# Medical Technology Industry
# Code of Practice

(Administered by the Medical Technology Association of Australia)

**9th Edition – 2015**

MTAA 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.

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.

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.

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

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.

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.

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.

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

## 3 BACKGROUND AND PURPOSE OF THE CODE

3.1 The medical technologies sector is a major component of the therapeutic 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.

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

## 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.

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.

## 5 EXPLANATORY NOTES AND APPENDICES

Explanatory notes are provided to assist with understanding and implementing the Code at an operational level. They are not binding on the Code Authority or its subcommittees.

Appendices form part of the Code. In case of any inconsistency between an appendix and any clause of the Code, the appendix takes precedence.

## 6 GLOSSARY

6.1 In the Code:

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

**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.

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.

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

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

**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:

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 including any subcommittee appointed by the CA to exercise any of its functions.

**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.

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.

**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 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 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 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.

**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.

**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:

a) independent;

b) of an educational, scientific, or policymaking nature; an

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.

## 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 9 of the Code replaces and supercedes all previous editions.

## 8 ADVERTISING AND PROMOTION OF PRODUCTS

8.1 Application

This section of the Code applies to Advertisements directed to:

a) Healthcare Professionals, and

b) those with responsibility for the purchasing of Medical Technology.

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:

a) Therapeutic Goods Act 1989
b) Therapeutic Goods Regulations
c) Competition and Consumer Act 2010

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

8.2 General

An Advertisement directed to Healthcare Professionals must:

Advertisements directed 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.

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

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.

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;

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

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 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.

a) A Company must not use the name or photograph of a Healthcare Professional without their written permission or in any way that is:

(i) contrary to the codes and ethical requirements of that Healthcare Professional, if so informed by the Healthcare Professional; or

(ii) 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, 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.

Advertisers/Sponsors are required to hold appropriate, balanced, comprehensive and credible evidence to substantiate Advertising/Promotional claims. It is fundamental that any therapeutic 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 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).

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 implication, exaggerated or unqualified superlative claims.

8.5 Specific Information Required

a) An Advertisement to a Healthcare Professional must contain the following information:

(i) the brand name of the Medical Technology (where applicable);

(ii) the name and contact details of the Sponsor (for devices entered in the Register) or the

(iii) supplier (for products not required to be entered in the Register);

(iv) claims consistent with the manufacturer's intended purpose of the Medical Technology; and

(v) 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.

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. Exempt devices include (but are not limited to):

- Custom-made Medical Devices;
- Devices supplied under the Special Access Scheme for 'Category A' patients in life threatening cases;
- Samples of devices supplied in Australia for the purposes of 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; and
- Devices supplied as part of an approved clinical trial.

Clause 8.5(a)(ii) of the Code limits the Advertising of Medical Technology to Healthcare Professionals to the following types of products:

1. Devices entered in the Register (which have a Sponsor), or
2. Products that are not required to be entered in the Register, such as:
   a. exempt devices;
   b. goods declared not to be Medical Devices; and
   c. goods that are not therapeutic goods.

In the case of products that are not required to be entered in the Register, the name and contact details of the supplier of those products must still be included in an Advertisement to Healthcare Professionals.

For products that are required to be entered in the Register in order to be supplied in Australia, but which are not entered in the Register, an Advertisement will not be able to comply with clause 8.5a(ii) of the Code. This means that the Advertising of 'unregistered' products to Healthcare Professionals is not permitted under the Code unless those products are not required to be entered in the Register (for example, exempt devices).

Clause 8.5a(iii) of the Code requires the Advertisement to be consistent with the manufacturer's intended purpose of the device.

For devices entered in the Register, this is the intended purpose identified in the Register for that product.

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 must have policies and procedures describing the roles and responsibilities of Company Representatives when interacting with Healthcare Professionals via Social Media, if such media are used.

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.

c) 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.

Any such content should be restricted only to Healthcare Professionals by way of a password.

