of ethics and good taste.
- b. If the program requires “hands on” training in medical procedures or Medical Technology Demonstration:
  - (i) it must be held at a training facility, medical institution, laboratory, or other appropriate facility;

Companies need to determine, with each interaction with Healthcare Professionals, if the interaction may constitute an inducement or would appear to an ordinary member of the public to be an inducement or dealing that influenced the decision or product choice of the Healthcare Professional.

The development of, and further research into, medical technology products is often dependent on the feedback and information provided by a Healthcare Professional. That relationship is therefore fundamental to beneficial outcomes for patients. Industry also invests heavily in training and educating Healthcare Professionals to ensure they use technology in the optimal manner.

The geographic location selected should not become the main attraction of the event. It should be centrally located with regard to the place of origin of the invited participants. It should also provide ease of access (close proximity to airports, train stations and highways) and have a good ground transportation infrastructure.

Holding Company training at a well known tourist destination may well attract negative public perception and complaints, regardless of the specific venue chosen for company training. This risk is

- and
- (ii) the training staff must have the proper qualifications and expertise to conduct such training.
  - c. A Company may pay for reasonable travel and modest lodging costs incurred by attending Healthcare Professionals.
  - d. A Company may pay for modest hospitality for attending Healthcare Professionals.
  - e. A Company must not pay for the Hospitality, travel, or other expenses of any guest of a Healthcare Professional, or for any other person who does not have a genuine professional interest in the information being shared at the program.
  - f. In the interests of transparency and accountability:
    - (i) a Company must enter into a simple written agreement with each Healthcare Professional attending the program, which sets out the nature of the program and the services to be provided by or on behalf of the Company;
    - (ii) the agreement must require the Company and the Healthcare Professional to make all necessary disclosures to any relevant Professional Association or Institutions; and
    - (iii) where the event is modest in nature, the requirement to enter into an agreement may be satisfied by the

heightened if the training is held during holiday season at the location, such as ski season. Companies should consider both the venue and surrounding town/region when deciding whether the training and education will meet the Code's requirement of being held in a setting that is conducive to the effective transmission of knowledge and has not been selected because of its entertainment, leisure or recreational facilities.

Extensive training and education is conducted by companies for the benefit of Healthcare Professionals and ultimately for enhanced patient outcomes. In conducting education and training, companies need to ensure that the focus of the relationship is educative and not inappropriate hospitality. Training and education includes both formal, structured sessions and the in-service instruction that occurs in a healthcare setting. It can also include working with Healthcare Professionals to better understand the technology and patient benefit to be derived from it.

The Code permits companies to provide training and education, which is defined as the provision of educational material, product specification material, lectures and training sessions to HCPs in relation to medical technologies. Training and education which does not relate to medical technologies may be construed as a gift or benefit rather than permitted training and education under the Code.

Hospitality (ie the provision of food and beverages) may be provided but as an ancillary offering. It must not be the main focus of the training event. In assessing whether hospitality and lodging costs are modest, companies should consider not only the financial cost but whether an ordinary member of the public would consider the venue and hospitality to be modest.

provision of a detailed program or agenda outlining the services to be provided to the Healthcare Professional.

- g. A Company must not impose any requirement on a Healthcare Professional to purchase or cause to be purchased any Medical Technologies or other goods or services associated with the training, in consideration for attending the program.
- h. A Company must not provide any free products to attending Healthcare Professionals, other than in compliance with clause 9.7.

A company may pay for the cost of the Healthcare Professional to attend the education or training but this does not extend to the partner of the Healthcare Professional.

Companies should use simple agreements with Healthcare Professionals to ensure that everyone is clear on the purpose of the event and what will be provided. An agreement is not required for an event that is modest in size, such as a short seminar. In these circumstances the program or agenda is sufficient as evidence of the agreed scope of services.

### 9.3 Third Party Educational Conferences

#### 9.3.1 General

An aspect of the relationship between industry and Healthcare Professionals is the financial support provided to healthcare conferences conducted by the professional organisations and conference organisers on behalf of groups of Healthcare Professionals.

This section sets out the parameters within which a company must operate to provide financial support to a conference aimed at Healthcare Professionals and others in the healthcare sector with responsibility for purchasing decisions. The overall aim of this section is to ensure that there are no direct payments to individual Healthcare Professionals that might be regarded as an inducement to make a recommendation on product selection.

The relationship regulated under the Code is between the company and the conference organiser. The conference organiser can be a professional association, a training organisation (i.e. a hospital or other body that provides training to Healthcare Professionals or trainees), or a bona fide commercial conference organiser that is independent of the company.

Companies should consider the image that may be projected to the public when deciding whether to support a conference. This would include whether or not an ordinary member of the public would consider that a conference is going to be for the genuine purpose of promoting scientific knowledge, medical advancement or the delivery of effective healthcare.