## 9 INTERACTIONS WITH HEALTHCARE PROFESSIONALS

9.1 General interactions

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

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.

9.2 Company-sponsored Training and Education, and Medical Technology Demonstrations

a) The program 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; and

(ii) the training staff must have the proper qualifications and expertise to conduct such training.

a) A Company may pay for reasonable travel and modest lodging costs incurred by attending Healthcare Professionals.

b) A Company may pay for modest Hospitality for attending Healthcare Professionals.

c) 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.

d) 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;

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

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 Healthcare Professionals 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.

(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 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.

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.

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. The overall aim of this clause is to ensure that, in providing financial support to Third Party Educational Conferences, there are no direct payments to individual Healthcare Professionals that might be regarded as an inducement to make a recommendation on product selection.

This clause 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 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 must 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 by the recipient;

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.

(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

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.

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 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.

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.

c) All Hospitality at Third Party Educational Conferences funded by or supplied by a Company must comply with the provisions of clause 9.5.

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 9.3.4a.

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 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

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

Companies should also have regard to the general provisions that regulate an Advertisement as set out in clause 8 of the Code.

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.

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;

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.

(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;

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.

(viii) Company-sponsored Hospitality that occurs in conjunction with a Consultant meeting or a 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

The intention of clause 9.4(f)(ix) is to prohibit side trips from consulting engagements where a Healthcare Professional will derive a benefit of a personal or private nature from the side trip.

(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.

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:

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.

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 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.

The provision of Hospitality to Healthcare Professionals or other product buyers or influencers is restricted. It can only be provided 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 9.8.

9.7 Gifts between Companies and Healthcare Professionals

a) A Company may not provide a gift to a Healthcare Professional.

b) 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.

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

d) A Company may not accept a gift from a Healthcare Professional.

e) 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.

f) 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.

Any provision of a 'gift' to a Healthcare Professional runs the risk of being perceived by the general public as an inducement; 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.

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.

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 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.

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, for example, a prize of cinema tickets or wine would not be appropriate.

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

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

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

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.

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 General

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 clause 10.2.

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.

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.

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.

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.

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.

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.

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.

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 Consumer

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.

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.

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/

11.4 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

12.1 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.

12.2 Where a Company is owned, in whole or in part, by a Healthcare Professional, it must require the Healthcare Professional to disclose their ownership interest to a Consumer before or at the time the Healthcare Professional recommends a product that is marketed by that Company.

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 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 a strategic committee of the Board of MTAA. CA members are appointed by the MTAA Board to represent Medical Technology companies, Consumers and Healthcare Professionals.

13.3 Code Authority (CA)

The CA is responsible for the effective operation and administration of the Code including monitoring, complaints handling and appeals. In this capacity, it may appoint subcommittees and delegate to them the management of any aspect of Code administration including monitoring, complaints handling, and appeals.

The terms of reference of the CA are outlined in Appendix 1.

13.4 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 Training on the Code

a) MTAA must ensure that ongoing training is provided to the Industry on the interpretation and application of the Code.

b) MTAA must ensure education programs are updated every time more than minor changes are made to the Code and at least once every three years.

## 14 COMPLAINTS

14.1 General

a) Subject to clause 14.1b, a Complaint regarding an Advertisement directed to Consumers must be forwarded to the bodies listed in Appendix 4.

In general, a Complaint regarding an Advertisement directed to Consumers is outside the scope of the Code.

b) Notwithstanding the provisions of clause 14.1a, 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.

c) All Complaints and responses must be in writing.

d) 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.

e) Before lodging a Complaint, the Complainant is encouraged to attempt to resolve the matter directly with the Respondent.

f) A Complainant may request to have their name withheld from the Respondent and from public release.

In circumstances where there is strong evidence of a Code Breach, but where lodging a Complaint could, in the judgement of the CA, result in the real risk of detriment to the Complainant, the CA may agree to accept an confidential Complaint. If the CA determines that a request for confidentiality is unjustified in the circumstances, it may reject the request and provide the Complainant with an opportunity to withdraw the Complaint.

g) The Complaints Secretary must, having completed the steps outlined in clause 14.4, forward any evidence of Code Breach provided by the Complainant for consideration by the CA.

h) If the CA determines that a Company may have Breached the Code, it may:

(i) decide not to proceed with a Complaint but notify the Company of the apparent Breach of the Code and offer Training or Education to assist the Company; or

Other options available to the CA include, but are not limited to, hearing the Complaint itself, referring a matter for examination by a Code monitoring subcommittee, requesting further information from the Complainant or Respondent, or referring the matter to another complaints handling forum.

(ii) contact the Company to indicate its view that a Breach of the Code may have occurred and advise the Company that the CA is giving consideration as to whether or not to prepare a Complaint for consideration by a Code Complaint subcommittee. The CA must also advise the Company of the circumstances giving rise to its concerns and invite the Company to supply any such further material which the Company considers relevant to the process.

i) Where clause 14.1h(ii) applies, the CA must, having given the Company a reasonable opportunity to respond, consider any response provided by the Company and, if it still considers that a Breach of the Code may have occurred, proceed either under clause 14.1h(i) or under clause 14.1k.

j) Where the CA, having considered any response of the Company under clause 14.1i, determines that it is appropriate to refer a matter to a Code Complaint subcommittee as a Complaint, it must:

(i) Send a copy of the Complaint to the Company and to MTAA; and

(ii) Request the Company to provide any written response to the Complaint to MTAA, within such period as it shall determine, being not less than 10 working days from the date the complaint is sent to the Company.

k) Without limiting its options, the CA may refer a complaint for consideration by a Complaints subcommittee. Where the Complainant's name is to be withheld from the Respondent and from public release, the CA must refer a complaint for consideration by a Complaints subcommittee.

14.2 Mediation

a) The CA may invite a Company, a Consumer or a Complainant to participate in mediation as an alternative to the Complaints process established under the Code.

b) A Company, Consumer or a Complainant may also request mediation as an alternative to participating in the Complaints process established under the Code.

c) Where the parties consent to mediation, the Complaints Secretary must arrange the mediation session in consultation with the parties and mediator in accordance with clause 18.

14.3 Process for making a complaint

a) A Complaint must be in writing with supporting material and should:

(i) state the nature of the conduct or Advertisement in question;

(ii) state the provision of the Code alleged to have been Breached and the reasons for asserting a Breach has occurred;

(iii) where relevant, provide supporting scientific or other technical data;

(iv) where the Complaint refers to a print Advertisement, include a copy of the Advertisement; and

(v) where the complaint refers to other Advertising, provide sufficient detail to enable the Complaints Secretary to obtain a copy of the Advertisement.

b) If the Complaint is brought under clause 8.3a(iii) on the basis that the Company has not provided substantiation of a claim, the Complainant must provide evidence to support the allegations.

14.4 Steps to be taken following receipt of Complaint

a) When a Complaint is received, the Complaints Secretary must acknowledge the Complaint in writing within seven working days of its receipt and deal with the Complaint expeditiously.

b) The Complaints Secretary must forward a copy of the Complaint to the Chief Executive Officer of the Respondent within seven working days of receiving the Complaint.

c) The Respondent must respond in writing to the Complaints Secretary within 15 working days.

d) The Complaints Secretary must provide the Complainant with a copy of the Respondent's response.

14.5 Complaints against an entity that is not a Company

a) When a Complaint is received about an entity that is not a Company, the Complaints Secretary must acknowledge the Complaint in writing within seven working days of its receipt and deal with the Complaint expeditiously.

b) The Complaints Secretary must forward a copy of the Complaint to the Chief Executive Officer of the entity which is the subject of the Complaint within seven working days of receiving the Complaint. The entity must be invited to have the complaint adjudicated by the CA and asked to indicate whether it agrees to abide by the CA's decision and any sanctions imposed.

c) If the entity accepts the invitation, the Complaint will proceed in accordance with the provisions of the Code.

d) If the entity declines or does not respond within 15 working days, MTAA shall have the right, but not the obligation, to forward the Complaint, together with the response from the subject of the Complaint to the relevant Regulator.

e) The Complaints Secretary must provide the Complainant with a copy of the response from the subject of the Complaint where one is received.