The appropriateness of the geographic location applies irrespective of who organises the event and members should take the appropriateness of the geographic location into account when making the decision to support an event whether this is by way of leasing booth space for company displays or any other form of event advertising or support.

Ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. Companies should not sponsor conferences, meetings or events at these locations during those seasons. The appropriateness of a geographic location may be assessed differently for strictly local events attended by local HCPs.

### 9.3.2 Sponsorship or grants for Third Party Educational Conferences

- a. A Company may provide sponsorship or a grant to the Conference Organiser to:
  - (i) reduce conference costs;
  - (ii) provide for attendance by a Healthcare

Professional or a Practitioner in Training; or

- (iii) provide a reasonable honorarium, travel, lodging, and Hospitality expenses for a Faculty Member.

b. A Company may provide sponsorship or a grant provided:

- (i) it is proportionate to the overall cost of the conference;
- (ii) the conference is primarily dedicated to promoting objective medical, scientific and educational activities and discourse;
- (iii) the Conference Organiser selects the recipient of the sponsorship or grant, who may be a Faculty Member
- (iv) the Conference Organiser makes the arrangements and pays for the travel and accommodation of the recipient;
- (v) the Conference Organiser is responsible for and controls the selection of program content, Faculty Members, educational methods and materials. A company may not direct the organiser on content but may suggest possible content if requested by the organiser.
- (vi) the sponsorship or grant:
  - (a) is not conditional on any obligation to or

It is recognised that some conferences are very large events with many attendees. Others may be quite small events directed to a smaller group of Healthcare Professionals (e.g. a regional meeting). For this reason the Code does not cap the amount that may be paid by a company by way of sponsorship but requires that it be proportionate to the overall cost of the conference.

If requested by the organiser, a company may suggest names of possible speakers or attendees for consideration. Where the sponsorship is used to pay for travel, accommodation or attendance costs, a company must not pay the participating Healthcare Professional directly. The payment may only be made to the Conference Organiser. This is to avoid the perception, or reality, of payments as inducements to Healthcare Professionals.

- by the recipient;
- (b) is not offered or provided in a manner or on conditions that would interfere with the independence or professional obligations of a Healthcare Professional or Practitioner in Training;
- (c) is consistent with guidelines established by the Conference Organiser; and
- (d) does not give rise to, or facilitate any breach of the Code;
- (vii) the Conference Organiser and the Company enter into a written agreement specifying the nature and conditions of the sponsorship or grant; and
- (viii) the agreement requires the Conference Organiser to account to the Company for the use of the sponsorship or grant, without being required to disclose the identity of recipient(s).

The purpose of a written agreement is to improve transparency reporting and facilitate Code monitoring.

### 9.3.3 Hospitality at Third Party Educational Conferences

- a. A Company may provide funding to the Conference Organiser to support Hospitality at a Third Party Educational Conference provided the Conference Organiser and the Company enter into a written agreement:
  - (i) specifying the nature and conditions of the

Any hospitality supported by or provided by a company must be looked at from the perspective of community expectations. This includes whether the behaviour of both industry and Healthcare Professionals can withstand public scrutiny in terms of perception.

Hospitality; and

- (ii) which requires the Conference Organiser to account to the Company for the use of the funding.

- b. A company may provide Hospitality at a Third Party Educational Conferences provided the Hospitality is provided in a manner that does not interfere with attendance at conference functions.
- c. All Hospitality at Third Party Educational Conferences funded by or supplied by a Company must comply with the provisions of clause 9.5.

This is intended to ensure that a company is not drawing conference attendees away from planned conference activities they would normally be expected to attend.

At large conferences it is acceptable to provide hospitality to a specialty sub-group rather than all attendees where the cost might be prohibitive.

Any hospitality must be appropriate in value. This will vary from conference to conference and will need to be measured against the overall size and scale of the event. With every event being considered for sponsorship, the company must determine if the event is lavish or excessive, even if the company has not itself organised the event.

#### 9.3.4 Company-sponsored symposia with Faculty Members

A Company may conduct a Company-sponsored symposium as part of a Third Party Educational Conference provided that:

- a. the symposium uses a Faculty Member, a Consultant or an employee of the Company to speak at or facilitate the symposium;
- b. any Hospitality complies with the provisions of clause 9.5; and
- c. a Company does not pay the costs of attendees to attend the symposium, other than those referred to in

A company may conduct a symposium which it sponsors under the wider umbrella of a third party conference provided that the symposium complies with the hospitality restrictions referred to above for general conference hospitality and uses either a conference speaker or a consultant who is subject to a contractual arrangement with the company.

This is to ensure that a company is not inviting Healthcare

9.3.4a.

Professionals directly to a conference in contravention of the restrictions on direct individual sponsorship. A company may invite its employees to participate as speakers.