14.6 CA consideration of Complaint

a) The CA may inform itself of any matter by:

(i) seeking further information from the Complainant or Respondent;

(ii) consulting such persons as it thinks fit; and

(iii) referring to publicly available information, provided that:

(A) any person consulted by the CA is bound to maintain confidentiality under a written non-disclosure agreement; and

(B) the parties are provided with a record of all information obtained pursuant to clauses 14.6a(i),(ii) or (iii), and are afforded a period of 10 working days within which to respond in writing.

b) Neither the Complainant nor the Respondent, nor a representative of either of them, may be present during the hearing of a Complaint. The CA must determine the outcome of the Complaint based on the material submitted by the parties.

c) The deliberations of the CA are confidential and must not be disclosed by a member of the CA.

d) The CA must consider a Complaint on the basis of all material properly before it and, in the case of an Advertisement or communication to third parties, in light of the target audience, and decide whether the Complaint is substantiated or not.

e) If the CA considers that a Breach of the Code has occurred, it must determine the appropriate sanction as provided under clause 15.2 of the Code.

f) The CA must provide a written notice of its decision to the Complainant and the Respondent, within 10 working days of the CA meeting, together with its reasons and any sanctions. The notice must include details of appeal procedures.

g) If a Complaint is upheld, the Respondent must reimburse MTAA its secretariat costs and out-of-pocket expenses associated with the determination of the Complaint, unless the CA determines otherwise. This payment is separate from and in addition to any fine payable under clause 15.2. In the case of a Complaint by an Industry Complainant, the CA may require such costs to be shared by the parties in proportions determined by the CA.

h) If in the course of hearing a Complaint the CA identifies a further possible Breach of the Code (not itself the subject of the Complaint) it may refer the matter for further investigation.

14.7 Complaints about matters which are the subject of court proceedings

a) A Complainant is not precluded from resorting to litigation, but the CA must not consider a Complaint while its substance is the subject of pending court proceedings.

b) A party to a Complaint must notify the Complaints Secretary immediately upon becoming aware of any court proceedings concerning the substance of the Complaint.

14.8 Withdrawal

a) The Complainant may withdraw a Complaint at any time in which event the Respondent must be informed in writing and the Complaints handling procedure must be terminated.

b) The CA may treat a Complaint as withdrawn if it is satisfied that:

(i) the Complaint is trivial, vexatious, misconceived or lacking in substance; or

(ii) the subject matter of the Complaint has been dealt with previously by the CA or another authority; or

(iii) the subject matter of the Complaint can be more effectively or conveniently dealt with by another authority and refers the Complaint to that authority.

c) If the Complaint is treated as withdrawn under clause 14.8b), the Complaints Secretary must inform the Complainant and the Respondent in writing, detailing the reasons.

d) Termination of the Complaints handling procedure under clause 14.8a) will not prevent the CA from referring to the Board for its consideration any action or conduct on the part of a Company which in its opinion may constitute a criminal offence or be likely to bring the Industry into disrepute.

e) An Industry Complainant who withdraws their Complaint must reimburse MTAA its secretariat costs and out-of-pocket expenses associated with the Complaint, unless the CA determines otherwise.

## 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 CA 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 the Complaint, similar products or the Industry.

*Moderate Breach:* 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 16 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 CA, 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 CA, 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) 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.

(v) 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.

(vi) A requirement that the Company issue a retraction, including corrective letters and advertising. The retraction must comply with all directions of the CA, 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 CA, 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.

(vii) 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 CA.

| | |
|---|---|
| *Minor Breach:* | Nil |
| *Moderate Breach:* | Maximum AUD $50,000 |
| *Severe Breach:* | Maximum AUD $75,000 |
| *Repeat Breach:* | Maximum AUD $100,000 |
| *Serial Breach:* | An amount not less than AUD $25,000 and not more than AUD $200,000. |

b) Subject to clause 16.2, 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 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.

In relation to clause 15.3a, 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.

## 16 APPEAL PROCEDURE

16.1 Appeals - general

a) A Company who has been found under clause 15 to be in Breach of the Code, or a Complainant who has had its Complaint dismissed, may lodge an appeal against the findings and any imposed sanctions with the Complaints Secretary.

b) The CA must establish a Code Complaints appeals subcommittee (CCAS) to hear the appeal.

c) A Company must lodge notice of its intention to appeal in writing with the Complaints Secretary within five working days of receiving advice of the decision and/or sanctions. The Company then has a further 10 working days in which to lodge material in support of its appeal.

d) The Complaints Secretary must provide a copy of the written appeal to the Complainant who has 10 working days in which to respond. The Complaints Secretary must provide a copy of the response to the appellant within five working days of receiving it.

e) The unsuccessful party to an appeal from an Industry Complainant must reimburse MTAA its secretariat costs and out-of-pocket expenses associated with the determination of the appeal. This payment is separate from and in addition to any fine payable under clause 15.2.

f) In the case of a Complaint by an Industry Complainant, the CCAS may require such costs to be shared by the parties in proportions determined by the CCAS. In all other circumstances the CCAS may determine the apportionment and responsibility for costs.

16.2 Appeal against fine for abuse of Code

A Complainant Company which has had a fine imposed under clause 15.2b) may lodge an appeal against the fine. The appeal, in writing, must be lodged with the Complaints Secretary within five working days of receiving notice of the fine.

16.3 Appeal process

a) The CCAS must consider:

(i) the material that was considered by the CA or Complaints subcommittee in the matter;

(ii) the appeal papers; and

(iii) any response from the Complainant.

b) The CCAS may consider any additional material which it reasonably believes will assist its deliberations.

c) The Complaints Secretary must provide a copy of any additional material before the CCAS to each party no later than five working days before the date of the appeal hearing.

Any appeal document should be in a form which is capable of being shown in its entirety to the Complainant and the Appellant.

d) The CCAS must consider whether findings of the CA or Complaints subcommittee, including the fines imposed, are correct and appropriate. It may not consider whether the Company has Breached sections of the Code that were not considered by the CA or Complaints subcommittee.

e) A party is entitled to be heard by the CCAS in person on prior arrangement with the Complaints Secretary.

f) The findings of the CCAS are final and binding on the parties. The Complaints Secretary must provide the outcome of the deliberations of the CCAS to each party no later than 10 working days after the CCAS reaches its decision.

g) The deliberations of the CCAS are confidential and must not be disclosed by a party, or a member of the CCAS.

## 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 14.1f.

## 18 MEDIATION

18.1 General

a) Where the parties have consented to mediation, MTAA 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 CA or Complaints subcommittee 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.

## Appendix 1

MTAA CODE AUTHORITY – General Terms of Reference

### 1.0 Role and Objectives of the Code Authority

1.1 The Code Authority (CA) is a strategic committee of MTAA.

The CA is responsible for the effective operation and administration of the Code of Practice. In this capacity it:

a) must support compliance with the Code by proactively monitoring Promotions and activities of Companies on a regular and ongoing basis;

b) must ensure that the Code complaints and appeals mechanisms are conducted in a fair, equitable and robust manner;

c) must collect statistical data of monitoring activities, complaints received and outcomes of complaints hearings, conduct a regular review and analysis of monitoring and complaints and the Industry issues they may raise, and make recommendations to the Board for improvements to Industry self-regulation;

d) must undertake an external review 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;

e) 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

f) must ensure education programs are updated every time more than minor changes are made to the Code and at least once every three years.

1.2 The CA may appoint subcommittees and delegate to them the management of any aspect of Code administration including, but not limited to, monitoring, complaints handling, and appeals.