9.3.5 Advertisements and Trade Displays at Third Party Educational Conferences

Companies should also have regard to the general provisions that regulate an advertisement as set out in clause 7 of the Code.

a. The purchase of an Advertisement or lease of booth space for a Trade Display by a Company at a Third Party Educational Conference must be done transparently and at commercially sensible rates.

b. A Trade Display must:

- (i) not display Advertisements that do not comply with clause 8 of the Code;
- (ii) prominently identify the Sponsor of the Medical Technology that is the subject of the Trade Display, unless;
  - (a) samples of the Medical Technology are provided for examination, demonstration or display and are not registered with the Regulator, in which case a notice must be included to the effect that the device is not available for general supply;
- (iii) comply with requirements of the Conference Organiser, provided that such requirements are lawful and do not conflict with any provision of the Code; and
- (iv) only include activities that can withstand public

Where a product has not yet been registered with the relevant regulator, the company must make it clear by use of a display notice that the product has not yet been registered and that it is on display for the purposes of a demonstration only. Any claimed use must be consistent with the intended purpose assigned by the manufacturer.

scrutiny and conform to professional and community standards of good taste.

9.4 Arrangements with Healthcare Professionals acting as Consultants

- a. A Company may engage a Healthcare Professional to provide genuine consulting services, including research, participation on advisory boards, presentations at Company-sponsored training, and product collaboration, provided that a legitimate need and purpose for the services is identified in advance, and the Promotion of a Medical Technology to the Healthcare Professional is not a purpose for the engagement.
- b. Arrangements with consultants who are clinical trial investigators may include attendance at third party educational conferences to present clinical trial results. Clinical research services should be addressed in a clinical research protocol.
- c. A Company must not engage a Healthcare Professional to provide services at a company-sponsored symposium at a Third Party Educational Conference in order to circumvent the prohibition on directly funding the Healthcare Professional to the Third Party Educational Conference. Where a Company engages a Healthcare Professional to provide such services at a company-sponsored symposium at a Third Party Educational Conference, there must be a legitimate need for the services and the engagement should generally be part of a broader range of services that the Company is engaging the Consultant to provide, rather than

a single engagement.

- d. A Company must not engage a Healthcare Professional to provide services at Company-Sponsored Training and Education in order to circumvent the prohibition on directly funding the Healthcare Professional to a Third Party Educational Conference. Where a Company engages a Healthcare Professional to provide services at Company-sponsored Training and Education which will take place in close proximity in date and location to a Third Party Educational Conference, there must be a legitimate need for the services on the part of the company and the engagement should generally be part of a broader range of services that the Company is engaging the Consultant to provide, rather than a single engagement.
- e. A Company may pay the Healthcare Professional reasonable compensation for performing services as a Consultant.
- f. Consulting arrangements between a Company and a Consultant must comply with the following:
  - (i) the arrangement must be documented in writing between the Company and the Consultant, specifying all services to be provided and compensation to be paid;
  - (ii) the compensation paid to a Consultant must be consistent with fair market value for the services provided;
  - (iii) selection of the Consultant must be on the basis

of the Consultant's qualifications and expertise in dealing with the subject matter of the engagement, and must not be on the basis of volume or value of business generated or potentially generated by the Consultant;

- (iv) when a Company contracts with a Consultant to conduct clinical research services there should be a written research protocol;
- (v) Consulting Arrangements should only be entered into where a legitimate need for the services relevant to the Company's products is identified in advance and documented;
- (vi) the calculation of royalties payable to a Healthcare Professional in exchange for intellectual property arising from the Consulting Arrangements should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence;
- (vii) the location and circumstances for any meetings between the Company and the Consultant must be appropriate to the subject matter of the engagement and the meeting must be conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of information;
- (viii) Company-sponsored Hospitality that occurs in conjunction with a Consultant meeting or a

The amount of any royalties to be paid for the intellectual property input of the Healthcare Professional should be based on objective factors such as the amount of effort of the Healthcare Professional reflected in the product development

In assessing whether hospitality and lodging costs for consultants are modest, companies should consider not only the financial cost but whether an ordinary member of the public would consider the choices to be modest.

The intention of clause 9.4(g)(ix) is to prohibit side trips from

meeting with a prospective Consultant must be modest in value and subordinate in time and focus to the primary purpose of the meeting;

- (ix) the Company may pay for reasonable and actual expenses incurred by a Consultant in carrying out the engagement, including reasonable and actual travel, modest Hospitality and lodging costs in attending meetings with, or on behalf of, the Company. The Company may not fund or facilitate personal or private side trips from a consulting engagement which the Company has engaged the Consultant for; and
- (x) the written agreement documenting the Consulting Arrangement must require the Company and the Consultant to make all necessary disclosures to any relevant Professional Association or Institutions concerning any existing or potential conflict of interest.

consulting engagements where a Healthcare Professional will derive a benefit of a personal or private nature from the side trip.