### 2.0 Membership

2.1 The CA shall consist of :

a) a Chair with knowledge of the Industry, marketing and the Code and who is independent of both MTAA and its members;

b) a Board director of MTAA, who is appointed by the Board;

c) a Healthcare Professional who is a representative of a Professional Association or a representative of a medical Institution and who is independent of both MTAA and its members;

d) a Consumer Representative; and

e) Four representatives nominated from among the MTAA Authorised Representatives or a senior delegate of an Authorised Representative.

2.2 The term of office for a CA member will be two years, with members eligible for reappointment for a further two years.

2.3 The chair, Healthcare Professional and Consumer Representative will be appointed by the Board.

2.4 Nominations will be invited annually by the MTAA secretariat from among the employees of voting members of the Association with marketing or regulatory experience to fill such vacancies as have occurred during the previous year, either by the expiration of a member's term of office or by the creation of a casual vacancy (para 3.0). The Board will appoint members of the CA from among the nominees. Representatives of Associate member companies or honorary members will not be eligible to nominate for membership of the CA.

2.5 Where more nominations are received for the CA than there are positions available, the Board shall select the members in consultation with the Chair of the CA. Where possible, members should be drawn from a cross section of companies, device sectors and states.

2.6 No member Company may have more than one representative on the CA.

2.7 The Board reserves the right to retain or recruit a CA member with subject expertise to ensure adequate Industry coverage.

2.8 Member Company Representatives who are not members of the CA may be invited by the chair to attend a meeting (or part of a meeting) to assist in discussion of a particular matter at issue.

**3.0 Casual Vacancies**

3.1 A casual vacancy in the office of an elected member of the CA occurs if:

a) the firm or company represented by the member ceases to be a member of the Association;

b) the member ceases to be employed by the firm or Company that nominated him/her as a member of the CA or the Company's nomination of the member is otherwise withdrawn;

c) the member resigns from the CA; or

d) the member is absent from three consecutive meetings of the CA or fails to attend 75% of meetings held in a calendar year, without leave of absence.

3.2 The Board may appoint a person with suitable expertise to fill a casual vacancy until the next annual nominations are sought.

3.3 If the chair, Healthcare Professional or Consumer Representative resigns their position before the completion of their term of office, the Board shall appoint a replacement whose two year term of office shall commence from the date of their appointment.

**4.0 Operation of the Committee**

4.1 The chief executive will appoint a member of the secretariat to act as the ex officio secretary of the CA.

4.2 The CA will meet not less than 4 times per year.

4.3 The Board representative on the CA will report to the MTAA Board at least quarterly, outlining its performance against its terms of reference.

4.4 Board directors and the MTAA Chief Executive may attend CA meetings with the approval of the chair.

4.5 The secretary of the CA may invite other members of the secretariat to attend a meeting or part of a meeting to provide information or seek input from CA members.

4.6 Members may attend meetings in person or by electronic means.

4.7 The chair and independent members of the CA may be paid an honorarium, as negotiated with the chief executive.

**5.0 Quorum**

5.1 A quorum consists of the chair plus 50% of the total number of other members of the CA.

**6.0 Governance**

6.1 A member of the CA must disclose any conflict of interest or likelihood of a conflict of interest, in any matter that will be considered. If a conflict is disclosed the member may not participate in the deliberations of the CA regarding the matter nor any vote relating to it.

6.2 All CA members shall be required to undertake the MTAA training programs on the Code of Practice and anti-competitive behaviour.

6.3 All CA members shall be required to abide by the confidentiality, trade practices legislation, and other requirements of the Association as may be determined by the Board from time to time.

**7.0 Agenda and Minutes**

7.1 The agenda and any accompanying documentation will be distributed to CA members no later than one week prior to the assigned meeting date.