## 9.5 Hospitality

A Company's business interactions with a Healthcare Professional may involve the presentation of scientific, educational, or commercial information. A Company may conduct such exchanges in conjunction with Hospitality as an occasional courtesy provided the Hospitality:

- a. is incidental to the bona fide presentation of scientific, educational, or commercial information and provided in a manner that is conducive to the presentation of such

Hospitality should not be provided to Healthcare Professionals where it may constitute an inducement or would appear to an ordinary member of the public to be an inducement or dealing that influenced the decision or product choice or recommendation of the Healthcare Professional.

The provision of hospitality to Healthcare Professionals or other product buyers or influencers is restricted. It can only be provided

information;

- b. does not include Entertainment;
- c. takes place in a setting that is conducive to bona fide scientific, educational, or business discussions and is not selected because of its leisure or recreational facilities;
- d. is modest in value;
- e. does not involve the Company paying for someone who did not actually participate in the meeting; and
- f. does not involve the Company paying for any person who does not have a bona fide professional interest in the information shared in the meeting.

in the context of a third party educational conference referred to above, or outside of a conference, where there is an educative element to the event or where there is a medical technology demonstration which is essential to the understanding by the Healthcare Professional of the use and operation of a medical technology. There will be many day-to-day interactions between industry and Healthcare Professionals, including assistance in procedures in the hospital setting. A company must ensure that the interaction is one that supports the Healthcare Professional to develop product knowledge and does not act to persuade or influence product choice on the basis of the hospitality provided.

Provision of hospitality such as refreshments should not be done in such a way as to create an expectation on the part of healthcare professionals that such hospitality is a normal and regular occurrence.

A meeting with a hospital buyer or procurement manager may address commercial information as part of the interaction. However any hospitality must be modest and a company must ensure that the interaction is not simply a social interchange funded by the company. The primary requirement is that any hospitality is modest and subordinate in focus to the primary intent of the meeting.

Companies need to exercise their own judgment on a case-by-case basis, bearing in mind that top category restaurants generally wouldn't meet this requirement. In assessing whether hospitality is modest, companies should consider not only the financial cost but whether an ordinary member of the public would consider the venue and hospitality arrangements to be modest.

## 9.6 Market Research

A Company may conduct Market Research with a Healthcare Professional provided that:

- a. the sole purpose is to collect data and the Market Research is not calculated to Promote to and/or reward the Healthcare Professional;
- b. the Market Research study is clearly identified as such to the Healthcare Professional;
- c. any compensation is kept to a minimum and does not exceed a level commensurate with the work performed by or on behalf of the Healthcare Professional; and
- d. where the Market Research includes a Competition or allows for the provision of any prize, it complies with clause 9.8.

Market research can provide useful feedback to a company about a product and identify issues in design or use. However in undertaking market research a company must not promote a product or reward the participants. It is appropriate for the company to make a payment to the participants in recognition of the time contributed to the research but this must be in line with the usual hourly rate for the level of experience or specialty of the Healthcare Professional.

If a company uses a competition as part of the participation it must meet the requirements for Healthcare Professional competitions in clause 7.8.

## 9.7 Items of an educational nature

- a. A Company occasionally may provide a Healthcare Professional with an item that benefits patients or serves a genuine educational function for the Healthcare Professional provided that the item has a fair market value of less than \$100, except in the case of medical textbooks or anatomical models.
- b. A Company may not give a Healthcare Professional any type of non-educational branded promotional item, even if the item is of minimal value and related to the Healthcare Professional's work or for the benefit of patients. This

Any provision of a "gift" to a Healthcare Professional runs the risk of being perceived by the general public as an inducement and should be avoided, however provision of an item that benefits patients or serves a genuine educational purpose may be appropriate.

Any such item must have a fair market value of no more than AUD\$100 and be of an educative nature. The limit of AUD\$100 does not apply if the item is a medical textbook or anatomical model given that these invariably cost more than \$100. Nonetheless they should not be extravagant. While branded promotional items are not permitted, it is permissible to have company or product branding on items that serve a genuine educational purpose. Examples of

restriction does not apply to Medical Technology marketed only to Consumers.

- c. A Company may not accept a gift from a Healthcare Professional.
- d. A Company must ensure that sales of Medical Technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a Healthcare Professional receiving payments, gifts or Hospitality.
- e. For the avoidance of doubt, this clause does not preclude the legitimate practice of providing to Healthcare Professionals appropriate sample Medical Technologies for genuine Training and Education or Medical Technology evaluation purposes.

#### 9.8 Competitions for Healthcare Professionals

- a. A Company may conduct a Competition for Healthcare Professionals that complies with the following provisions:
  - (i) the Competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge;
  - (ii) all Competition prizes must be:
    - (a) directly relevant to the practice of medicine or field of other specialist healthcare; and
    - (b) of minimal monetary value or be an item

such items include:

Sample Medical Technologies can only be provided for a reasonable time period, which will depend on the type of medical technology and whether it is being used for training, education or evaluation.

A company may conduct a competition aimed at Healthcare Professionals and others with product-purchasing authority in limited circumstances. A competition is any promotional activity as a result of which a person may win a prize or receive a reward. It includes a game that involves skill or chance, or both.