7.2 CA meetings will be minuted by the secretary and confirmed at the CA's next meeting.

**8.0 Voting**

8.1 Where possible, decisions of the CA should be arrived at by consensus. Where a consensus vote is not achieved, a decision must be made by a simple majority vote of the attending committee members, that is, more than 50% of the members in attendance at the meeting (in person or via electronic means), providing that at least one of the Independent chair, the Healthcare Professional or the Consumer Representative concur with the majority decision.

8.2 Experts and observers do not have voting rights at meetings.

**9.0 Liaison with Members**

9.1 The CA will ensure that non-confidential information relating to its areas of operation is disseminated by the secretary to the Members of the Association on a regular basis either in person or electronically, and that Member input is sought on matters at issue.

**10.0 Liaison with Government Representatives**

10.1 With the approval of the chief executive, the CA and relevant senior members of the secretariat may engage in discussion and/or negotiation with relevant government representatives and may invite such representatives to attend CA meetings.

**11.0 Authority**

11.1 Recommendations of the CA regarding policy matters will be placed on the agenda for the next meeting of the MTAA Board for approval.

**12.0 Reporting by the CA**

12.1 Each year, the CA must provide at least two updates to the Board, of which one must be a written report on the operation of the Code including a review of the Code's effectiveness.

## Appendix 2

MTAA CODE PANEL –Terms of Reference

### 1.0 Role and Objectives of the Code Panel

1.1 The Code panel (the panel) is the body from which members may be drawn to serve on such subcommittees of the Code Authority as may be established from time to time to assist in the effective operation and administration of the Code of Practice.

### 2.0 Membership

2.1 All panelists must be approved by the Board. CA members may not serve on a panel.

2.2 The MTAA secretariat will maintain a list of panelists in the following groups:

a) Panel of chairs

At least 3 lawyers with experience in dispute resolution and in the regulation of Advertising and marketing.

b) Independent panelists

i) At least 3 representatives of Professional Associations in the medical or related fields

ii) At least 3 representatives of medical Institutions (e.g. hospitals)

iii) At least 3 Consumer Representatives

Chairs and independent panelists may be paid an honorarium, as negotiated with the chief executive.

c) Industry representatives

i) At least 3 Industry representatives with marketing experience.

ii) At least 3 Industry representatives with experience in regulatory matters.

Nominations will be invited annually by the MTAA secretariat from among the employees of voting Members of the Association to fill such vacancies as have occurred during the previous year, either by the expiration of a member's term of office or by the creation of a casual vacancy (para 3.0). Representatives of associate member companies or honorary members will not be eligible to nominate for membership of the Panel.

2.3 The term of office for a panelist will be two years, with members eligible for reappointment for a further two years.

2.4 Where more nominations are received for the Industry positions on the panel than there are positions available, the Board shall select the panelist in consultation with the chair of the Code Authority. Where possible, panelists should be drawn from a cross section of Companies, device sectors and states.

2.5 No Member Company may have more than one representative on the panel.

2.6 The Board reserves the right to retain or recruit a panel member with subject expertise to ensure adequate Industry coverage.

**3.0 Casual Vacancies**

3.1 A casual vacancy in the office of an Industry panelist occurs if:

a) the firm or company represented by the panelist ceases to be a Member of the Association;

b) the panelist ceases to be employed by the firm or company that nominated him/her as a member of the panel or the company's nomination of the member is otherwise withdrawn;

c) the panelist resigns from the panel; or

d) the panelist declines on three separate occasions to participate in a meeting of a Code subcommittee on three consecutive occasions or fails to attend 75% of meetings held in a calendar year, without leave of absence.

3.2 The Board may appoint a person with suitable expertise to fill a casual vacancy until the next annual nominations are sought.

3.3 If a member of the panel of chairs or an independent member resigns their position before the completion of their term of office, the Board shall appoint a suitably qualified replacement whose two year term of office shall commence from the date of their appointment.

**4.0 Governance**

4.1 A panelist must disclose any conflict of interest or likelihood of a conflict of interest in any matter under consideration by a meeting in which they are invited to participate. If a conflict is disclosed the panelist may not participate in the deliberations of the group regarding the matter nor any vote relating to it.