The competition must be based on the participant's medical or other specialist knowledge. The prize must be modest (i.e. no more than AUD\$100) and directly relevant to the practice of medicine or area of healthcare. This means that e.g. a prize of cinema tickets or wine would not be appropriate.

Entry must not be dependent on ordering or using a particular product.

of an educational nature; and

- (iii) entry into a Competition must not be dependent on the ordering, recommending, using or prescribing of a Medical Technology;

- b. The conduct of a Competition must comply in all respects with all relevant Laws and Regulations.

## 9.9 Research and educational grants and charitable donations

### a. General

A Company may provide research and educational grants and charitable donations provided that the Company:

- (i) adopts objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient;
- (ii) implements appropriate procedures to ensure that such grants and donations are not used as a condition of purchase of the Company's products;
- (iii) does not participate in any decision on the part of the receiving organisation as to which individuals may benefit from the grant or donation;
- (iv) ensures that the recipient of the funds has an appropriate process in place for impartially

Research grants to support independent medical research with scientific merit must have well-defined objectives and milestones. A company may make an educational grant for the advancement of medical education where the program is delivered by an organisation with an academic affiliation, or advancement of public education.

Clause 9.9a(iii) requires companies to ensure that the recipient of research or educational funds or charitable donations makes an independent decision on how the funds will be used. This means that the company must satisfy itself that the recipient has processes in place to appropriately manage conflicts of interest. In particular, the recipient of the funds should demonstrate that the person or panel allocating the grant will not be potential beneficiaries.

allocating the funds or selecting any beneficiary of the funds; and

- (v) ensures that all such grants and donations are appropriately documented.

b. Research grants

A Company may provide research grants to support independent medical research with scientific merit provided that such activities have well-defined objectives and milestones (and subject to clause 9.4 where a Healthcare Professional is engaged by a Company to undertake research on its behalf).

c. Educational grants

A Company may make an educational grant for the following purposes:

- (i) *Advancement of medical education* – a Company may make a grant to support the genuine medical education of Healthcare Professionals and Practitioners in Training participating in programs which are charitable or have an academic affiliation;
- (ii) *Advancement of public education* – a Company may make grants for the purposes of supporting genuine education of Consumers or the public about important healthcare topics.

d. A Company must not make an educational grant directly

to an individual Healthcare Professional or a Practitioner in Training (whether to attend a Third Party Educational Conference or not). A Company may make an educational grant to an institution which falls within the definition of Healthcare Professional where the other requirements of clause 9.9 are met.

- e. A Company must not make an educational grant if it has a reasonable concern that the educational grant will be used to directly fund a nominated individual Healthcare Professional or Practitioner in Training to a Third Party Educational Conference.

- f. Charitable donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should only be made to organisations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission.

It would not be appropriate, for example, to direct the donation to funding a dinner or similar social event unless the cost of a dinner ticket was a subsidiary part of the donation. The amount and purpose of the donation must be documented.

- g. A Company must not make any charitable donation or philanthropic gift for the purpose of inducing a Healthcare Professional to purchase, lease, recommend, use, or arrange for the purchase, lease or use of the Company's Medical Technology.
- h. The Company must fully document every donation made by the Company.

## 9.10 Fellowships

A Company may grant funds to an organisation accredited by a Professional Association or with an academic affiliation to deliver specialty education to provide a fellowship for the specialty education of a Healthcare Professional or a Practitioner in Training.

## 9.11 Provision of reimbursement and other information

- a. In Australia, a Company may support accurate and responsible billing to Medicare and other payers by providing reimbursement information to a Healthcare Professional regarding the Company's products, including identifying appropriate coverage, coding, or billing of the Company's products, or of procedures using those products.
- b. A Company may provide to a Healthcare Professional who has acquired or uses a Medical Technology of the Company, information for the purposes of aiding in the appropriate and efficient use or installation of the Medical Technology.

## 9.12 Disclosure of Company interest in published research

A Company should ensure that its involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of publication.

Disclosure should be made in a prominent place such as the 'preface' or 'introduction' to the publication or presentation.

## 10 COMPANY REPRESENTATIVES

### 10.1 Company representatives

#### a. A Company must:

- (i) ensure that its Company Representatives are fully aware of the provisions of the Code
- (ii) provide ongoing training to Company Representatives on compliance with the provisions of the Code as detailed in 8.2.

In order to ensure that the Code is well-understood within a company, the employees and agents who have primary contact with Healthcare Professionals and others with product-purchasing authority must be fully trained in the Code and its provisions.

#### b. A Company must ensure that its Company Representatives at all times:

- (i) maintain a high standard of ethical conduct and professionalism;
- (ii) conduct themselves in a manner that complies with the Code;
- (iii) act in a manner that does not compromise, appear to compromise or appear likely to compromise the professional behaviour or independence of a Healthcare Professional
- (iv) act in a manner that does not compromise, appear to compromise or appear likely to compromise patient care.