4.2 All panelists shall be required to undertake the MTAA training programs on the Code of Practice and anti-competitive behaviour.

4.3 All panelists shall be required to abide by the confidentiality, trade practices legislation, and other requirements of the Association as may be determined by the Board from time to time.

## Appendix 3

MTAA CODE AUTHORITY – Subcommittee Terms of Reference

### 1.0 Role and Objectives of the Code Authority Subcommittees

1.1 The Code Authority (CA) may appoint subcommittees and delegate to them the management of any aspect of Code administration including, but not limited to, monitoring, complaints handling, and appeals.

1.2 A Code monitoring subcommittee may be established as required to support compliance with the Code by proactively monitoring Member Companies' adherence to the Code.

1.3 A Code complaints subcommittee may be established as required to hear a complaint lodged in accordance with the complaints provisions of the Code.

1.4 A Code complaints appeals subcommittee may be established as required to hear an appeal against the decision of the Code complaints subcommittee in relation to a particular complaint.

### 2.0 Membership

2.1 All subcommittee members must be drawn from the Code panel.

2.2 The selection of members to form a subcommittee will be determined by the chair of the Code Authority in consultation with the MTAA secretariat, having regard to potential conflicts of interest with the matter/s at issue.

2.3 All subcommittees must comprise:

a) an independent Chair drawn from the Panel of Chairs;

b) at least 2 independent panelists, representing different bodies; and

c) at least 2 Industry representatives, one with marketing experience and one with regulatory experience.

2.4 Chairs and independent subcommittee members may be paid an honorarium as negotiated with the chief executive.

2.5 No member of a subcommittee which heard an initial complaint may serve on an appeals subcommittee in relation to that complaint.

2.6 A member may not sit on a subcommittee if he or she has declared a conflict of interest or perceived conflict of interest in the subject matter or with a party to the matters at issue. If a member becomes aware of any conflict of interest or likelihood of a conflict of interest once the subcommittee has commenced its discussions, they must declare the conflict of interest to the secretary, withdraw from the subcommittee for that matter, and a new member from the same category appointed from the panel.

### 3. Quorum

3.1 A quorum for a meeting of a subcommittee formed to hear a complaint or appeal is the chair and all members selected from the Code panel to serve on the subcommittee in relation to the complaint or appeal.

3.2 A quorum for all other subcommittees is the chair plus 50% of the total number of other members of the subcommittee.

### 4. Voting

4.1 Subcommittee decisions should be made by consensus wherever possible. Where consensus cannot be achieved, decisions may be made by a majority vote providing that the independent chair and at least one of the independent representatives concur with the majority decision.

### 5. Reporting

5.1 Each subcommittee shall provide a written report to the Code Authority at the conclusion of its consideration of the matter at issue, detailing the outcome of its determinations.

## Appendix 4

### Complaints on Advertisements directed to Consumers

Complaints about Advertising directed to Consumers must be directed to:

For complaints on Advertisements in media including TV, radio, newspapers, magazines, billboards, posters, bus shelters, taxi backs:

Complaints Resolution Panel
PO Box 764
North Sydney NSW 2059
Australia

Information on the procedure to make a complaint can be found at http://tgacc.com.au/complaints.cfm

For Complaints on Advertisements or Promotions directed to Consumers in stores, brochures, labels:

Complaints Secretary
Medical Technology Association of Australia
PO Box 2016
North Sydney NSW 2059
Australia

P: +61 2 9900 0650

F: +61 2 9900 0655

E: code@mtaa.org.au

## Appendix 5

### Complaints on Advertisements to and interactions with Healthcare Professionals

Complaints regarding Advertisements directed to, and interactions with, Healthcare Professionals must be directed to:

Complaints Secretary
Medical Technology Association of Australia
PO Box 2016
North Sydney NSW 2059
Australia

P: +61 2 9900 0650

F: +61 2 9900 0655

E: code@mtaa.org.au