All employees within the medical technology industry should receive, as a minimum, broad training on the Code and the need for ethical and professional dealings.

A company has the responsibility of ensuring adequate awareness of the Code and its provisions. A company must also ensure that employees understand the nature of the professional relationship with Healthcare Professionals to ensure that there is no inappropriate behaviour that might compromise the professional independence of the Healthcare Professional.

#### c. A Company must ensure that a Company Representative

who attends procedures at the invitation of a Healthcare Professional complies with all relevant institutional requirements, standards, codes and all relevant Laws and Regulations.

## 10.2 Requirements for training

- a. A Company must ensure that every Company Representative working with Healthcare Professionals undertakes training on the Code which is approved by the Association. This is a requirement of each new edition of the Code. For new employees, this training must be completed within six months of commencing in the role.
- b. A Company must ensure that every employee employed in a role that involves Promotional activities or purchasing decisions on behalf of the Company undertakes training on the Code approved by the Association. This is a requirement of each new edition of the Code.

In support of the requirement to ensure adequate knowledge of the Code, employees who work directly with Healthcare Professionals, those that make purchasing decisions, or work in marketing or customer service roles must undertake training in the Code within six months of commencing employment with the company and for each new edition of the Code.

To ensure that training in the Code is consistent, all training must either be delivered by MTAA or reviewed and approved by MTAA.

## 10.3 Company Representatives - compliance program

- a. Companies must take all measures reasonably required to ensure compliance with the Code by Company Representatives. Companies must adopt effective compliance programs by issuing written policies and procedures, conducting training programs and implementing clear procedures, controls and enforcement mechanisms.
- b. Companies are encouraged to inform all customers,

Institutions and Healthcare Professionals of the requirements of the Code.

## **11 INTERACTIONS WITH CONSUMERS**

### **11.1 General**

- a. If a Company receives a request from a Consumer for advice of a medical or diagnostic nature, the Company must recommend that the Consumer consult an appropriate Healthcare Professional.
- b. A media release to one or more organisations or through one or more channels intended or likely to result in publication to Consumers:
  - (i) must not be an Advertisement unless it conforms with the Code; and
  - (ii) must be issued conditionally upon the publisher ensuring that the release or extracts be published in compliance with the Code and all relevant Laws and Regulations.
- c. MTAA recognises and supports relationships between Industry and Health Consumer Organisations, government bodies and other independent bodies having an interest in

consumer education in relation to Medical Technologies, which are used by Consumers for the sole purpose of facilitating education of Consumers and enhancing their quality use of those products.

## 11.2 Competitions for Consumers

- a. A Competition must not be directed to Consumers in relation to any Restricted Medical Device.
- b. To the extent a Competition comprises an Advertisement, it must comply with the Advertising Code.
- c. The conduct of a Competition must comply in all respects with all relevant State and Federal Laws and Regulations.

Information about the Laws and Regulations relevant to Competitions can be found at:

<http://businesslounge.net.au/2012/09/competitions-and-giveaways-part-2-the-legal-side/>

## 11.3 Disease awareness campaigns for Consumers

Disease education activities may provide information, promote awareness and educate the public about health, disease and their management.

- a. A disease education activity may make reference to the availability of different treatment options but not direct the Consumer to purchase a specific Medical Technology where to do so would be in breach of the Therapeutic Goods Act.
- b. The emphasis of the disease education activity should be on the condition and its recognition rather than on the treatment options, unless discussion of treatment options directly with the public is permissible under the Therapeutic Goods Act. The appropriate treatment for an individual Consumer is for

the Healthcare Professional to decide in consultation with the Consumer.

#### 11.4 Funding of Health Consumer Organisations

MTAA recognises and supports positive and beneficial relationships between the Industry and Health Consumer Organisations. Companies may enter into relationships with Health Consumer Organisations with the objective of enhancing the quality use of Medical Technology and supporting better outcomes for the Australian community.

In supporting Health Consumer Organisations, Companies should have regard to the guidelines developed in collaboration between Medicines Australia and the Consumers Health Forum.

Each Company is encouraged to make publicly available on its website, a list of Health Consumer Organisations to which it provides financial support and/or significant direct/indirect non-financial support. The list could be updated on an annual basis.

## 12 INTERESTS HELD BY HEALTHCARE PROFESSIONALS IN MEDICAL TECHNOLOGY COMPANIES

- a. Where a Healthcare Professional owns an interest in a Medical Technology company, the Company must ensure that any conflict of interest is managed in such a way that public trust is not compromised and a recommendation to a Consumer for the use of a Medical Technology is made consistent with ensuring the best health outcomes of the Consumer.
- b. Where a Company is owned, in whole or in part, by a Healthcare Professional, it must require the HCP to

In practice, this can be done by having in place contractual arrangements with Healthcare Professionals that require them to disclose their ownership interest in the company. Note: most

disclose their ownership interest to a Consumer before or at the time the Healthcare Professional recommends a product that is marketed by that Company.

professional colleges require their members to disclose such interests.

### **13 ADMINISTRATION OF CODE OF PRACTICE**

13.1 A Medical Technology company is entitled to fair and equitable treatment under the Code.

13.2 General

The Code is administered by the Code Authority (CA) which is appointed by the Board of MTAA. CA members represent MT companies, consumers and Healthcare Professionals.

13.3 Role of the Code Authority

The CA is responsible for the effective operation and administration of the Code including monitoring, complaints handling and appeals. In this capacity, it:

- a. may appoint subcommittees and delegate to them the management of any aspect of Code administration including monitoring, complaints handling, and appeals;
- b. must conduct external reviews of the Code every three years to ensure it continues to reflect community, Industry and regulatory standards, submit all proposed amendments to the Board for approval, and publicise all amendments;
- c. must collate statistical data of complaints received and

their outcomes, conduct a regular review and analysis of complaints and Industry issues they may raise, and make recommendations to the Board for improvements to industry self-regulation;

- d. must identify and recommend the optimal means for MTAA to promote the Code to Companies, the Industry, Healthcare Professionals, Regulators and other relevant stakeholders and participants in the healthcare industry; and
- e. must ensure education programs are updated every time more than minor changes are made to the Code and at least once every three years.

#### 13.4 Role of MTAA in Promoting Awareness of the Code

- a. MTAA must undertake an awareness campaign every time more than minor changes are made to the Code.
- b. MTAA must ensure the Code is available on the MTAA website at all times and encourage Companies to reference and provide links to the Code on their own websites.
- c. MTAA must encourage Companies to promote awareness of the Code by their staff, suppliers and clients on a regular basis.

#### 13.5 Role of MTAA in promoting Training on the Code

- a. MTAA must ensure that ongoing training is provided to the

Industry on the interpretation and application of the Code.

## 14 COMPLAINTS

- a. A Complaint regarding:
  - (i) an Advertisement (other than an Advertisement directed to Consumers), or Promotional activities by a Company; or
  - (ii) an interaction with a Healthcare Professional,must be dealt with by the CA. .
- b. A Complaint regarding an Advertisement directed to Consumers must be forwarded to the bodies listed in Appendix 5.
- c. Notwithstanding the provisions of clause 14(b), if a Complaint:
  - (i) is made in relation to an Advertisement directed to Consumers; and
  - (ii) in addition, asserts other conduct that may be in breach of the Code,the CA may deal with any assertion in the Complaint insofar as it relates to the other conduct.

- d. All Complaints and responses must be in writing.
- e. A Complainant may apply to the CA to have their name withheld from the Respondent and from public release. The Complaints Secretary must assemble any evidence provided by the Complainant and prepare a report for the CA. The CA must then determine whether to refer the complaint for consideration by a Complaints subcommittee.
- f. The CA must deal with all Complaints it receives in accordance with the provisions outlined in Appendix 3 of the Code.
- g. Notwithstanding the obligations on MTAA to report on the outcome of Complaints as provided in the Code, all information about a Company, a Complainant, and the subject matter of a Complaint, must be kept confidential until all avenues of appeal are exhausted and outcomes of appeals known.

## 15 SANCTIONS

### 15.1 Classification of Breaches

Where a breach of the Code has been established, before determining any sanction under clause 15.2, the CCC must first classify the severity of the breach, in accordance with the classification set out below.

**Minor Breach:** a breach of the Code that has no safety implications and will have no adverse effect on how Healthcare Professionals or the general public view the Medical Technology the subject of

- Moderate Breach:** the Complaint, similar products or the Industry. a breach of the Code with no safety implications but which may adversely impact on the perceptions of Healthcare Professionals or the general public regarding the Medical Technology the subject of the Complaint, similar products or the Industry.
- Severe Breach:** a breach of the Code that has safety implications or may have a major adverse impact on how Healthcare Professionals or the general public view the Medical Technology the subject of the Complaint, similar products or the Industry.
- Repeat Breach:** when a Company commits the same or similar breach of the Code to a breach found against the Company within the preceding 24 months.
- Serial Breach:** when a Company breaches the Code, and that Company has been found to have breached the Code on not less than two previous occasions in the preceding 24 months.

## 15.2 Available Sanctions

- a. Where the CA finds that a Company breached the Code, the CA must apply one or more of the following sanctions. The time periods specified for response or action are subject to any appeal that may be lodged under clause 20 of the Code.
  - (i) A requirement that the Company take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code, in which event the Company must confirm in writing to the CA that it has taken the required

action within 10 working days of receipt of the decision.

- (ii) A requirement that the Company recall and destroy any offending material in which event the Company must confirm in writing to the CA, within 10 working days of receipt of the decision, that it has taken the required action.
- (iii) A requirement that the Company issue a retraction, including corrective letters and advertising. The retraction must comply with all directions of the CCC, including directions in relation to recipient, number, format, size, wording, mode of publication, prominence, timing and method of distribution. The Company must confirm in writing to the CCC, within 10 working days of receipt of the decision, that it has taken the required action and provide a copy of the retraction once published.
- (iv) The imposition by the CA of a fine in accordance with the following schedule. The Respondent must pay the fine to the Complaints Secretary within 30 days of being advised of the decision of the CCC.

<b>Minor Breach:</b>	Nil
<b>Moderate Breach:</b>	Maximum AUD \$50,000
<b>Severe Breach:</b>	Maximum AUD \$75,000
<b>Repeat Breach:</b>	Maximum AUD \$100,000
<b>Serial Breach:</b>	An amount not less than AUD \$25,000 and not more than AUD \$200,000.

- b. Subject to clause 18.2, if the CA resolves that a Complaint from a member of the Industry is frivolous or vexatious, the CA may request the Complainant to show cause why it should not pay the Complaints Secretary costs and any out of pocket expenses associated with the Complaint as well as a fine not exceeding AUD\$10,000 for abuse of the Code.
- c. If the CA resolves that a breach of the Code by a Company warrants the suspension or the expulsion of the Company from MTAA, it must make such a recommendation to the relevant Board. The Board may deal with the recommendation under the provisions of its constitution.
- d. In the event that the CA requires a Respondent to cease a conduct or withdraw an Advertisement and the Respondent wishes to appeal the decision, the CA's decision will stand and must be complied with, pending the outcome of the appeal.

### 15.3 Failure to comply with sanctions

- a. If a Company, having been found by the CA to have breached the Code, fails to comply with any sanctions imposed on it by the CA, such failure:
  - (i) is a further breach of the Code;
  - (ii) is deemed to increase the classification of the previously imposed sanction by one level; and
  - (iii) in addition to any further sanctions imposed pursuant to clause 15.2, entitles the CA to direct

In relation to clause 15.3(a), failure to comply with any sanction imposed by the CA amounts to a further breach of the Code. It also increases the classification of the previously imposed sanction by one level as follows:

- If the previously imposed sanction was a minor breach, it becomes a moderate breach;
- If the previous imposed sanction was a moderate breach, it becomes a severe breach.

MTAA to publish in the next edition of its newsletter and/or on its website details of the breach of the Code and the subsequent failure to undertake remedial action.

- b. The continued refusal by the Company to undertake the required remedial action/s entitles the CA to direct MTAA to publish in the trade media details of the breach of the Code and the subsequent failure to undertake remedial action.
- c. In addition to the sanction set out in clause 15.2 above, the CA may direct MTAA to notify the Regulator of the continued breach of the Code.

## **16 APPEALS**

A company found to be in breach of the Code, or a Complainant who has had their complaint dismissed, may lodge an appeal against the findings and any imposed sanctions in accordance with the Appeal Procedures outlined in Appendix 4.

## **17 PUBLICATION OF OUTCOME OF COMPLAINTS AND APPEALS**

- a. To ensure transparency of procedures, MTAA must publish

on its website the outcome of every upheld Complaint and appeal finalised during the year. The website publication must be removed after 12 months.

- b. When a Complaint or appeal is not upheld, the published information must be limited to the date, the name of the Respondent, and a statement that the Complaint or appeal was not upheld. When a Complaint or appeal is partially upheld, only that portion of the complaint that is upheld must be published.
- c. MTAA must not publish in any form the name of a complainant if it has been withheld in accordance with clause 14e.

## **18 MEDIATION**

### **18.1 General**

- a. Where the parties have consented to mediation, the Code Authority may appoint an independent mediator to assist the parties to discuss, negotiate and achieve a resolution.
- b. The Complaints Secretary must arrange the mediation session in consultation with the parties and mediator.
- c. The Complaints Secretary must ensure that all relevant documentation is provided to the parties and the mediator at least one week before the scheduled mediation.
- d. The parties must be present in person at the mediation. It is not expected that the parties will be legally represented at

mediation.

- e. The parties must agree to pay their own costs and MTAA's reasonable costs to undertake mediation.
- f. Any agreement reached as a result of mediation shall be confidential, binding, in writing and signed by the parties and the mediator. The agreement must remain confidential to the parties and the mediator, unless the parties agree it be made available to MTAA.

## 18.2 Mediator

- a. The mediator must be a person with demonstrable mediation experience.
- b. The parties to the mediation must approve the selection of mediator.
- c. The mediator may seek the advice or participation of an expert, as required.
- d. The mediator is responsible for arranging and conducting the mediation and, subject to confidentiality arrangement agreed between the parties, reporting to the CCC on progress and any outcome.
- e. Subject to any agreement reached before the mediator to the contrary, the Complaints Secretary may seek from the parties a reimbursement of the mediator's charges and the costs incurred in arranging a mediation session. The parties will meet their own expenses of participating in mediation.